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| Part 1 of 6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                           | <b>Abbott Point of Care</b><br><b>Jeff Abney</b> jeff.abney@abbott.com<br><b>Princeton, NJ</b><br><b>609-454-9000</b> www.pointofcare.abbott/us/en/home                                                                                 | <b>Awareness Technology</b><br><b>Rafael Castillo</b> rcastillo@awaretech.com<br><b>Palm City, FL</b><br><b>772-283-6540</b> www.awaretech.com                                                                                                                          | <b>Awareness Technology</b><br><b>Rafael Castillo</b> rcastillo@awaretech.com<br><b>Palm City, FL</b><br><b>772-283-6540</b> www.awaretech.com                                                                                                                                                                       |
| <b>FOR POINT-OF-CARE USE AND LOW-VOLUME LABORATORIES</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                           |                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                      |
| Name of instrument<br>Type of instrument                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | i-STAT 1 analyzer†<br>combination chemistry/immunoassay                                                                   | ChemWell 2910<br>combination chemistry/immunoassay                                                                                                                                                                                      | ChemWell-T 4620<br>chemistry                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                           |                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                      |
| Operational type/Model type<br>List price/First year sold in U.S.<br>Targeted hospital bed size/Targeted test volume<br>Company manufactures instrument                                                                                                                                                                                                                                                                                                                                                                                                                                              | discrete/handheld<br>—/2000<br>all/—<br>yes (also sold by McKesson, Henry Schein, Medline, Cardinal, Concordance, others) | batch, random access, discrete/benchtop<br>\$29,000/1998<br>200/daily: 200–500; monthly: 200–400<br>yes (also sold by GMI, Monobind, ASI, others)                                                                                       | batch, random access, discrete/benchtop<br>\$14,000/2014<br>200/—<br>yes                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                      |
| Other models in this family of analyzers<br>No. of units in clinical use in U.S./Outside U.S. (countries)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | i-STAT Alinity<br>> 30,000/> 10,000 (Europe, Latin America, Africa, Middle East, Asia Pacific)                            | ChemWell Fusion, ChemWell-T, ChemWell 2902<br>500/7,000 (worldwide)                                                                                                                                                                     | ChemWell Fusion, ChemWell 2910, ChemWell 2902<br>200/4,500 (worldwide)                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                      |
| Dimensions (H × W × D)/Instrument footprint<br>Weight empty/Weight fully loaded<br>No. of different measured assays onboard simultaneously<br>No. of user-definable (open chemistry) channels<br>Test throughput per hour/Assay run time                                                                                                                                                                                                                                                                                                                                                             | 9.25 × 3 × 2.85 in./< 1 sq. ft.<br>< 2 lbs./< 2 lbs.<br>—<br>—<br>—/2–15 min.                                             | 18.625 × 36.25 × 21.5 in./< 7.905 sq. ft.<br>77 lbs./78 lbs.<br>15 (12 can be run and calibrated at one time)<br>—<br>200 (27 tests in throughput)/6–120 min.                                                                           | 20.87 × 19.69 × 18.5 in./2.853 sq. ft.<br>37 lbs./—<br>15 (12 can be run and calibrated at one time)<br>—<br>100/—                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                      |
| <b>Chemistry:</b><br>No. of direct ion-selective electrode channels<br>Detection methods<br>Stat time until completion/specimen throughput for:<br>• Ion-selective electrode<br>• Basic metabolic panel<br>• Complete metabolic panel<br>Typical time delay from ordering stat test until aspiration of sample                                                                                                                                                                                                                                                                                       |                                                                                                                           |                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                           | up to 26<br>potentiometry, amperometry, conductometry                                                                                                                                                                                   | —<br>photometry                                                                                                                                                                                                                                                         | —<br>photometry                                                                                                                                                                                                                                                                                                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                           | 2 min./20–25<br>2 min./20–25<br>—<br>none                                                                                                                                                                                               | —<br>assay dependent<br>assay dependent<br>assay dependent                                                                                                                                                                                                              | —<br>assay dependent<br>assay dependent<br>assay dependent                                                                                                                                                                                                                                                           |
| <b>Immunoassay:</b><br>Fully automated microplate immunoassay system<br>Methodologies supported<br>Separation methodologies<br>Stat time until completion of a β-hCG test<br>• Typical time delay from test order to aspiration of sample<br>Stat time until completion of a cTn test<br>• Typical time delay from test order to aspiration of sample                                                                                                                                                                                                                                                |                                                                                                                           |                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                           | yes (up to 26 tests per unit)<br>potentiometry, amperometry, conductometry<br>none necessary<br>—<br>10 min.<br>none                                                                                                                    | yes (27–44 tests per unit; 96 wells per microplate)<br>enzyme immunoassay, colorimetric analysis<br>none necessary, coated microwell<br>assay dependent<br>assay dependent<br>assay dependent<br>assay dependent                                                        | —<br>—<br>—<br>—<br>—<br>—<br>—                                                                                                                                                                                                                                                                                      |
| Approximate No. of tests per reagent set/Reagent type<br>Reagents refrigerated onboard/Reagents ready to use<br>Reagent lot tracking/Reagent inventory<br>Reagent form/Reagents barcoded<br>Separate reagent pack for each specimen/for each test run<br>Walkaway capability/Walkaway duration                                                                                                                                                                                                                                                                                                       |                                                                                                                           | —/self-contained single use<br>no/—<br>no/no<br>dry chemistry, liquid chemistry (closed reagent system)/yes<br>no/no<br>yes/2–10 min. or 1 specimen or up to 13 tests                                                                   | assay dependent/open reagent system<br>yes (12°–15°C on optional cooling accessory)/yes<br>yes/yes<br>liquid chemistry (open reagent system)/yes<br>no/yes<br>yes/480 min.                                                                                              | assay dependent/open reagent system<br>yes (8°–15°C)/yes<br>yes/yes<br>liquid chemistry (open reagent system)/yes<br>no/yes<br>yes/120 min.                                                                                                                                                                          |
| Design of sample-handling system<br>Uses washable cuvettes/Uses disposable cuvettes<br>Min.–max. sample volume that can be aspirated at one time<br>Min. reaction volume/Min. specimen volume/Min. dead volume<br>Dedicated pediatric sample cup<br>Primary tube sampling<br>Accommodates most standard tube sizes/Accepts nonstandard tube sizes<br>Pierces caps on primary tubes<br>Protects against probe collision<br>Detects clots/liquid level/short sample<br>Detection or quantitation for hemolysis, icterus, lipemia, clots<br>Dilutes patient samples onboard/Susceptibility to carryover |                                                                                                                           | —<br>no/no<br>17–95 µL<br>—<br>no<br>no<br>no/no<br>no<br>no<br>yes/yes/yes<br>detection for hemolysis, icterus, lipemia, clots<br>no/—                                                                                                 | rack (custom reagent and sample racks)<br>yes/yes<br>2–250 µL<br>100 µL/100 µL/100 µL<br>no<br>yes<br>yes/yes (13 mm)<br>no<br>yes<br>no/yes/yes<br>assay dependent<br>yes (can be programmed to perform dilutions prior to analysis)/no carryover<br>yes<br>yes<br>yes | rack (custom reagent and sample racks)<br>yes/yes (can store up to 40 cuvettes)<br>2–388 µL<br>240 µL/2 µL/40 µL<br>no<br>yes<br>yes/yes (12 × 75 mm, 13 × 100 mm)<br>no<br>yes<br>no/yes/yes<br>assay dependent<br>yes (can be programmed to perform dilutions prior to analysis)/no carryover<br>yes<br>yes<br>yes |
| Automatic rerun capability<br>Sample volume can be diluted to rerun out-of-linear-range high results<br>Sample volume can be concentrated to rerun out-of-linear-range low results                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                           | no<br>no<br>no                                                                                                                                                                                                                          | yes<br>yes<br>yes                                                                                                                                                                                                                                                       | yes<br>yes<br>yes                                                                                                                                                                                                                                                                                                    |
| Analyzer requires dedicated water supply<br>Autocalibration/Multipoint calibration supported                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                           | no<br>yes (calibrants are not stored onboard)/yes (recommended avg. frequency: each test)<br>—/—/—/each test/each test                                                                                                                  | no<br>no (calibrants can be stored onboard)/yes (recommended avg. frequency: test dependent)<br>—                                                                                                                                                                       | no<br>no (calibrants can be stored onboard)/yes (recommended avg. frequency: test dependent)<br>—                                                                                                                                                                                                                    |
| Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays<br>Automatic programmable start/Automatic programmable shutdown<br>Onboard real-time QC/Onboard software capability to review QC<br>Supports multiple QC lot numbers per analyte<br>Waste management                                                                                                                                                                                                                                                                                        |                                                                                                                           | yes/yes<br>yes/yes<br>yes<br>manually by user                                                                                                                                                                                           | no/no<br>yes/yes<br>yes<br>manually by user or automated collection onboard instrument or direct to drain                                                                                                                                                               | no/no<br>yes/yes<br>yes<br>direct to drain                                                                                                                                                                                                                                                                           |
| Sample barcode-reading capability/Autodiscrimination                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                           | yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, EAN-8, EAN-13)/—                                                                                                                                                                   | yes (Code 39, Code 129)/no                                                                                                                                                                                                                                              | yes (Code 39, Code 129)/no                                                                                                                                                                                                                                                                                           |
| Lab can control analyzer from remote computer<br>Instrument can diagnose its own malfunctions<br>System malfunctions can be diagnosed via remote monitoring<br>UPS backup power supply<br>Data-management capability/LIS or EHR systems interfaced                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                           | yes<br>yes (operator intervention required to order parts)<br>yes<br>no<br>optional add-on/—                                                                                                                                            | yes<br>yes (operator intervention required to order parts)<br>yes<br>no<br>onboard/—                                                                                                                                                                                    | yes<br>yes (operator intervention required to order parts)<br>yes<br>no<br>onboard/—                                                                                                                                                                                                                                 |
| LIS interface provided/Bidirectional interface capability                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                           | yes (additional cost)/no                                                                                                                                                                                                                | yes/yes                                                                                                                                                                                                                                                                 | yes/yes                                                                                                                                                                                                                                                                                                              |
| Modem servicing provided/Service engineer on-site response time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                           | —/— (product replacement within 24 hrs.)                                                                                                                                                                                                | no/72 hrs.                                                                                                                                                                                                                                                              | no/72 hrs.                                                                                                                                                                                                                                                                                                           |
| Mean time between failures                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                           | — (displays error codes for troubleshooting)                                                                                                                                                                                            | 1–2 service visits per year (displays error codes for troubleshooting)<br>daily: 15 min.<br>no/no<br>no<br>yes (1 training slot)/4 days (at customer or vendor site)<br>yes (at customer or vendor site)/yes                                                            | 1–2 service visits per year (displays error codes for troubleshooting)<br>daily: 15 min.<br>no/no<br>no<br>yes (1 training slot)/2 days (at customer or vendor site)<br>yes (at customer or vendor site)/yes                                                                                                         |
| Average scheduled maintenance time by lab personnel<br>Maintenance records kept onboard for user/vendor<br>Maintenance training demonstration module onboard<br>Training included with purchase/Avg. time for basic user training<br>Advanced operator training/Extra charge for follow-up or advanced training<br>Warranty provided/Cost of annual service contract (24 h/7 d)                                                                                                                                                                                                                      |                                                                                                                           | —<br>—<br>—<br>—/4 hrs. (at customer site)<br>yes (at customer site)/no<br>yes (1 year)/—                                                                                                                                               | yes (1 year from date of shipment)/contract dependent                                                                                                                                                                                                                   | yes (1 year from date of shipment)/contract dependent                                                                                                                                                                                                                                                                |
| Distinguishing features (supplied by company)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                           | • handheld portable analyzer; unit use system can perform chemistry, blood gas, cardiac marker, hematology, and coagulation tests<br>• CLIA-waived tests, including glucose and creatinine<br>• uses 2–3 drops of whole blood or plasma | • vertical plate reading for biochemistries<br>• 2-in-1 utility with the ability to run in ELISA mode or biochemistry mode<br>• low-cost analyzer that saves on reagent use; open system; remote access; software included (free)                                       | • compact low-cost analyzer that saves on reagent use; open system; remote access<br>• flexibility of hardware/software<br>• software included (free)                                                                                                                                                                |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                           | †all information listed was provided to CAP TODAY in 2025; company did not provide updated information by 2026 entry deadline                                                                                                           |                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                      |

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| Part 2 of 6                                                                                                  | <b>Beckman Coulter</b><br><b>Doug Lee</b> dylee@beckman.com<br><b>Brea, CA</b><br><b>800-526-3821</b> www.beckmancoulter.com                                                                                                                                                 | <b>Beckman Coulter</b><br><b>Doug Lee</b> dylee@beckman.com<br><b>Brea, CA</b><br><b>800-526-3821</b> www.beckmancoulter.com                                                                                                                                           | <b>Beckman Coulter</b><br><b>Shannon Garegnani</b> sgaregnani@beckman.com<br><b>Brea, CA</b><br><b>800-526-3821</b> www.beckmancoulter.com                                                                                                                                |
| <b>FOR POINT-OF-CARE USE AND LOW-VOLUME LABORATORIES</b>                                                     |                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                           |
| Name of instrument                                                                                           | Access 2                                                                                                                                                                                                                                                                     | DxC 500 AU Clinical Chemistry Analyzer                                                                                                                                                                                                                                 | DxC 500i Clinical Analyzer                                                                                                                                                                                                                                                |
| Type of instrument                                                                                           | immunoassay                                                                                                                                                                                                                                                                  | chemistry                                                                                                                                                                                                                                                              | combination chemistry/immunoassay                                                                                                                                                                                                                                         |
| Operational type/Model type                                                                                  | continuous random access/benchtop                                                                                                                                                                                                                                            | continuous random access/floor standing                                                                                                                                                                                                                                | continuous random access/floor standing                                                                                                                                                                                                                                   |
| List price/First year sold in U.S.                                                                           | —/2001                                                                                                                                                                                                                                                                       | —/2024                                                                                                                                                                                                                                                                 | —/2025                                                                                                                                                                                                                                                                    |
| Targeted hospital bed size/Targeted test volume                                                              | —/annual: < 40,000                                                                                                                                                                                                                                                           | —/annual: 50,000–350,000                                                                                                                                                                                                                                               | —/annual: 50,000–350,000                                                                                                                                                                                                                                                  |
| Company manufactures instrument                                                                              | yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific)                                                                                                                                                                                                 | yes (also sold by distribution partners)                                                                                                                                                                                                                               | yes (also sold by distribution partners)                                                                                                                                                                                                                                  |
| Other models in this family of analyzers                                                                     | Unicel Dxl 600, Unicel Dxl 800                                                                                                                                                                                                                                               | DxC 700 AU, AU5800                                                                                                                                                                                                                                                     | DxC 500 AU, DxC 700 AU, AU5800, Access 2, Dxl 600, Dxl 9000                                                                                                                                                                                                               |
| No. of units in clinical use in U.S./Outside U.S. (countries)                                                | —                                                                                                                                                                                                                                                                            | —                                                                                                                                                                                                                                                                      | —/— (worldwide)                                                                                                                                                                                                                                                           |
| Dimensions (H × W × D)/Instrument footprint                                                                  | 19.5 × 39 × 24 in./6.5 sq. ft.                                                                                                                                                                                                                                               | 48 × 61 × 31 in./52.1 sq. ft.                                                                                                                                                                                                                                          | 48.8 × 100 × 30.3 in./21 sq. ft.                                                                                                                                                                                                                                          |
| Weight empty/Weight fully loaded                                                                             | 200 lbs./—                                                                                                                                                                                                                                                                   | —/maximum 992 lbs.                                                                                                                                                                                                                                                     | 1,430 lbs./—                                                                                                                                                                                                                                                              |
| No. of different measured assays onboard simultaneously                                                      | 24 (24 can be run and calibrated at one time)                                                                                                                                                                                                                                | 63 (60 plus 3 ISE can be run and calibrated at one time)                                                                                                                                                                                                               | —                                                                                                                                                                                                                                                                         |
| No. of user-definable (open chemistry) channels                                                              | —                                                                                                                                                                                                                                                                            | 18                                                                                                                                                                                                                                                                     | —                                                                                                                                                                                                                                                                         |
| Test throughput per hour/Assay run time                                                                      | up to 100/13–55 min.                                                                                                                                                                                                                                                         | up to 800: 400 photometric, 400 ISE/< 9 min.                                                                                                                                                                                                                           | 800 chemistry with ISE, 100 immunoassay/—                                                                                                                                                                                                                                 |
| <b>Chemistry:</b>                                                                                            |                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                           |
| No. of direct ion-selective electrode channels                                                               | —                                                                                                                                                                                                                                                                            | 3 indirect                                                                                                                                                                                                                                                             | —                                                                                                                                                                                                                                                                         |
| Detection methods                                                                                            | —                                                                                                                                                                                                                                                                            | photometry, potentiometry                                                                                                                                                                                                                                              | photometry, potentiometry                                                                                                                                                                                                                                                 |
| Stat time until completion/specimen throughput for:                                                          |                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                           |
| • Ion-selective electrode                                                                                    | —                                                                                                                                                                                                                                                                            | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| • Basic metabolic panel                                                                                      | —                                                                                                                                                                                                                                                                            | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| • Complete metabolic panel                                                                                   | —                                                                                                                                                                                                                                                                            | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| Typical time delay from ordering stat test until aspiration of sample                                        | —                                                                                                                                                                                                                                                                            | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| <b>Immunoassay:</b>                                                                                          |                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                           |
| Fully automated microplate immunoassay system                                                                | no                                                                                                                                                                                                                                                                           | —                                                                                                                                                                                                                                                                      | no                                                                                                                                                                                                                                                                        |
| Methodologies supported                                                                                      | chemiluminescence                                                                                                                                                                                                                                                            | —                                                                                                                                                                                                                                                                      | chemiluminescence                                                                                                                                                                                                                                                         |
| Separation methodologies                                                                                     | magnetic particle                                                                                                                                                                                                                                                            | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| Stat time until completion of a β-hCG test                                                                   | 15 min.                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| • Typical time delay from test order to aspiration of sample                                                 | 36 sec.                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| Stat time until completion of a cTn test                                                                     | 17 min.                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| • Typical time delay from test order to aspiration of sample                                                 | 36 sec.                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| Approximate No. of tests per reagent set/Reagent type                                                        | 50 per pack or 100 per kit/self-contained multiuse                                                                                                                                                                                                                           | —/self-contained single use                                                                                                                                                                                                                                            | 50–6,744 per pack (varies by assay)/—                                                                                                                                                                                                                                     |
| Reagents refrigerated onboard/Reagents ready to use                                                          | yes (2°–8°C)/yes                                                                                                                                                                                                                                                             | yes (4.5°–12°C)/variable; reagent specific                                                                                                                                                                                                                             | yes (4.5°–12°C)/variable; reagent specific                                                                                                                                                                                                                                |
| Reagent lot tracking/Reagent inventory                                                                       | yes/yes                                                                                                                                                                                                                                                                      | yes/no                                                                                                                                                                                                                                                                 | yes/yes                                                                                                                                                                                                                                                                   |
| Reagent form/Reagents barcoded                                                                               | liquid chemistry (closed reagent system)/yes                                                                                                                                                                                                                                 | liquid chemistry (closed reagent system)/yes                                                                                                                                                                                                                           | liquid chemistry (open reagent system)/yes                                                                                                                                                                                                                                |
| Separate reagent pack for each specimen/for each test run                                                    | no/no                                                                                                                                                                                                                                                                        | no/no                                                                                                                                                                                                                                                                  | no/no                                                                                                                                                                                                                                                                     |
| Walkaway capability/Walkaway duration                                                                        | yes/180 min. or 60 specimens                                                                                                                                                                                                                                                 | yes/168 specimens                                                                                                                                                                                                                                                      | yes/168 specimens                                                                                                                                                                                                                                                         |
| Design of sample-handling system                                                                             | rack                                                                                                                                                                                                                                                                         | rack                                                                                                                                                                                                                                                                   | rack                                                                                                                                                                                                                                                                      |
| Uses washable cuvettes/Uses disposable cuvettes                                                              | no/yes (can store up to 294 cuvettes)                                                                                                                                                                                                                                        | yes (can store up to 88 cuvettes)/no                                                                                                                                                                                                                                   | yes (can store up to 88 cuvettes)/no                                                                                                                                                                                                                                      |
| Min.—max. sample volume that can be aspirated at one time                                                    | 5–200 µL                                                                                                                                                                                                                                                                     | 1–25 µL                                                                                                                                                                                                                                                                | 1–25 µL                                                                                                                                                                                                                                                                   |
| Min. reaction volume/Min. specimen volume/Min. dead volume                                                   | varies by assay/varies by assay/80 µL                                                                                                                                                                                                                                        | 90 µL/50 µL/80 µL                                                                                                                                                                                                                                                      | 90 µL/50 µL/80 µL                                                                                                                                                                                                                                                         |
| Dedicated pediatric sample cup                                                                               | yes (dead volume: 80 µL)                                                                                                                                                                                                                                                     | no                                                                                                                                                                                                                                                                     | no                                                                                                                                                                                                                                                                        |
| Primary tube sampling                                                                                        | yes                                                                                                                                                                                                                                                                          | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                       |
| Accommodates most standard tube sizes/Accepts nonstandard tube sizes                                         | yes/no                                                                                                                                                                                                                                                                       | yes/—                                                                                                                                                                                                                                                                  | yes/—                                                                                                                                                                                                                                                                     |
| Pierces caps on primary tubes                                                                                | no                                                                                                                                                                                                                                                                           | no                                                                                                                                                                                                                                                                     | no                                                                                                                                                                                                                                                                        |
| Protects against probe collision                                                                             | no                                                                                                                                                                                                                                                                           | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                       |
| Detects clots/liquid level/short sample                                                                      | yes/yes/yes                                                                                                                                                                                                                                                                  | yes/yes/yes                                                                                                                                                                                                                                                            | yes/yes/yes                                                                                                                                                                                                                                                               |
| Detection or quantitation for hemolysis, icterus, lipemia, clots                                             | detection for clots; hemolysis, icterus, lipemia not available                                                                                                                                                                                                               | detection for hemolysis, icterus, lipemia, clots                                                                                                                                                                                                                       | detection for hemolysis, icterus, lipemia, clots                                                                                                                                                                                                                          |
| Dilutes patient samples onboard/Susceptibility to carryover                                                  | yes (can be programmed to perform dilutions prior to analysis)/—                                                                                                                                                                                                             | yes (can be programmed to perform dilutions prior to analysis)/—                                                                                                                                                                                                       | yes (can be programmed to perform dilutions prior to analysis)/—                                                                                                                                                                                                          |
| Automatic rerun capability                                                                                   | no                                                                                                                                                                                                                                                                           | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                       |
| Sample volume can be diluted to rerun out-of-linear-range high results                                       | yes                                                                                                                                                                                                                                                                          | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                       |
| Sample volume can be concentrated to rerun out-of-linear-range low results                                   | no                                                                                                                                                                                                                                                                           | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                       |
| Analyzer requires dedicated water supply                                                                     | no                                                                                                                                                                                                                                                                           | yes (20 L/hr. consumption during operation)                                                                                                                                                                                                                            | yes (10 L/hr. consumption during operation)                                                                                                                                                                                                                               |
| Autocalibration/Multipoint calibration supported                                                             | no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)                                                                                                                                                                                             | yes (calibrants are not stored onboard)/yes                                                                                                                                                                                                                            | yes (calibrants are not stored onboard)/yes                                                                                                                                                                                                                               |
| Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays     | —/—/—/28 days                                                                                                                                                                                                                                                                | 1 day/—/—/1–90 days/—                                                                                                                                                                                                                                                  | 1 day/—/—/1–90 days/—                                                                                                                                                                                                                                                     |
| Automatic programmable start/Automatic programmable shutdown                                                 | no (< 5 min. start-up time)/no                                                                                                                                                                                                                                               | yes/no                                                                                                                                                                                                                                                                 | —                                                                                                                                                                                                                                                                         |
| Onboard real-time QC/Onboard software capability to review QC                                                | no/yes                                                                                                                                                                                                                                                                       | no/yes                                                                                                                                                                                                                                                                 | yes/yes                                                                                                                                                                                                                                                                   |
| Supports multiple QC lot numbers per analyte                                                                 | yes                                                                                                                                                                                                                                                                          | —                                                                                                                                                                                                                                                                      | yes                                                                                                                                                                                                                                                                       |
| Waste management                                                                                             | automated collection onboard instrument                                                                                                                                                                                                                                      | direct to drain                                                                                                                                                                                                                                                        | direct to drain                                                                                                                                                                                                                                                           |
| Sample barcode-reading capability/Autodiscrimination                                                         | yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no                                                                                                                                                                                                                      | yes (Interleaved 2 of 5, Code 39, Code 128, NW7, EAN-13, ISBT 128, Standard 2 of 5)/—                                                                                                                                                                                  | yes (Interleaved 2 of 5, Code 39, Code 128, NW7, EAN-13, ISBT 128, Standard 2 of 5)/—                                                                                                                                                                                     |
| Lab can control analyzer from remote computer                                                                | yes                                                                                                                                                                                                                                                                          | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                       |
| Instrument can diagnose its own malfunctions                                                                 | yes (operator intervention required to order parts)                                                                                                                                                                                                                          | yes (operator intervention required to order parts)                                                                                                                                                                                                                    | yes (instrument can order malfunctioning parts)                                                                                                                                                                                                                           |
| System malfunctions can be diagnosed via remote monitoring                                                   | yes                                                                                                                                                                                                                                                                          | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                       |
| UPS backup power supply                                                                                      | no                                                                                                                                                                                                                                                                           | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                       |
| Data-management capability/LIS or EHR systems interfaced                                                     | onboard/Oracle Health, Antrim, CCA, Chemware, Dawning Technologies, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson, more                                                                                                                                                 | onboard/Medicus, Evident, CGM LabDaq, Oracle Health, Clinisys                                                                                                                                                                                                          | onboard/Medicus, Evident, CGM LabDaq, Oracle Health, Clinisys                                                                                                                                                                                                             |
| LIS interface provided/Bidirectional interface capability                                                    | yes (included in instrument price)/yes (host query)                                                                                                                                                                                                                          | no/yes (host query)                                                                                                                                                                                                                                                    | yes (additional cost)/yes (host query)                                                                                                                                                                                                                                    |
| Modem servicing provided/Service engineer on-site response time                                              | yes/< 24 hrs.                                                                                                                                                                                                                                                                | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| Mean time between failures                                                                                   | 1.4 down service calls per year (displays error codes for troubleshooting)                                                                                                                                                                                                   | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| Average scheduled maintenance time by lab personnel                                                          | daily: 7 min.; weekly: 12 min.                                                                                                                                                                                                                                               | daily: 4 min.; weekly: 10 min.; monthly: 45 min.                                                                                                                                                                                                                       | daily: 9 min.; weekly: 26 min.; monthly: 45 min.                                                                                                                                                                                                                          |
| Maintenance records kept onboard for user/vendor                                                             | no/no                                                                                                                                                                                                                                                                        | yes/no                                                                                                                                                                                                                                                                 | yes/no                                                                                                                                                                                                                                                                    |
| Maintenance training demonstration module onboard                                                            | yes                                                                                                                                                                                                                                                                          | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                       |
| Training included with purchase/Avg. time for basic user training                                            | yes (2 training slots)/2 days (at vendor site)                                                                                                                                                                                                                               | yes (2 training slots)/—                                                                                                                                                                                                                                               | yes (2 training slots)/— (at customer site)                                                                                                                                                                                                                               |
| Advanced operator training/Extra charge for follow-up or advanced training                                   | yes (at vendor site)/—                                                                                                                                                                                                                                                       | yes (at vendor site)/—                                                                                                                                                                                                                                                 | yes (at vendor site)/—                                                                                                                                                                                                                                                    |
| Warranty provided/Cost of annual service contract (24 h/7 d)                                                 | yes (1 year)/—                                                                                                                                                                                                                                                               | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                         |
| Distinguishing features (supplied by company)                                                                | • offers the robustness of a reference laboratory immunoassay analyzer in convenient size of a benchtop system<br>• standardization of results and reagents across all volume segments<br>• reliable benchtop system providing the same high-quality results as the core lab | • intuitive user interface with user-friendly software that guides workflow and anticipates laboratory needs<br>• commonly replaced parts can be changed in 3 steps, in 60 seconds, and without tools<br>• standardization across the AU family of chemistry analyzers | • independent and integrated operations, reagent load on the fly, rapid throughput<br>• single point of sample loading, intuitive interface and guided workflows, easy to maintain parts<br>• offers a menu of more than 170 assays for complete disease state management |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i> |                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                           |

|                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | CHEMISTRY AND IMMUNOASSAY ANALYZERS                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                 | JUNE 2026   CAP TODAY 49                                                                                                                           |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| Part 3 of 6                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>bioMérieux</b><br><b>Kara Hardin</b> kara.hardin@biomerieux.com<br><b>Salt Lake City, UT</b><br><b>800-682-2666</b> www.biomerieux-usa.com                                                                   | <b>Diatron MI</b><br><b>Frank Matuszak</b> frank.matuszak@diatron.com<br><b>Medley, FL</b><br><b>833-228-7931</b> www.diatron.com                                                                                                                                                                                               | <b>Dynex Technologies</b><br><b>Global Customer Service</b> customerservice@dynex.com<br><b>Chantilly, VA</b><br><b>800-288-2354</b> www.dynex.com |
| <b>FOR POINT-OF-CARE USE AND LOW-VOLUME LABORATORIES</b>                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                    |
| Name of instrument                                                                                           | VIDAS 3                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Pictus 500 (P500) <sup>†</sup>                                                                                                                                                                                  | DS2 Elite Automated ELISA System                                                                                                                                                                                                                                                                                                |                                                                                                                                                    |
| Type of instrument                                                                                           | immunoassay                                                                                                                                                                                                                                                                                                                                                                                                                                                        | chemistry                                                                                                                                                                                                       | immunoassay                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                    |
| Operational type/Model type                                                                                  | batch, random access, continuous random access/ benchtop                                                                                                                                                                                                                                                                                                                                                                                                           | batch, random access, continuous random access, discrete/ benchtop                                                                                                                                              | batch/benchtop                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                    |
| List price/First year sold in U.S.                                                                           | —/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                             | \$42,860/2016                                                                                                                                                                                                   | —/2007                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                    |
| Targeted hospital bed size/Targeted test volume                                                              | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 20–100/daily; 500–2,500; monthly: 15,000–75,000; annual: 182,500–912,500                                                                                                                                        | —/daily: < 4 microplates (96-well microplates)                                                                                                                                                                                                                                                                                  |                                                                                                                                                    |
| Company manufactures instrument                                                                              | yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                | yes                                                                                                                                                                                                             | yes                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| Other models in this family of analyzers                                                                     | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Pictus 700 (P700)                                                                                                                                                                                               | DSX                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| No. of units in clinical use in U.S./Outside U.S. (countries)                                                | > 500/—                                                                                                                                                                                                                                                                                                                                                                                                                                                            | > 40/≤ 200 (Europe, Latin America, Africa, Middle East, Asia)                                                                                                                                                   | —/4,510 (worldwide)                                                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| Dimensions (H × W × D)/Instrument footprint                                                                  | 24 × 29.5 × 25.5 in./5.2 sq. ft.                                                                                                                                                                                                                                                                                                                                                                                                                                   | 24.4 × 35.4 × 26 in./6.4 sq. ft.                                                                                                                                                                                | 26.25 × 21 × 27.5 in./3.9 sq. ft.                                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| Weight empty/Weight fully loaded                                                                             | 154 lbs./—                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 253 lbs./271 lbs.                                                                                                                                                                                               | 105 lbs./—                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                    |
| No. of different measured assays onboard simultaneously                                                      | 12 (several different lots of assays can be stored at one time)                                                                                                                                                                                                                                                                                                                                                                                                    | 72 (999 can be run and calibrated at one time)                                                                                                                                                                  | up to 12 assays per microplate (up to 12 can be run)                                                                                                                                                                                                                                                                            |                                                                                                                                                    |
| No. of user-definable (open chemistry) channels                                                              | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | —                                                                                                                                                                                                               | — (open system; up to 12 can be active simultaneously)                                                                                                                                                                                                                                                                          |                                                                                                                                                    |
| Test throughput per hour/Assay run time                                                                      | up to 36/assay dependent                                                                                                                                                                                                                                                                                                                                                                                                                                           | 500/30–1,200 sec. (avg. 300 sec.)                                                                                                                                                                               | assay dependent (up to 384 tests per run)/assay dependent                                                                                                                                                                                                                                                                       |                                                                                                                                                    |
| <b>Chemistry:</b>                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                    |
| No. of direct ion-selective electrode channels                                                               | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 3                                                                                                                                                                                                               | —                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| Detection methods                                                                                            | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | photometry, potentiometry                                                                                                                                                                                       | —                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| Stat time until completion/specimen throughput for:                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                    |
| • Ion-selective electrode                                                                                    | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 2 min./60 specimens per hr.                                                                                                                                                                                     | —                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| • Basic metabolic panel                                                                                      | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 7.5 min./45 specimens per hr.                                                                                                                                                                                   | —                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| • Complete metabolic panel                                                                                   | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 9 min./25 specimens per hr.                                                                                                                                                                                     | —                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| Typical time delay from ordering stat test until aspiration of sample                                        | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 24 sec.                                                                                                                                                                                                         | —                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| <b>Immunoassay:</b>                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                    |
| Fully automated microplate immunoassay system                                                                | no                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | —                                                                                                                                                                                                               | yes (up to 12 tests per unit; 96 wells per microplate)                                                                                                                                                                                                                                                                          |                                                                                                                                                    |
| Methodologies supported                                                                                      | enzyme-linked fluorescent assay (ELFA) technology                                                                                                                                                                                                                                                                                                                                                                                                                  | —                                                                                                                                                                                                               | enzyme immunoassay                                                                                                                                                                                                                                                                                                              |                                                                                                                                                    |
| Separation methodologies                                                                                     | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | —                                                                                                                                                                                                               | coated microwell                                                                                                                                                                                                                                                                                                                |                                                                                                                                                    |
| Stat time until completion of a β-hCG test                                                                   | 25 min. (measures intact molecule)                                                                                                                                                                                                                                                                                                                                                                                                                                 | —                                                                                                                                                                                                               | —                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| • Typical time delay from test order to aspiration of sample                                                 | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | —                                                                                                                                                                                                               | —                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| Stat time until completion of a cTn test                                                                     | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | —                                                                                                                                                                                                               | —                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| • Typical time delay from test order to aspiration of sample                                                 | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | —                                                                                                                                                                                                               | —                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| Approximate No. of tests per reagent set/Reagent type                                                        | 30–60 per kit/self-contained single use                                                                                                                                                                                                                                                                                                                                                                                                                            | 50–200 per set, 400–1,800 per pack/self-contained multiuse, open reagent system                                                                                                                                 | —/open reagent system                                                                                                                                                                                                                                                                                                           |                                                                                                                                                    |
| Reagents refrigerated onboard/Reagents ready to use                                                          | no/yes                                                                                                                                                                                                                                                                                                                                                                                                                                                             | yes (8°±2°C)/yes                                                                                                                                                                                                | no (23°±4°C)/—                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                    |
| Reagent lot tracking/Reagent inventory                                                                       | yes/—                                                                                                                                                                                                                                                                                                                                                                                                                                                              | yes/yes                                                                                                                                                                                                         | yes/yes                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                    |
| Reagent form/Reagents barcoded                                                                               | liquid chemistry (closed reagent system)/yes                                                                                                                                                                                                                                                                                                                                                                                                                       | liquid chemistry (open reagent system)/no                                                                                                                                                                       | liquid chemistry (open reagent system)/yes                                                                                                                                                                                                                                                                                      |                                                                                                                                                    |
| Separate reagent pack for each specimen/for each test run                                                    | yes/yes                                                                                                                                                                                                                                                                                                                                                                                                                                                            | no/no                                                                                                                                                                                                           | no/yes                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                    |
| Walkaway capability/Walkaway duration                                                                        | yes/27 specimens or 12 tests                                                                                                                                                                                                                                                                                                                                                                                                                                       | yes/180 min. or 95 specimens or 1,200 tests/assays                                                                                                                                                              | yes/up to 192 specimens or up to 192 tests/assays                                                                                                                                                                                                                                                                               |                                                                                                                                                    |
| Design of sample-handling system                                                                             | rack                                                                                                                                                                                                                                                                                                                                                                                                                                                               | rack                                                                                                                                                                                                            | rack                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                    |
| Uses washable cuvettes/Uses disposable cuvettes                                                              | no/—                                                                                                                                                                                                                                                                                                                                                                                                                                                               | yes/yes (can store up to 80 cuvettes)                                                                                                                                                                           | no/—                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                    |
| Min.–max. sample volume that can be aspirated at one time                                                    | 100–300 µL                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 2–100 µL                                                                                                                                                                                                        | 10–250 µL                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                    |
| Min. reaction volume/Min. specimen volume/Min. dead volume                                                   | 100 µL/100 µL/125 µL for aliquot tubes                                                                                                                                                                                                                                                                                                                                                                                                                             | 180 µL/22 µL/100 µL                                                                                                                                                                                             | 10 µL/—/—                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                    |
| Dedicated pediatric sample cup                                                                               | yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                | yes (dead volume: 20 µL)                                                                                                                                                                                        | no                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                    |
| Primary tube sampling                                                                                        | yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                | yes                                                                                                                                                                                                             | yes                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| Accommodates most standard tube sizes/Accepts nonstandard tube sizes                                         | yes/—                                                                                                                                                                                                                                                                                                                                                                                                                                                              | yes/no                                                                                                                                                                                                          | yes/yes (17 × 100 mm)                                                                                                                                                                                                                                                                                                           |                                                                                                                                                    |
| Pierces caps on primary tubes                                                                                | no                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | yes                                                                                                                                                                                                             | no                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                    |
| Protects against probe collision                                                                             | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | yes                                                                                                                                                                                                             | no                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                    |
| Detects clots/liquid level/short sample                                                                      | yes/yes/yes                                                                                                                                                                                                                                                                                                                                                                                                                                                        | yes/yes/yes                                                                                                                                                                                                     | yes/yes/yes                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                    |
| Detection or quantitation for hemolysis, icterus, lipemia, clots                                             | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | detection for clots; hemolysis, icterus, lipemia not available                                                                                                                                                  | detection for clots; hemolysis, icterus, lipemia not available                                                                                                                                                                                                                                                                  |                                                                                                                                                    |
| Dilutes patient samples onboard/Susceptibility to carryover                                                  | yes (can be programmed to perform dilutions prior to analysis)/no carryover                                                                                                                                                                                                                                                                                                                                                                                        | yes (can be programmed to perform dilutions prior to analysis)/30 parts per million                                                                                                                             | yes (can be programmed to perform dilutions prior to analysis)/0 parts per million                                                                                                                                                                                                                                              |                                                                                                                                                    |
| Automatic rerun capability                                                                                   | no                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | yes                                                                                                                                                                                                             | no                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                    |
| Sample volume can be diluted to rerun out-of-linear-range high results                                       | yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                | yes                                                                                                                                                                                                             | yes                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| Sample volume can be concentrated to rerun out-of-linear-range low results                                   | no                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | yes                                                                                                                                                                                                             | no                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                    |
| Analyzer requires dedicated water supply                                                                     | no                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | no (2 L/hr. consumption during operation)                                                                                                                                                                       | no                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                    |
| Autocalibration/Multipoint calibration supported                                                             | yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 14, 28, or 56 days)                                                                                                                                                                                                                                                                                                                                                                       | yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 7 days)                                                                                                                                 | no (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)                                                                                                                                                                                                                                        |                                                                                                                                                    |
| Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays     | —/—/—/—/every 14, 28, or 56 days                                                                                                                                                                                                                                                                                                                                                                                                                                   | 8 hrs./—/7 days/14 days/14 days                                                                                                                                                                                 | —/assay dependent/assay dependent/—/assay dependent                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| Automatic programmable start/Automatic programmable shutdown                                                 | yes (5 min. warm-up time)/yes                                                                                                                                                                                                                                                                                                                                                                                                                                      | no/no                                                                                                                                                                                                           | no/no                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                    |
| Onboard real-time QC/Onboard software capability to review QC                                                | yes/yes                                                                                                                                                                                                                                                                                                                                                                                                                                                            | yes/yes                                                                                                                                                                                                         | yes/yes                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                    |
| Supports multiple QC lot numbers per analyte                                                                 | yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                | yes                                                                                                                                                                                                             | yes                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| Waste management                                                                                             | manually by user or automated collection onboard instrument                                                                                                                                                                                                                                                                                                                                                                                                        | manually by user or direct to drain                                                                                                                                                                             | automated collection onboard instrument                                                                                                                                                                                                                                                                                         |                                                                                                                                                    |
| Sample barcode-reading capability/Autodiscrimination                                                         | yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes                                                                                                                                                                                                                                                                                                                                                                                                      | yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no                                                                                                                                                    | yes (UPC, Codabar, Code 39, Code 128, Code 93)/yes                                                                                                                                                                                                                                                                              |                                                                                                                                                    |
| Lab can control analyzer from remote computer                                                                | yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                | yes                                                                                                                                                                                                             | no                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                    |
| Instrument can diagnose its own malfunctions                                                                 | yes (operator intervention required to order parts)                                                                                                                                                                                                                                                                                                                                                                                                                | yes (operator intervention required to order parts)                                                                                                                                                             | yes (operator intervention required to order parts)                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| System malfunctions can be diagnosed via remote monitoring                                                   | yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                | yes                                                                                                                                                                                                             | yes                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| UPS backup power supply                                                                                      | yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                | yes                                                                                                                                                                                                             | yes                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| Data-management capability/LIS or EHR systems interfaced                                                     | onboard/Oracle Health, SCC Soft Computer, Meditech, Epic, more                                                                                                                                                                                                                                                                                                                                                                                                     | onboard/AP Vision, Medicus, Schuyler, LabTrack, CGM LabDaq, Medytox                                                                                                                                             | onboard/Clinisys, Oracle Health                                                                                                                                                                                                                                                                                                 |                                                                                                                                                    |
| LIS interface provided/Bidirectional interface capability                                                    | yes (additional cost)/yes (broadcast download and host query)                                                                                                                                                                                                                                                                                                                                                                                                      | yes (additional cost)/yes (broadcast download and host query)                                                                                                                                                   | no/yes (host query)                                                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| Modem servicing provided/Service engineer on-site response time                                              | no/< 24 hrs.                                                                                                                                                                                                                                                                                                                                                                                                                                                       | no/48 hrs.                                                                                                                                                                                                      | no/24 hrs.                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                    |
| Mean time between failures                                                                                   | > 1 year (displays error codes for troubleshooting)                                                                                                                                                                                                                                                                                                                                                                                                                | 1 per year (displays error codes for troubleshooting)                                                                                                                                                           | 250 days (displays error codes for troubleshooting)                                                                                                                                                                                                                                                                             |                                                                                                                                                    |
| Average scheduled maintenance time by lab personnel                                                          | weekly: 10–15 min.                                                                                                                                                                                                                                                                                                                                                                                                                                                 | daily: 30 min.; weekly: 1 hr.; monthly: 2 hrs.                                                                                                                                                                  | daily: 10 min.; weekly: 5 min.                                                                                                                                                                                                                                                                                                  |                                                                                                                                                    |
| Maintenance records kept onboard for user/vendor                                                             | yes/no                                                                                                                                                                                                                                                                                                                                                                                                                                                             | no/no                                                                                                                                                                                                           | no/no                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                    |
| Maintenance training demonstration module onboard                                                            | no                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | no                                                                                                                                                                                                              | no                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                    |
| Training included with purchase/Avg. time for basic user training                                            | yes/— (at customer site)                                                                                                                                                                                                                                                                                                                                                                                                                                           | yes (2 training slots)/3 days (at customer site)                                                                                                                                                                | no/3 days (at customer site)                                                                                                                                                                                                                                                                                                    |                                                                                                                                                    |
| Advanced operator training/Extra charge for follow-up or advanced training                                   | —                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | yes (at customer or vendor site)/yes                                                                                                                                                                            | yes (at customer site)/yes                                                                                                                                                                                                                                                                                                      |                                                                                                                                                    |
| Warranty provided/Cost of annual service contract (24 h/7 d)                                                 | yes (1 year)/—                                                                                                                                                                                                                                                                                                                                                                                                                                                     | yes (1 year)/\$5,500                                                                                                                                                                                            | yes (1 year)/—                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                    |
| Distinguishing features (supplied by company)                                                                | <ul style="list-style-type: none"><li>• specialty menu of critical care (mild traumatic brain injury, acute kidney injury, sepsis, thrombosis), infectious disease (MMRV, Lyme, <i>C. difficile</i>, <i>H. pylori</i>, toxoplasmosis, CMV), and hormone (hCG, progesterone, estradiol, LH, FSH) assays</li><li>• easy-to-use benchtop immunoassay system with single-test, ready-to-use reagent format</li><li>• mean time between failure &gt; 370 days</li></ul> | <ul style="list-style-type: none"><li>• uninterrupted workflow</li><li>• Windows-based, intuitive, user-friendly software</li><li>• high-quality components for long stability and result reliability</li></ul> | <ul style="list-style-type: none"><li>• run any assay from any vendor—fully automated open system</li><li>• reliable workload scheduling—more than 98 percent mean time between failures</li><li>• saves space—less than 4 sq. ft. of linear counter space to process up to two 96-well microplates and 100 specimens</li></ul> |                                                                                                                                                    |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <sup>†</sup> <i>all information listed was provided to CAP TODAY in 2025; company did not provide updated information by 2026 entry deadline</i>                                                                |                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                    |

|                                                                                                              |                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                        |
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| Part 4 of 6                                                                                                  | <b>Gold Standard Diagnostics</b><br>gsd.sales@us.goldstandarddiagnostics.com<br><b>Davis, CA</b><br><b>530-759-8000</b> https://clinical.goldstandarddiagnostics.com/us                                                                                                | <b>HORIBA</b><br><b>Susan Behnke</b> medical-marketing.us@horiba.com<br><b>Irvine, CA</b><br><b>888-903-5001</b> www.horiba.com/us/en/medical/                                                                                                                                                                                                                                 | <b>Nova Biomedical</b><br>info@novabio.com<br><b>Waltham, MA</b><br><b>800-458-5813</b> www.novabiomedical.com                                                                                                                                                                                                                                                                         |
| <b>FOR POINT-OF-CARE USE AND LOW-VOLUME LABORATORIES</b>                                                     |                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                        |
| Name of instrument                                                                                           | Bolt                                                                                                                                                                                                                                                                   | Pentra C400                                                                                                                                                                                                                                                                                                                                                                    | Stat Profile Prime Plus†                                                                                                                                                                                                                                                                                                                                                               |
| Type of instrument                                                                                           | immunoassay                                                                                                                                                                                                                                                            | chemistry                                                                                                                                                                                                                                                                                                                                                                      | chemistry                                                                                                                                                                                                                                                                                                                                                                              |
| Operational type/Model type                                                                                  | batch/benchtop                                                                                                                                                                                                                                                         | batch, random access, continuous random access, discrete/benchtop                                                                                                                                                                                                                                                                                                              | random access/benchtop                                                                                                                                                                                                                                                                                                                                                                 |
| List price/First year sold in U.S.                                                                           | —/2016                                                                                                                                                                                                                                                                 | \$100,000/2006                                                                                                                                                                                                                                                                                                                                                                 | —/2018                                                                                                                                                                                                                                                                                                                                                                                 |
| Targeted hospital bed size/Targeted test volume                                                              | —                                                                                                                                                                                                                                                                      | ≤ 250/daily: 1,200; monthly: 24,000; annual: 288,000                                                                                                                                                                                                                                                                                                                           | —                                                                                                                                                                                                                                                                                                                                                                                      |
| Company manufactures instrument                                                                              | yes (also sold by distribution partners)                                                                                                                                                                                                                               | yes (also sold by distribution partners)                                                                                                                                                                                                                                                                                                                                       | yes (also sold by distribution partners)                                                                                                                                                                                                                                                                                                                                               |
| Other models in this family of analyzers                                                                     | Thunderbolt                                                                                                                                                                                                                                                            | Pentra 400, Pentra C200                                                                                                                                                                                                                                                                                                                                                        | Stat Profile Prime CCS, Stat Profile Prime, Stat Profile Prime ES                                                                                                                                                                                                                                                                                                                      |
| No. of units in clinical use in U.S./Outside U.S. (countries)                                                | —                                                                                                                                                                                                                                                                      | 650/1,900                                                                                                                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                                                                                                                                      |
| Dimensions (H × W × D)/Instrument footprint                                                                  | 21.5 × 38.5 × 24 in. (width includes laptop)/6.42 sq. ft.                                                                                                                                                                                                              | 25 × 40 × 28 in./7.7 sq. ft.                                                                                                                                                                                                                                                                                                                                                   | 18 × 14 × 16 in./1.5 sq. ft.                                                                                                                                                                                                                                                                                                                                                           |
| Weight empty/Weight fully loaded                                                                             | 60 lbs./110 lbs.                                                                                                                                                                                                                                                       | 264 lbs./266 lbs.                                                                                                                                                                                                                                                                                                                                                              | 35 lbs./42 lbs.                                                                                                                                                                                                                                                                                                                                                                        |
| No. of different measured assays onboard simultaneously                                                      | open EIA platform (up to 12 with limit of two washes, nine reagents and common incubation temperature, plate frame type)                                                                                                                                               | 55 (55 can be run and calibrated at one time)                                                                                                                                                                                                                                                                                                                                  | 20 (20 can be run and calibrated at one time)                                                                                                                                                                                                                                                                                                                                          |
| No. of user-definable (open chemistry) channels                                                              | —                                                                                                                                                                                                                                                                      | 40 (40 can be active simultaneously)                                                                                                                                                                                                                                                                                                                                           | 30 (30 can be active simultaneously)                                                                                                                                                                                                                                                                                                                                                   |
| Test throughput per hour/Assay run time                                                                      | assay dependent (96 tests in throughput)/20 min.—4 hr. (avg. 2 hr.)                                                                                                                                                                                                    | 420 (4 tests in throughput)/1–10 min. (avg. 5 min.)                                                                                                                                                                                                                                                                                                                            | up to 38 (760 tests in throughput)/avg. 90 sec.                                                                                                                                                                                                                                                                                                                                        |
| <b>Chemistry:</b>                                                                                            |                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                        |
| No. of direct ion-selective electrode channels                                                               | —                                                                                                                                                                                                                                                                      | 3                                                                                                                                                                                                                                                                                                                                                                              | 7                                                                                                                                                                                                                                                                                                                                                                                      |
| Detection methods                                                                                            | —                                                                                                                                                                                                                                                                      | photometry, potentiometry, enzyme immunoassay                                                                                                                                                                                                                                                                                                                                  | photometry, potentiometry, Severinghaus, amperometry, conductivity, enzyme                                                                                                                                                                                                                                                                                                             |
| Stat time until completion/specimen throughput for:                                                          |                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                        |
| • Ion-selective electrode                                                                                    | —                                                                                                                                                                                                                                                                      | < 5 min./37 specimens per hr.                                                                                                                                                                                                                                                                                                                                                  | 90 sec./38 specimens per hr.                                                                                                                                                                                                                                                                                                                                                           |
| • Basic metabolic panel                                                                                      | —                                                                                                                                                                                                                                                                      | 7.5 min./35 specimens per hr.                                                                                                                                                                                                                                                                                                                                                  | 90 sec./38 specimens per hr.                                                                                                                                                                                                                                                                                                                                                           |
| • Complete metabolic panel                                                                                   | —                                                                                                                                                                                                                                                                      | < 11 min./23 specimens per hr.                                                                                                                                                                                                                                                                                                                                                 | 90 sec./38 specimens per hr.                                                                                                                                                                                                                                                                                                                                                           |
| Typical time delay from ordering stat test until aspiration of sample                                        | —                                                                                                                                                                                                                                                                      | < 1 min.                                                                                                                                                                                                                                                                                                                                                                       | 3 sec.                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Immunoassay:</b>                                                                                          |                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                        |
| Fully automated microplate immunoassay system                                                                | yes (96 tests per unit; 96 wells per microplate)                                                                                                                                                                                                                       | —                                                                                                                                                                                                                                                                                                                                                                              | —                                                                                                                                                                                                                                                                                                                                                                                      |
| Methodologies supported                                                                                      | chemiluminescence, enzyme immunoassay                                                                                                                                                                                                                                  | —                                                                                                                                                                                                                                                                                                                                                                              | —                                                                                                                                                                                                                                                                                                                                                                                      |
| Separation methodologies                                                                                     | coated microwell                                                                                                                                                                                                                                                       | —                                                                                                                                                                                                                                                                                                                                                                              | —                                                                                                                                                                                                                                                                                                                                                                                      |
| Stat time until completion of a β-hCG test                                                                   | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                                                                                                                              | —                                                                                                                                                                                                                                                                                                                                                                                      |
| • Typical time delay from test order to aspiration of sample                                                 | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                                                                                                                              | —                                                                                                                                                                                                                                                                                                                                                                                      |
| Stat time until completion of a cTn test                                                                     | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                                                                                                                              | —                                                                                                                                                                                                                                                                                                                                                                                      |
| • Typical time delay from test order to aspiration of sample                                                 | —                                                                                                                                                                                                                                                                      | —                                                                                                                                                                                                                                                                                                                                                                              | —                                                                                                                                                                                                                                                                                                                                                                                      |
| Approximate No. of tests per reagent set/Reagent type                                                        | 96/open reagent system                                                                                                                                                                                                                                                 | 100–400/self-contained multiuse, open reagent system                                                                                                                                                                                                                                                                                                                           | 100, 200, 300, 400, or 500/self-contained multiuse                                                                                                                                                                                                                                                                                                                                     |
| Reagents refrigerated onboard/Reagents ready to use                                                          | no (room temperature–40°C)/variable; reagent specific                                                                                                                                                                                                                  | yes (2°–8°C)/variable; reagent specific                                                                                                                                                                                                                                                                                                                                        | no/yes                                                                                                                                                                                                                                                                                                                                                                                 |
| Reagent lot tracking/Reagent inventory                                                                       | yes/no                                                                                                                                                                                                                                                                 | yes/yes                                                                                                                                                                                                                                                                                                                                                                        | yes/yes                                                                                                                                                                                                                                                                                                                                                                                |
| Reagent form/Reagents barcoded                                                                               | liquid chemistry (open reagent system)/no                                                                                                                                                                                                                              | liquid chemistry (open reagent system)/yes                                                                                                                                                                                                                                                                                                                                     | liquid chemistry (closed reagent system)/yes                                                                                                                                                                                                                                                                                                                                           |
| Separate reagent pack for each specimen/for each test run                                                    | no/yes                                                                                                                                                                                                                                                                 | no/no                                                                                                                                                                                                                                                                                                                                                                          | no/no                                                                                                                                                                                                                                                                                                                                                                                  |
| Walkaway capability/Walkaway duration                                                                        | yes/avg. 120 min.                                                                                                                                                                                                                                                      | yes/180 min. or 60 specimens or > 800 tests/assays                                                                                                                                                                                                                                                                                                                             | yes/1 min. or 1 specimen or 20 tests/assays                                                                                                                                                                                                                                                                                                                                            |
| Design of sample-handling system                                                                             | rack                                                                                                                                                                                                                                                                   | rack                                                                                                                                                                                                                                                                                                                                                                           | probe                                                                                                                                                                                                                                                                                                                                                                                  |
| Uses washable cuvettes/Uses disposable cuvettes                                                              | no/no                                                                                                                                                                                                                                                                  | no/yes (can store up to 432 cuvettes)                                                                                                                                                                                                                                                                                                                                          | no/yes                                                                                                                                                                                                                                                                                                                                                                                 |
| Min.–max. sample volume that can be aspirated at one time                                                    | 1–300 µL                                                                                                                                                                                                                                                               | 2–60 µL                                                                                                                                                                                                                                                                                                                                                                        | 90–135 µL                                                                                                                                                                                                                                                                                                                                                                              |
| Min. reaction volume/Min. specimen volume/Min. dead volume                                                   | 25 µL/151 µL/150 µL                                                                                                                                                                                                                                                    | 180 µL/2 µL/100 µL                                                                                                                                                                                                                                                                                                                                                             | 135 µL/135 µL/—                                                                                                                                                                                                                                                                                                                                                                        |
| Dedicated pediatric sample cup                                                                               | no                                                                                                                                                                                                                                                                     | yes (dead volume: 100 µL)                                                                                                                                                                                                                                                                                                                                                      | no                                                                                                                                                                                                                                                                                                                                                                                     |
| Primary tube sampling                                                                                        | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                                                                                                                            | yes                                                                                                                                                                                                                                                                                                                                                                                    |
| Accommodates most standard tube sizes/Accepts nonstandard tube sizes                                         | yes/no                                                                                                                                                                                                                                                                 | yes/yes                                                                                                                                                                                                                                                                                                                                                                        | yes/yes                                                                                                                                                                                                                                                                                                                                                                                |
| Pierces caps on primary tubes                                                                                | no                                                                                                                                                                                                                                                                     | no                                                                                                                                                                                                                                                                                                                                                                             | no                                                                                                                                                                                                                                                                                                                                                                                     |
| Protects against probe collision                                                                             | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                                                                                                                            | yes                                                                                                                                                                                                                                                                                                                                                                                    |
| Detects clots/liquid level/short sample                                                                      | no/yes/yes                                                                                                                                                                                                                                                             | yes/yes/yes                                                                                                                                                                                                                                                                                                                                                                    | yes/yes/yes                                                                                                                                                                                                                                                                                                                                                                            |
| Detection or quantitation for hemolysis, icterus, lipemia, clots                                             | hemolysis, icterus, lipemia, clots not available                                                                                                                                                                                                                       | detection for clots; hemolysis, icterus, lipemia not available                                                                                                                                                                                                                                                                                                                 | detection for hemolysis, clots                                                                                                                                                                                                                                                                                                                                                         |
| Dilutes patient samples onboard/Susceptibility to carryover                                                  | yes (can be programmed to perform dilutions prior to analysis)/assay specific                                                                                                                                                                                          | yes (can be programmed to perform dilutions prior to analysis)/—                                                                                                                                                                                                                                                                                                               | no/—                                                                                                                                                                                                                                                                                                                                                                                   |
| Automatic rerun capability                                                                                   | no                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                                                                                                                            | no                                                                                                                                                                                                                                                                                                                                                                                     |
| Sample volume can be diluted to rerun out-of-linear-range high results                                       | no                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                                                                                                                            | no                                                                                                                                                                                                                                                                                                                                                                                     |
| Sample volume can be concentrated to rerun out-of-linear-range low results                                   | no                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                                                                                                                            | no                                                                                                                                                                                                                                                                                                                                                                                     |
| Analyzer requires dedicated water supply                                                                     | no                                                                                                                                                                                                                                                                     | no (average of 0.5 L/hr. consumption during operation)                                                                                                                                                                                                                                                                                                                         | no                                                                                                                                                                                                                                                                                                                                                                                     |
| Autocalibration/Multipoint calibration supported                                                             | no (calibrants are not stored onboard)/yes (recommended avg. frequency: per batch)                                                                                                                                                                                     | yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 14 days)                                                                                                                                                                                                                                                                                               | yes (calibrants can be stored onboard)/yes                                                                                                                                                                                                                                                                                                                                             |
| Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays     | —/—/—/—/per batch                                                                                                                                                                                                                                                      | 2 hrs. (automatic)/—/—/avg. 14 days/—                                                                                                                                                                                                                                                                                                                                          | —                                                                                                                                                                                                                                                                                                                                                                                      |
| Automatic programmable start/Automatic programmable shutdown                                                 | no (5 min. start-up time)/no                                                                                                                                                                                                                                           | yes (5 min. start-up time)/no                                                                                                                                                                                                                                                                                                                                                  | yes (5 min. avg. start-up time)/yes                                                                                                                                                                                                                                                                                                                                                    |
| Onboard real-time QC/Onboard software capability to review QC                                                | yes/yes                                                                                                                                                                                                                                                                | yes/yes                                                                                                                                                                                                                                                                                                                                                                        | yes/yes                                                                                                                                                                                                                                                                                                                                                                                |
| Supports multiple QC lot numbers per analyte                                                                 | yes                                                                                                                                                                                                                                                                    | no                                                                                                                                                                                                                                                                                                                                                                             | yes                                                                                                                                                                                                                                                                                                                                                                                    |
| Waste management                                                                                             | manually by user                                                                                                                                                                                                                                                       | direct to drain or container if no drain available                                                                                                                                                                                                                                                                                                                             | automated collection onboard instrument                                                                                                                                                                                                                                                                                                                                                |
| Sample barcode-reading capability/Autodiscrimination                                                         | yes (unspecified)/no                                                                                                                                                                                                                                                   | yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes                                                                                                                                                                                                                                                                                                                  | yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes                                                                                                                                                                                                                                                                                                                          |
| Lab can control analyzer from remote computer                                                                | no                                                                                                                                                                                                                                                                     | no                                                                                                                                                                                                                                                                                                                                                                             | yes                                                                                                                                                                                                                                                                                                                                                                                    |
| Instrument can diagnose its own malfunctions                                                                 | yes (operator intervention required to order parts)                                                                                                                                                                                                                    | yes (operator intervention required to order parts)                                                                                                                                                                                                                                                                                                                            | yes (operator intervention required to order parts)                                                                                                                                                                                                                                                                                                                                    |
| System malfunctions can be diagnosed via remote monitoring                                                   | yes                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                                                                                                                            | yes                                                                                                                                                                                                                                                                                                                                                                                    |
| UPS backup power supply                                                                                      | no                                                                                                                                                                                                                                                                     | no                                                                                                                                                                                                                                                                                                                                                                             | yes (optional)                                                                                                                                                                                                                                                                                                                                                                         |
| Data-management capability/LIS or EHR systems interfaced                                                     | onboard/—                                                                                                                                                                                                                                                              | onboard/CGM LabDaq, Clinisys, Oracle Health, Meditech, Schuyler House                                                                                                                                                                                                                                                                                                          | onboard, optional add-on (NovaNet, more)/—                                                                                                                                                                                                                                                                                                                                             |
| LIS interface provided/Bidirectional interface capability                                                    | no/yes (host query)                                                                                                                                                                                                                                                    | no/yes (broadcast download and host query)                                                                                                                                                                                                                                                                                                                                     | yes (included in instrument price)/yes (broadcast download and host query)                                                                                                                                                                                                                                                                                                             |
| Modem servicing provided/Service engineer on-site response time                                              | yes/48 hrs.                                                                                                                                                                                                                                                            | no/< 24 hrs.                                                                                                                                                                                                                                                                                                                                                                   | no/within 8 hrs.                                                                                                                                                                                                                                                                                                                                                                       |
| Mean time between failures                                                                                   | — (displays error codes for troubleshooting)                                                                                                                                                                                                                           | avg. 250 days (displays error codes for troubleshooting)                                                                                                                                                                                                                                                                                                                       | — (displays error codes for troubleshooting)                                                                                                                                                                                                                                                                                                                                           |
| Average scheduled maintenance time by lab personnel                                                          | daily: 5 min.; weekly: 15 min.; monthly: 20 min.                                                                                                                                                                                                                       | daily: < 5 min.; weekly: < 15 min.; monthly: < 30 min.                                                                                                                                                                                                                                                                                                                         | —                                                                                                                                                                                                                                                                                                                                                                                      |
| Maintenance records kept onboard for user/vendor                                                             | yes/some records (dye tests and calibrations)                                                                                                                                                                                                                          | yes (includes audit trail of who replaced parts)/no                                                                                                                                                                                                                                                                                                                            | yes/yes (both include audit trail of who replaced parts)                                                                                                                                                                                                                                                                                                                               |
| Maintenance training demonstration module onboard                                                            | no                                                                                                                                                                                                                                                                     | no                                                                                                                                                                                                                                                                                                                                                                             | yes                                                                                                                                                                                                                                                                                                                                                                                    |
| Training included with purchase/Avg. time for basic user training                                            | yes (No. of training slots client dependent)/4 hrs. (at customer or vendor site)                                                                                                                                                                                       | yes/2.5 days (at customer or vendor site)                                                                                                                                                                                                                                                                                                                                      | yes/30 min. (at customer site)                                                                                                                                                                                                                                                                                                                                                         |
| Advanced operator training/Extra charge for follow-up or advanced training                                   | yes (at customer or vendor site)/yes (client dependent)                                                                                                                                                                                                                | yes (at vendor site)/yes                                                                                                                                                                                                                                                                                                                                                       | yes/no                                                                                                                                                                                                                                                                                                                                                                                 |
| Warranty provided/Cost of annual service contract (24 h/7 d)                                                 | yes (1 year)/—                                                                                                                                                                                                                                                         | yes (1 year)/—                                                                                                                                                                                                                                                                                                                                                                 | yes (5 years)/—                                                                                                                                                                                                                                                                                                                                                                        |
| Distinguishing features (supplied by company)                                                                | • open architecture: program any EIA or CLIA protocol, fully customizable with flexible, intuitive software<br>• space saving: high capacity (96 samples) in 2 ft. × 2 ft. footprint<br>• cost saving: low instrument price point with no routine consumables required | • full menu of moderately complex drugs of abuse and general chemistry assays; can run up to 55 assays onboard with 420 results/hr.<br>• no requirement for external water system, no drain or special electrical required; remote diagnostics available for real-time troubleshooting<br>• flexible, open-channel system capable of running ≤ 40 third-party reagents onboard | • maintenance-free MicroSensor Card and disposable cartridge technology for sensors and reagents<br>• broad menu including iMg, BUN, creatinine/eGFR CO-oximetry, estimated plasma volume<br>• automated, liquid QC and supplemental quality monitoring for EP23-A compliance and real-time verification of all analytical components during calibration, sample analysis, QC analysis |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i> |                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                | <i>†all information listed was provided to CAP TODAY in 2025; company did not provide updated information by 2026 entry deadline</i>                                                                                                                                                                                                                                                   |

|                                                                                                              |                                                                                                                                                                                                                                                                                                                                       | CHEMISTRY AND IMMUNOASSAY ANALYZERS                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                              | JUNE 2026   CAP TODAY 51 |
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| Part 5 of 6                                                                                                  | <b>QuidelOrtho</b><br><b>Laura Osborne</b> laura.osborne@quidelortho.com<br><b>Raritan, NJ</b><br><b>800-828-6316</b> www.quidelortho.com                                                                                                                                                                                             | <b>Roche Diagnostics</b><br><b>Brianna Frederick</b> brianna.frederick@roche.com<br><b>Indianapolis, IN</b><br><b>800-428-5074</b> diagnostics.roche.com/us/en/home.html                                                                                                                | <b>Roche Diagnostics</b><br><b>Brianna Frederick</b> brianna.frederick@roche.com<br><b>Indianapolis, IN</b><br><b>800-428-5074</b> diagnostics.roche.com/us/en/home.html                                                                                                     |                          |
| <b>FOR POINT-OF-CARE USE AND LOW-VOLUME LABORATORIES</b>                                                     |                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                              |                          |
| Name of instrument                                                                                           | VITROS XT 3400 Chemistry Systems                                                                                                                                                                                                                                                                                                      | cobas e 411                                                                                                                                                                                                                                                                             | cobas pure integrated solutions                                                                                                                                                                                                                                              |                          |
| Type of instrument                                                                                           | chemistry                                                                                                                                                                                                                                                                                                                             | immunoassay                                                                                                                                                                                                                                                                             | combination chemistry/immunoassay                                                                                                                                                                                                                                            |                          |
| Operational type/Model type                                                                                  | batch, random access, continuous random access, discrete/floor standing                                                                                                                                                                                                                                                               | random access, continuous random access/benchtop                                                                                                                                                                                                                                        | random access, continuous random access/floor standing                                                                                                                                                                                                                       |                          |
| List price/First year sold in U.S.                                                                           | —/2019                                                                                                                                                                                                                                                                                                                                | —/2008                                                                                                                                                                                                                                                                                  | —/2022                                                                                                                                                                                                                                                                       |                          |
| Targeted hospital bed size/Targeted test volume                                                              | —/annual: 50,000–4 million                                                                                                                                                                                                                                                                                                            | < 100/daily: < 200; monthly: < 40,000; annual: < 500,000                                                                                                                                                                                                                                | < 200/daily: 410–2,054; monthly: 12,500–62,500; annual: 150,000–750,000                                                                                                                                                                                                      |                          |
| Company manufactures instrument                                                                              | no (manufactured by JABIL; also sold by Cardinal, McKesson, more)                                                                                                                                                                                                                                                                     | no (manufactured by Hitachi High-Technologies)                                                                                                                                                                                                                                          | no (manufactured by Hitachi High-Technologies)                                                                                                                                                                                                                               |                          |
| Other models in this family of analyzers                                                                     | VITROS 4600 Chemistry System, VITROS 350 Chemistry System                                                                                                                                                                                                                                                                             | —                                                                                                                                                                                                                                                                                       | chem: cobas c 303; immuno: cobas c 402                                                                                                                                                                                                                                       |                          |
| No. of units in clinical use in U.S./Outside U.S. (countries)                                                | > 140/> 225 (North, Central, and South Americas, more)                                                                                                                                                                                                                                                                                | > 800/> 10,000 (> 50 countries)                                                                                                                                                                                                                                                         | < 1,000/> 1,000 (> 50 countries)                                                                                                                                                                                                                                             |                          |
| Dimensions (H × W × D)/Instrument footprint                                                                  | 53 × 58 × 34 in./—                                                                                                                                                                                                                                                                                                                    | disk: 31.4 × 47.2 × 28.7 in./9.4 sq. ft.; rack: 31.4 × 67 × 37.4 in./17.4 sq. ft.                                                                                                                                                                                                       | 5.8 × 8 × 2.6 ft./21 sq. ft.                                                                                                                                                                                                                                                 |                          |
| Weight empty/Weight fully loaded                                                                             | 1,150 lbs./—                                                                                                                                                                                                                                                                                                                          | disk: 397 lbs./397 lbs.; rack: 551 lbs./551 lbs.                                                                                                                                                                                                                                        | 2,205 lbs./2,205 lbs.                                                                                                                                                                                                                                                        |                          |
| No. of different measured assays onboard simultaneously                                                      | 89 (89 can be run and calibrated at one time)                                                                                                                                                                                                                                                                                         | 18 (18 can be run and calibrated at one time)                                                                                                                                                                                                                                           | up to 73 (up to 73 can be run and calibrated at one time [chem: 42, immuno: 28, ISE: 3])                                                                                                                                                                                     |                          |
| No. of user-definable (open chemistry) channels                                                              | —                                                                                                                                                                                                                                                                                                                                     | 0                                                                                                                                                                                                                                                                                       | 10 (10 can be active simultaneously)                                                                                                                                                                                                                                         |                          |
| Test throughput per hour/Assay run time                                                                      | 1,130/2.5–9 min. (avg. 5 min.)                                                                                                                                                                                                                                                                                                        | 86 (86 tests in throughput)/9–27 min. (avg. 18 min.)                                                                                                                                                                                                                                    | 870 (up to 300 photometric, 450 ISE tests in throughput)/chem: 4–10 min. (avg. 10 min.); immuno: 9–27 min. (avg. 18 min.)                                                                                                                                                    |                          |
| <b>Chemistry:</b>                                                                                            |                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                              |                          |
| No. of direct ion-selective electrode channels                                                               | 3                                                                                                                                                                                                                                                                                                                                     | —                                                                                                                                                                                                                                                                                       | 3                                                                                                                                                                                                                                                                            |                          |
| Detection methods                                                                                            | photometry, potentiometry, turbidimetry                                                                                                                                                                                                                                                                                               | —                                                                                                                                                                                                                                                                                       | photometry, potentiometry                                                                                                                                                                                                                                                    |                          |
| Stat time until completion/specimen throughput for:                                                          |                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                              |                          |
| • Ion-selective electrode                                                                                    | 5 min./126 specimens per hr.                                                                                                                                                                                                                                                                                                          | —                                                                                                                                                                                                                                                                                       | 4.5 min. for ISE, 10 min. with CO2/ISE: 150 specimens per hr.                                                                                                                                                                                                                |                          |
| • Basic metabolic panel                                                                                      | 6 min./95 specimens per hr.                                                                                                                                                                                                                                                                                                           | —                                                                                                                                                                                                                                                                                       | 10 min./—                                                                                                                                                                                                                                                                    |                          |
| • Complete metabolic panel                                                                                   | 7.5 min./74 specimens per hr.                                                                                                                                                                                                                                                                                                         | —                                                                                                                                                                                                                                                                                       | 10 min./—                                                                                                                                                                                                                                                                    |                          |
| Typical time delay from ordering stat test until aspiration of sample                                        | 1 min.                                                                                                                                                                                                                                                                                                                                | —                                                                                                                                                                                                                                                                                       | < 1 min.                                                                                                                                                                                                                                                                     |                          |
| <b>Immunoassay:</b>                                                                                          |                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                              |                          |
| Fully automated microplate immunoassay system                                                                | —                                                                                                                                                                                                                                                                                                                                     | no                                                                                                                                                                                                                                                                                      | no                                                                                                                                                                                                                                                                           |                          |
| Methodologies supported                                                                                      | —                                                                                                                                                                                                                                                                                                                                     | electrochemiluminescence                                                                                                                                                                                                                                                                | electrochemiluminescence                                                                                                                                                                                                                                                     |                          |
| Separation methodologies                                                                                     | —                                                                                                                                                                                                                                                                                                                                     | magnetic particle                                                                                                                                                                                                                                                                       | magnetic particle                                                                                                                                                                                                                                                            |                          |
| Stat time until completion of a β-hCG test                                                                   | —                                                                                                                                                                                                                                                                                                                                     | ~10 min.                                                                                                                                                                                                                                                                                | ~10 min.                                                                                                                                                                                                                                                                     |                          |
| • Typical time delay from test order to aspiration of sample                                                 | —                                                                                                                                                                                                                                                                                                                                     | < 1 min.                                                                                                                                                                                                                                                                                | < 1 min.                                                                                                                                                                                                                                                                     |                          |
| Stat time until completion of a cTn test                                                                     | —                                                                                                                                                                                                                                                                                                                                     | ~10 min.                                                                                                                                                                                                                                                                                | ~10 min.                                                                                                                                                                                                                                                                     |                          |
| • Typical time delay from test order to aspiration of sample                                                 | —                                                                                                                                                                                                                                                                                                                                     | < 1 min.                                                                                                                                                                                                                                                                                | < 1 min.                                                                                                                                                                                                                                                                     |                          |
| Approximate No. of tests per reagent set/Reagent type                                                        | 18–120/self-contained single use                                                                                                                                                                                                                                                                                                      | 100–200/self-contained multiuse                                                                                                                                                                                                                                                         | up to 3,300 (chem), 300 (immuno)/self-contained multiuse                                                                                                                                                                                                                     |                          |
| Reagents refrigerated onboard/Reagents ready to use                                                          | yes (10°C)/yes                                                                                                                                                                                                                                                                                                                        | no (20° ±3°C)/yes                                                                                                                                                                                                                                                                       | yes (5°–15°C [chemistry], 6°–10°C [immunoassay])/yes                                                                                                                                                                                                                         |                          |
| Reagent lot tracking/Reagent inventory                                                                       | yes/yes                                                                                                                                                                                                                                                                                                                               | yes/yes                                                                                                                                                                                                                                                                                 | yes/yes                                                                                                                                                                                                                                                                      |                          |
| Reagent form/Reagents barcoded                                                                               | dry chemistry (closed reagent system)/yes                                                                                                                                                                                                                                                                                             | liquid chemistry (closed reagent system)/yes                                                                                                                                                                                                                                            | liquid chemistry (open reagent system)/yes                                                                                                                                                                                                                                   |                          |
| Separate reagent pack for each specimen/for each test run                                                    | no/no                                                                                                                                                                                                                                                                                                                                 | no/no                                                                                                                                                                                                                                                                                   | no/yes                                                                                                                                                                                                                                                                       |                          |
| Walkaway capability/Walkaway duration                                                                        | yes/—                                                                                                                                                                                                                                                                                                                                 | yes/30–60 min. or 30 specimens (disk), 75 specimens (rack) or 2,000–3,000 tests/assays                                                                                                                                                                                                  | yes/30–45 min.                                                                                                                                                                                                                                                               |                          |
| Design of sample-handling system                                                                             | universal sample tray, continuous load and unload, circular routine sample center                                                                                                                                                                                                                                                     | disk: ring; rack: rack                                                                                                                                                                                                                                                                  | 5-position rack                                                                                                                                                                                                                                                              |                          |
| Uses washable cuvettes/Uses disposable cuvettes                                                              | no/no                                                                                                                                                                                                                                                                                                                                 | no/yes (can store up to 360 assay tips, 180 assay cups)                                                                                                                                                                                                                                 | yes/yes (can store up to 210 cuvettes)                                                                                                                                                                                                                                       |                          |
| Min.–max. sample volume that can be aspirated at one time                                                    | 2–200 µL                                                                                                                                                                                                                                                                                                                              | 10–50 µL                                                                                                                                                                                                                                                                                | 1–60 µL                                                                                                                                                                                                                                                                      |                          |
| Min. reaction volume/Min. specimen volume/Min. dead volume                                                   | —/2.5 µL/35 µL                                                                                                                                                                                                                                                                                                                        | 100 µL/10 µL/100 µL                                                                                                                                                                                                                                                                     | 75 µL/1.5 µL (chemistry), 4 µL (immunoassay)/50 µL                                                                                                                                                                                                                           |                          |
| Dedicated pediatric sample cup                                                                               | yes (dead volume: 35 µL)                                                                                                                                                                                                                                                                                                              | yes (dead volume: 50 µL)                                                                                                                                                                                                                                                                | yes (dead volume: 50 µL)                                                                                                                                                                                                                                                     |                          |
| Primary tube sampling                                                                                        | yes                                                                                                                                                                                                                                                                                                                                   | yes                                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                          |                          |
| Accommodates most standard tube sizes/Accepts nonstandard tube sizes                                         | yes/yes (micro sample cups, micro collection containers, 10.25 × 45 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, more)                                                                                                                                                                                                                    | yes/yes (12 × 100 mm)                                                                                                                                                                                                                                                                   | yes/yes (11 x 102 mm [chem], 13 x 102 mm [immuno])                                                                                                                                                                                                                           |                          |
| Pierces caps on primary tubes                                                                                | no                                                                                                                                                                                                                                                                                                                                    | no                                                                                                                                                                                                                                                                                      | no                                                                                                                                                                                                                                                                           |                          |
| Protects against probe collision                                                                             | yes                                                                                                                                                                                                                                                                                                                                   | yes                                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                          |                          |
| Detects clots/liquid level/short sample                                                                      | yes/yes/yes                                                                                                                                                                                                                                                                                                                           | yes/yes/yes                                                                                                                                                                                                                                                                             | yes/yes/yes                                                                                                                                                                                                                                                                  |                          |
| Detection or quantitation for hemolysis, icterus, lipemia, clots                                             | detection for clots; detection and quantitation for hemolysis, icterus, lipemia                                                                                                                                                                                                                                                       | detection for clots; hemolysis, icterus, lipemia not available                                                                                                                                                                                                                          | quantitation for hemolysis, icterus, lipemia; detection for clots                                                                                                                                                                                                            |                          |
| Dilutes patient samples onboard/Susceptibility to carryover                                                  | yes/0                                                                                                                                                                                                                                                                                                                                 | yes (can be programmed to perform sample dilutions prior to analysis)/0 (uses disposable tips)                                                                                                                                                                                          | yes (can be programmed to perform dilutions prior to analysis)/< 1 part per million (chemistry), no carryover (immunoassay)                                                                                                                                                  |                          |
| Automatic rerun capability                                                                                   | yes                                                                                                                                                                                                                                                                                                                                   | yes                                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                          |                          |
| Sample volume can be diluted to rerun out-of-linear-range high results                                       | yes                                                                                                                                                                                                                                                                                                                                   | yes                                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                          |                          |
| Sample volume can be concentrated to rerun out-of-linear-range low results                                   | yes                                                                                                                                                                                                                                                                                                                                   | yes                                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                          |                          |
| Analyzer requires dedicated water supply                                                                     | no                                                                                                                                                                                                                                                                                                                                    | no (3 L consumption for 250 tests)                                                                                                                                                                                                                                                      | yes (12 L/hr. consumption during operation for chemistry, 16 L/hr. for immunoassay)                                                                                                                                                                                          |                          |
| Autocalibration/Multipoint calibration supported                                                             | no (calibrants are not stored onboard)/yes (recommended avg. frequency: 6 months or lot change)                                                                                                                                                                                                                                       | yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)                                                                                                                                                                                                       | yes (calibrants are not stored onboard)/yes (recommended avg. frequency: once per lot [chem], up to 84 days per lot [immuno])                                                                                                                                                |                          |
| Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays     | 6 months/6 months/6 months/6 months or lot change for most chemistry assays/—                                                                                                                                                                                                                                                         | —/—/—/—/28 days                                                                                                                                                                                                                                                                         | once per lot/once per lot/once per lot/once per lot/up to 84 days per lot                                                                                                                                                                                                    |                          |
| Automatic programmable start/Automatic programmable shutdown                                                 | no/no                                                                                                                                                                                                                                                                                                                                 | yes (4 min. avg. start-up time)/yes                                                                                                                                                                                                                                                     | yes (6.5 min. avg. start-up time)/yes                                                                                                                                                                                                                                        |                          |
| Onboard real-time QC/Onboard software capability to review QC                                                | yes/yes                                                                                                                                                                                                                                                                                                                               | yes/yes                                                                                                                                                                                                                                                                                 | yes/yes                                                                                                                                                                                                                                                                      |                          |
| Supports multiple QC lot numbers per analyte                                                                 | yes                                                                                                                                                                                                                                                                                                                                   | yes                                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                          |                          |
| Waste management                                                                                             | manually by user                                                                                                                                                                                                                                                                                                                      | automated collection onboard instrument                                                                                                                                                                                                                                                 | direct to drain                                                                                                                                                                                                                                                              |                          |
| Sample barcode-reading capability/Autodiscrimination                                                         | yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/yes                                                                                                                                                                                                                                                               | yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, PDF417)/yes                                                                                                                                                                                                                        | yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes                                                                                                                                                                                                                     |                          |
| Lab can control analyzer from remote computer                                                                | no                                                                                                                                                                                                                                                                                                                                    | no                                                                                                                                                                                                                                                                                      | yes                                                                                                                                                                                                                                                                          |                          |
| Instrument can diagnose its own malfunctions                                                                 | yes (operator intervention required to order parts)                                                                                                                                                                                                                                                                                   | yes (operator intervention required to order parts)                                                                                                                                                                                                                                     | yes (operator intervention required to order parts)                                                                                                                                                                                                                          |                          |
| System malfunctions can be diagnosed via remote monitoring                                                   | yes                                                                                                                                                                                                                                                                                                                                   | yes                                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                          |                          |
| UPS backup power supply                                                                                      | yes                                                                                                                                                                                                                                                                                                                                   | yes                                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                          |                          |
| Data-management capability/LIS or EHR systems interfaced                                                     | onboard/—                                                                                                                                                                                                                                                                                                                             | onboard/SCC Soft Computer, Meditech, Oracle Health, Epic, Clinisys, more                                                                                                                                                                                                                | onboard, optional add-on (Bio-Rad MAS)/SCC Soft Computer, Meditech, Oracle Health, Epic, Clinisys, more                                                                                                                                                                      |                          |
| LIS interface provided/Bidirectional interface capability                                                    | yes (included in instrument price)/yes (broadcast download and host query)                                                                                                                                                                                                                                                            | yes (included in instrument price)/yes (broadcast download and host query)                                                                                                                                                                                                              | yes (included in instrument price)/yes (broadcast download and host query)                                                                                                                                                                                                   |                          |
| Modem servicing provided/Service engineer on-site response time                                              | yes/4 hrs.                                                                                                                                                                                                                                                                                                                            | yes/< 24 hrs.                                                                                                                                                                                                                                                                           | yes/—                                                                                                                                                                                                                                                                        |                          |
| Mean time between failures                                                                                   | — (displays error codes for troubleshooting)                                                                                                                                                                                                                                                                                          | 368 days (displays error codes for troubleshooting)                                                                                                                                                                                                                                     | — (displays error codes for troubleshooting)                                                                                                                                                                                                                                 |                          |
| Average scheduled maintenance time by lab personnel                                                          | daily: ~7 min. (incl. automated); weekly: ~10 min.; monthly: ~10 min.                                                                                                                                                                                                                                                                 | daily: 5 min.; weekly: 6 min.; monthly: 11 min.                                                                                                                                                                                                                                         | daily: < 5 min.; weekly: 30 min.; monthly: 59 min.                                                                                                                                                                                                                           |                          |
| Maintenance records kept onboard for user/vendor                                                             | yes/yes (both include audit trail of who replaced parts)                                                                                                                                                                                                                                                                              | some records/some records                                                                                                                                                                                                                                                               | yes/yes (both include audit trail of who replaced parts)                                                                                                                                                                                                                     |                          |
| Maintenance training demonstration module onboard                                                            | no                                                                                                                                                                                                                                                                                                                                    | yes                                                                                                                                                                                                                                                                                     | yes                                                                                                                                                                                                                                                                          |                          |
| Training included with purchase/Avg. time for basic user training                                            | yes (1 training slot)/4 days (at customer site)                                                                                                                                                                                                                                                                                       | yes (1 training slot)/1 week (at both vendor and customer sites)                                                                                                                                                                                                                        | yes (~2 training slots per module)/4–5 days (at both vendor and customer sites)                                                                                                                                                                                              |                          |
| Advanced operator training/Extra charge for follow-up or advanced training                                   | yes (at customer site)/yes                                                                                                                                                                                                                                                                                                            | yes (at vendor site)/yes                                                                                                                                                                                                                                                                | yes (at vendor site)/yes                                                                                                                                                                                                                                                     |                          |
| Warranty provided/Cost of annual service contract (24 h/7 d)                                                 | yes (1 year)/—                                                                                                                                                                                                                                                                                                                        | yes (1 year)/configuration dependent                                                                                                                                                                                                                                                    | yes (1 year)/contract dependent                                                                                                                                                                                                                                              |                          |
| Distinguishing features (supplied by company)                                                                | • XT Microslide performs two tests on one slide, which doubles testing output, increases productivity, and fulfills more requests from difficult draws<br>• designed to use single-patient consumables without the need for water, eliminating risk of carryover<br>• MicroSensor technology automates detection of HIL interferences | • drives lab efficiency with standardized instrumentation, reference ranges, consumables, and usage<br>• minimizes downtime with industry-leading engineering and service; 325-day mean time between repair visits (average)<br>• speeds up turnaround time for high-volume stat assays | • minimal operator intervention with automated maintenance, automated calibration, and continuous loading of reagents<br>• maximizes reagent use; long onboard reagent (up to 6 months) and calibration stabilities<br>• increases revenue through expanded testing services |                          |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i> |                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                              |                          |

|                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Part 6 of 6                                                                                                                                                                                                                                                                                                                                                                        | <b>Thermo Fisher Scientific/BRAHMS</b><br>kryptor.analyzer@thermofisher.com<br><b>Hennigsdorf, Germany</b><br><b>+49(0)33028830</b> www.thermoscientific.com/kryptor                                                                                         | <b>Tosoh Bioscience</b><br>info.diag.am@tosoh.com<br><b>Grove City, OH</b><br><b>800-248-6764</b> www.diagnostics.us.tosohbioscience.com                                                                                      |
| <b>FOR POINT-OF-CARE USE AND LOW-VOLUME LABORATORIES</b>                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                               |
| Name of instrument<br>Type of instrument                                                                                                                                                                                                                                                                                                                                           | B-R-A-H-M-S KRYPTOR compact PLUS<br>immunoassay                                                                                                                                                                                                              | AIA-360<br>immunoassay                                                                                                                                                                                                        |
| Operational type/Model type<br>List price/First year sold in U.S.<br>Targeted hospital bed size/Targeted test volume                                                                                                                                                                                                                                                               | batch, random access, continuous random access/benchtop<br>—/2015<br>—/daily: 450; monthly: 9,000; annual: 125,000                                                                                                                                           | continuous random access/benchtop<br>—/2004<br>—/monthly: < 500                                                                                                                                                               |
| Company manufactures instrument<br>Other models in this family of analyzers<br>No. of units in clinical use in U.S./Outside U.S. (countries)                                                                                                                                                                                                                                       | yes (also sold by distribution partners)<br>B-R-A-H-M-S KRYPTOR GOLD<br>—/> 900 (worldwide)                                                                                                                                                                  | yes<br>AIA-900, AIA-2000<br>~600/> 7,000 (worldwide)                                                                                                                                                                          |
| Dimensions (H × W × D)/Instrument footprint<br>Weight empty/Weight fully loaded<br>No. of different measured assays onboard simultaneously                                                                                                                                                                                                                                         | 24 × 29 × 29 in./4.59 sq. ft.<br>119 lbs./—<br>8 (8 can be run and calibrated at one time)                                                                                                                                                                   | 21 × 16 × 16 in./2.1 sq. ft.<br>61 lbs./—<br>25 (25 can be run and calibrated at one time)                                                                                                                                    |
| No. of user-definable (open chemistry) channels<br>Test throughput per hour/Assay run time                                                                                                                                                                                                                                                                                         | —<br>up to 60 (up to 60 tests in throughput)/9–59 min.                                                                                                                                                                                                       | —<br>36/20 min.                                                                                                                                                                                                               |
| <b>Chemistry:</b><br>No. of direct ion-selective electrode channels<br>Detection methods<br>Stat time until completion/specimen throughput for:<br>• Ion-selective electrode<br>• Basic metabolic panel<br>• Complete metabolic panel<br>Typical time delay from ordering stat test until aspiration of sample                                                                     | —<br>—<br>—<br>—<br>—<br>—                                                                                                                                                                                                                                   | —<br>—<br>—<br>—<br>—<br>—                                                                                                                                                                                                    |
| <b>Immunoassay:</b><br>Fully automated microplate immunoassay system<br>Methodologies supported<br>Separation methodologies<br>Stat time until completion of a β-hCG test<br>• Typical time delay from test order to aspiration of sample<br>Stat time until completion of a cTn test<br>• Typical time delay from test order to aspiration of sample                              | no<br>fluorescence, enzyme immunoassay<br>none necessary<br>14 min.<br>2 min.<br>—<br>—                                                                                                                                                                      | —<br>fluorescence enzyme immunoassay (FEIA)<br>—<br>20 min.<br>—<br>20 min.<br>—                                                                                                                                              |
| Approximate No. of tests per reagent set/Reagent type<br>Reagents refrigerated onboard/Reagents ready to use<br>Reagent lot tracking/Reagent inventory<br>Reagent form/Reagents barcoded<br>Separate reagent pack for each specimen/for each test run<br>Walkaway capability/Walkaway duration                                                                                     | 50–100/self-contained single use<br>yes (2°–8°C)/yes<br>yes/yes<br>liquid chemistry (closed reagent system)/yes<br>no/no<br>yes/max. 220 min. (assay dependent) or up to 64 specimens or up to 96 tests                                                      | 100 (20 tests per tray)/unit dose test cup<br>no/yes<br>yes/no<br>dry chemistry (closed reagent system)/yes<br>yes/—<br>yes/58 min. or 25 specimens or 25 tests/assays                                                        |
| Design of sample-handling system<br>Uses washable cuvettes/Uses disposable cuvettes<br>Min.–max. sample volume that can be aspirated at one time<br>Min. reaction volume/Min. specimen volume/Min. dead volume                                                                                                                                                                     | sample cassette placed in sample carousel<br>no/no<br>8–70 µL<br>150 µL/sample tube and assay dependent/150 µL (sample tube dependent)                                                                                                                       | carousel<br>no/no<br>10–100 µL<br>10 µL/110 µL/100 µL                                                                                                                                                                         |
| Dedicated pediatric sample cup<br>Primary tube sampling<br>Accommodates most standard tube sizes/Accepts nonstandard tube sizes<br>Pierces caps on primary tubes<br>Protects against probe collision<br>Detects clots/liquid level/short sample<br>Detection or quantitation for hemolysis, icterus, lipemia, clots<br>Dilutes patient samples onboard/Susceptibility to carryover | yes (dead volume: 75 µL)<br>yes<br>yes/yes (11–17 × 60–120 mm)<br>no<br>no<br>yes/yes/yes<br>detection for hemolysis, icterus, lipemia, clots<br>yes (can be programmed to perform dilutions prior to analysis)/<br>≤ 2 parts per million (no contamination) | no<br>yes<br>yes/—<br>no<br>—<br>yes/yes/yes<br>—<br>no/no/no                                                                                                                                                                 |
| Automatic rerun capability<br>Sample volume can be diluted to rerun out-of-linear-range high results<br>Sample volume can be concentrated to rerun out-of-linear-range low results                                                                                                                                                                                                 | yes<br>yes<br>yes                                                                                                                                                                                                                                            | no<br>no<br>no                                                                                                                                                                                                                |
| Analyzer requires dedicated water supply                                                                                                                                                                                                                                                                                                                                           | no                                                                                                                                                                                                                                                           | no                                                                                                                                                                                                                            |
| Autocalibration/Multipoint calibration supported                                                                                                                                                                                                                                                                                                                                   | yes (calibrants are not stored onboard)/no                                                                                                                                                                                                                   | no (calibrants are not stored onboard)/yes                                                                                                                                                                                    |
| Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays<br>Automatic programmable start/Automatic programmable shutdown<br>Onboard real-time QC/Onboard software capability to review QC<br>Supports multiple QC lot numbers per analyte<br>Waste management                                                                      | —/—/—/—/5–15 days<br>no/no<br>yes/yes<br>yes<br>manually by user or automated collection onboard instrument                                                                                                                                                  | —/—/—/—/90 days most assays<br>no (5 min. start-up time)/no<br>no/no<br>—<br>automated collection onboard instrument                                                                                                          |
| Sample barcode-reading capability/Autodiscrimination<br>Lab can control analyzer from remote computer<br>Instrument can diagnose its own malfunctions<br>System malfunctions can be diagnosed via remote monitoring<br>UPS backup power supply<br>Data-management capability/LIS or EHR systems interfaced                                                                         | yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes<br>no<br>yes (operator intervention required to order parts)<br>yes<br>yes<br>onboard/—                                                                                                        | yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes<br>no<br>no<br>—<br>yes<br>Tosoh 501RP+/—                                                                                                                            |
| LIS interface provided/Bidirectional interface capability                                                                                                                                                                                                                                                                                                                          | yes (additional cost)/yes (broadcast download and host query)                                                                                                                                                                                                | no/no                                                                                                                                                                                                                         |
| Modem servicing provided/Service engineer on-site response time                                                                                                                                                                                                                                                                                                                    | yes/Mon.–Fri.: 26 hrs. at total breakdown, 72 hrs. at workaround                                                                                                                                                                                             | —                                                                                                                                                                                                                             |
| Mean time between failures<br>Average scheduled maintenance time by lab personnel<br>Maintenance records kept onboard for user/vendor<br>Maintenance training demonstration module onboard<br>Training included with purchase/Avg. time for basic user training                                                                                                                    | — (displays error codes for troubleshooting)<br>daily: 3 min.; weekly: 3 min.; monthly: 5 min.<br>yes/yes (both include audit trail of who replaced parts)<br>no<br>yes (1 training slot)/1.5–2 days (at customer site)                                      | 888 days (displays error codes for troubleshooting)<br>daily: 5 min.<br>no/no<br>no<br>yes/2 days (at customer site)                                                                                                          |
| Advanced operator training/Extra charge for follow-up or advanced training<br>Warranty provided/Cost of annual service contract (24 h/7 d)                                                                                                                                                                                                                                         | yes (at vendor site)/yes<br>yes (1 year)/contract dependent                                                                                                                                                                                                  | —<br>yes (1 year)/—                                                                                                                                                                                                           |
| Distinguishing features (supplied by company)                                                                                                                                                                                                                                                                                                                                      | • fully automated random-access immunoanalyzer with unique Nobel Prize–winning TRACE technology<br>• automated timely onboard dilution in less than 5 minutes with integrated self-determining dilution factor<br>• no biotin interferences of the assays    | • unit dose test cup; dry reagent, no premixing or reagent preparation<br>• immunoassay method free from biotin interference;<br>compact size, broad menu with fast results<br>• 90-day calibration stability for most assays |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                               |

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