| Part 1 of 10<br>See accompanying article on page 56   | Abaxis Inc.<br>Rick Betts rickbetts@abaxis.com<br>3240 Whipple Road, Union City, CA 94587<br>800-822-2947 www.abaxis.com   | Abbott Point of Care<br>Glen Tinevez glen.tinevez@abbott.com<br>104 Windsor Center Dr., East Windsor, NJ 08520<br>800-827-7828 www.abbottpointofcare.com        | Alfa Wassermann Diagnostic Technologies LLC<br>Lauren DiPrima Idiprima@alfawassermannus.com<br>4 Henderson Dr., West Caldwell, NJ 07006<br>800-220-4488 www.alfawassermannus.com             |
|---|--|---|--|
| Name of instrument/First year sold in U.S./List price<br>No. of units in clinical use in U.S./Outside U.S.<br>Country where designed/Manufactured/Reagents manufactured<br>Operational type/Reagent type  | Piccolo Xpress/2006/16,500<br>2,500/4,000<br>U.S./U.S./U.S.<br>discrete/self-contained single-use cartridges-<br>packages-slides                                       | i-Stat 1 analyzer/2000/—<br>30,000+ worldwide<br>U.S./U.S./Canada<br>—/self-contained single-use cartridges packages-<br>slides                                 | ACE/1993; ACE Alera Clinical Chemistry System/2004/—<br>1,300/800+<br>U.S./U.S./U.S.<br>batch, random access, discrete, continuous random<br>access/stat and closed reagent system with open |
| Sample handling system/Model type   | disk loaded directly into instrument/benchtop  | —/handheld  | ring with up to 5 segments (15 samples per   |
| Dimensions in inches (H $\times$ W $\times$ D)/Instrument footprint   | 12.75 $\times$ 6 $\times$ 8/<1 square foot   | $9.25 \times 3.0 \times 2.85/{<1}$ square foot  | ACE: 15.75 $\times$ 27.25 $\times$ 22.50; ACE Alera: 23 $\times$ 27.5 $\times$ 22.5/4.3 square feet  |
| Tests available on instrument in U.S.   | ALP, ALT, AST, GGT, amylase, albumin, total protein,<br>bilirubin total, BUN, creatinine, calcium, cholesterol,<br>glucose, uric acid, sodium, creatine kinase, others | tropinin I, CK-MB, lactate, BUN, creatinine, glucose,<br>ionized calcium, sodium, potassium, chloride, hema-<br>tocrit, pH, PCO2, PO2, TCO2, ACTc, ACTk, others | albumin, gamma GT, bilirubin direct & total, calcium,<br>creatinine, glucose, HbA1c, phosphorus, total iron,<br>magnesium, total protein, BUN, uric acid, many others                        |
| Research-use-only assays/Tests in development   |  |   | —/enzymatic creatinine, neonatal bilirubin, hsCRP,<br>urine applications (creatinine, urea, calcium,<br>phosphorous)   |
| Analytes for which user-defined methods have been implemented   | _  | _   | open-channel bottles are available for user-derived<br>or third-party reagents   |
| Methods supported/Immunoassay methods   | photometry, enzymatic/—  | potentiometry, amperometric, conductometric/—   | photometry, potentiometry (ion-selective electrode),<br>turbidimetric homogeneous EIA  |
| No. of direct ion selective electrode channels <ul> <li>Must load separate reagent pack for each specimen</li> <li>Separate reagent pack for each test run</li> </ul>   | 0 (system is enzymatic)<br>yes<br>no   | 10<br>no (unit-use cartridge based)<br>yes  | 3<br>no<br>no  |
| <ul> <li>No. of different measured assays onboard simultaneously</li> <li>No. of different assays programmed and calibrated at once</li> </ul>  | CLIA-waived CMP has 14 analytes<br>14  | <br>18  | 40<br>200  |
| No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reagent   | 0/—<br>29/up to 14   | —<br>—/unit use   | 15/15<br>40/30–250 tests per bottle  |
| containers onboard at once/Tests per container set <ul> <li>Shortest/Median onboard reagent stability/Refrigerated onboard</li> </ul>   | —/—/ves (0°–8°C)   | —/14 days/no  | 5 days/30 days/yes (10°–14°G)  |
| Multiple reagent configurations supported     Provide a supported     Providea supported     Prov | yes  | no  | yes  |
| Instrument has same capabilities when third-party reagent used  | yes<br>—<br>   |   | yes<br>yes   |
| Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays   | 30 seconds nands-on; 12 minutes to printed<br>result/1/up to 29 available analytes in menu, up to<br>14 per reagent disk   | 2/1/up to 18  |  |
| Uses disposable cuvettes/Maximum No. stored   | no/28 cuvettes per reagent disk  | <br>no/   | yes/248  |
| • Uses washable cuvettes/Replacement frequency<br>Minimum sample volume aspirated precisely at one time   | no/—<br>requires 80–100 μL of whole blood, serum, or plasma  | no/—<br>16 μL   | no/—<br>3 μL   |
| System supplied with UPS (backup power)/Requires floor drain<br>Requires dedicated water system/Water consumption in L per hour   | yes/no<br>no/—   | no/no<br>no/  | yes/no<br>no/  |
| Noise generated in decibels   | none<br>no/  | none  | 55<br>no/  |
| Primary tube sampling/Pierces caps on primary tubes   | no/no  | no/no   | yes/yes  |
| Sample bar-code reading capability/Autodiscrimination   | reads bar code on disk/—   | code)/yes   | UPC, Codabar, code 39, code 128 set B and C)/yes   |
| Reagent bar-code reading capability     Onboard test auto inventory (determines volume in container)     Measures No. of tests remaining/Short sample detection/  | yes<br>—<br>—/yes/yes  | yes<br>—<br>—/yes/yes   | yes, proprietary dot coding<br>yes<br>yes/yes/no   |
| Automatic detection of adequate reagent for aspiration and analysis   | yes  | yes   | yes  |
| <ul> <li>Hemolysis/Turbidity detection-quantitation</li> <li>Dilution of patient samples onboard</li> </ul>   | yes/yes<br>yes   | no/no<br>no   | yes  |
| Automatic rerun capability <ul> <li>Sample volume can be reduced to rerun out-of-linear-range high</li> </ul>   | no<br>/  | no<br>no/no   | yes<br>ves/no  |
| results/Increased to rerun out-of-linear-range low results  | ves  | Ves   | ves  |
| Calibrants stored onboard/Multipoint calibration supported     Trained to the formation of the formatio | yes/yes  | no/yes  | no/yes<br>Desure (20 days (45 days with 40 been undetes (  |
| Drugs of abuse  | onboard/—/—  | each test/each test/—/—   | 3 nours/30 days/45 days with 48-nour updates/—   |
| Automatic shutdown/Startup programmable   | yes/yes  | yes/yes   | _  |
| Stat time to completion of all analytes/throughput per hour for:<br>• Sodium, potassium, chloride, TCO2   | 30 seconds hands-on, 10–12 minutes to printed result/2–14 tests per disk   | 2 minutes/—   | 4 minutes/35 specimens   |
| Sodium, potassium, chloride, TCO2, glucose, urea, creatinine  | 30 seconds hands-on, 10–12 minutes to printed result, 2–14 tests per disk  | 2 minutes, —  | 7 minutes, 20 specimens  |
| Albumin, direct and total bilirubin, AST, ALT, ALP  | 30 seconds hands-on, 10–12 minutes to printed<br>result 2–14 tests ner disk  | _   | 10 minutes, 12 specimens   |
| • Typical time delay from ordering stat test to aspiration of sample<br>Frequency of QC required/Onboard SW capability to review QC   | none<br>shortest: automatic QC onboard with every run;<br>longest: external high/low QC required monthly,  | none<br>shortest interval: 24 hours; longest interval: each<br>new lot or reagent/yes   | immediate response, as soon as 10 seconds<br>daily/yes   |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS   | according to CLIA guidelines/yes<br>yes/yes<br>yes   | yes/yes<br>yes  | yes/yes<br>yes   |
| Data-management capability/Instrument vendor supplies LIS interface   | onboard/no   | optional add-on (<\$30,000, SW mftr: Abbott Point of<br>Care)/yes (additional cost)   | onboard/no   |
| LISs with which system interfaces in active user sites Bidirectional interface capability   | many<br>yes (broadcast download and host query)  | all systems<br>yes (broadcast download and host query)  | Antek, Apex, LabPak, Schuyler House, others<br>yes (broadcast download)  |
| LIS interface operates simultaneously with running assays<br>Uses LOINC to transmit orders and results  | yes<br>ves   | yes<br>ves  | yes<br>no  |
| How labs get LOINC codes for reagent kits   | Web site, package insert, e-mail query   | customized on site  | -  |
| Lab can control analyzer remotely   | yes  | yes   | no   |
| Modem servicing available/System can diagnose own malfunctions<br>On-site time of service engineer/Onboard error codes for troubleshooting  | yes/yes<br>not necessary, 24-hour RMA turnaround of loaner<br>instruments/yes  | yes/yes<br>replacement within 24 hours/yes  | no/yes<br>24 hours/yes   |
| Mean time between failures/To repair failures     Onboard maintenance records/Maintenance training demo module  | none/replacement within 24 hours ves/ves   | not determined/replacement within 24 hours  | 8 months/1 hour<br>ves/no  |
| Training provided with purchase/Advanced operator training<br>Annual service contract cost (24 h/7 d)   | 1–2 hours (supplemented by free Webcast)/yes<br>1-year warranty standard; 3 years often free through<br>distribution partners; \$1,195 for additional years            | —/yes<br>based on volume  | 4.5 days at manufacturer's facility/yes several programs available   |
| Distinguishing features (supplied by company)   | comprehensive CLIA-waived menu of tests; 15 disks<br>(11 CLIA-waived) represent commonly ordered chem-   | handheld portable analyzer; unit use system can<br>perform chemistry, blood gas, cardiac marker, and  | closed-tube sampling; stat interrupt capability;<br>onboard sample and reagent refrigeration; onboard  |
| Note: a dash in lieu of an answer means company did not answer question or question is not applicable   | connectivity extends reach to the point of care, while<br>maintaining centralized control of test data   | coayunanon tests with two grops of whole blood or<br>plasma   | reagent inventory management; ready-to-use<br>reagents; integrated ISE module; self-contained<br>analyzer; no external water source or waste drainage  |
|   |  |   |  |

| Part 2 of 10  | AMS Diagnostics, LLC   | Awareness Technology   | Awareness Technology                                |
|---|--|--|---|
|   | Bruno Borganti bb@amsdiagnostics.com   | Rob Guerin info@awaretech.com  | Rob Guerin info@awaretech.com                       |
|   | 2410 Settlers Street, Charleston, SC 29492   | 1935 S.W. Martin Highway, Palm City, FL 34990  | 1935 S.W. Martin Highway, Palm City, FL 34990       |
|   | 866-419-7839 www.amsdiagnostics.com  | 772-283-6540 www.awaretech.com   | 772-283-6540 www.awaretech.com                      |
|   |  |  |   |
| Name of instrument/First year sold in U.S./List price   | LIASYS (330)/2009/—  | ChemWell-1/2010/\$12,500   | Stat Fax 4500/2009/\$2,695                          |
| NO. OT UNITS IN CIINICAL USE IN U.S./OUTSIDE U.S.   |  | 5/250  | 150/1,500   |
| Country where designed/manufactured/keagents manufactured   | Europe-U.S./Europe-U.S./Europe-U.S.  | U.S./U.S./Open system  | U.S./U.S./open system                               |
| operational type/Reagent type   | Datch, random access, discrete, continuous random  | Datch, random access, continuous random access/  | -/open reagent system                               |
|   | access/seit-contained single-use cartridges-   | open reagent system  |   |
| Sample handling system/Model type   | packages-silves  | ouctom-configurable rack/honobton  | tube cuvatta or flowcall/hanahtan                   |
| Sample nationity system/model type  | diameter from 40, 100 mm beight abort ouns 1 ml  | custom-configurable rack/benchtop  | tube, cuvette, or nowcen/benchtop                   |
|   | chort cups 2 ml. conical/bonebton  |  |   |
| Dimensions in inches ( $H \sim W \sim D$ )/Instrument footnrint                                     | $165 \times 303 \times 256/A$ equare feet  | $20 \sim 21 \sim 16/3$ causer feet   | $5 \times 0 \times 13$ 5/~1 square feet             |
|   | 10.0 × 00.0 × 20.0/4.4 3quale feet   |  |   |
| Tests available on instrument in II S   | general chemistries electrolytes enzyme assays   | onen system  | onen system   |
|   | linid assays HhA1c linase microalhumin   | open system  |   |
|   | microprotein, rheumatoid factor, DOA, others   |  |   |
|   |  |  |   |
|   |  |  |   |
| Research-use-only assays/Tests in development   | —/vitamin D  | _  | _   |
| ······  |  |  |   |
| Analytes for which user-defined methods have been implemented                                       | _  | _  | _   |
| · ·   |  |  |   |
| Methods supported/Immunoassay methods   | photometry, potentiometry (ion-selective   | photometry   | photometry  |
|   | electrode)/turbidimetry  |  |   |
| No. of direct ion selective electrode channels  | 3  | -  | -   |
| <ul> <li>Must load separate reagent pack for each specimen</li> </ul>                               | no   | —  | _   |
|   |  |  |   |
| <ul> <li>Separate reagent pack for each test run</li> </ul>   | -  | -  | —   |
| No. of different measured assays onboard simultaneously   | 36   | 40   | -   |
| <ul> <li>No. of different assays programmed and calibrated at once</li> </ul>                       | 36   |  | 1   |
| No. of user-definable (open) channels/No. active simultaneously                                     | 200/36   | PC-based   | 99/1  |
| No. of different analytes for which system accommodates reagent                                     | 36/250-400   | variable/—   | -   |
| containers onboard at once/Tests per container set  |  |  |   |
| Snortest/Median onboard reagent stability/Refrigerated onboard                                      | / days/20 days/yes (2°–8°C)  | —/—/yes (9°–12°C below ambient)  | —/no  |
| multiple reagent configurations supported   | yes  | yes  | -   |
| Reagent container placed directly on system for use   | yes  | yes  | —   |
| Instrument has same capabilities when third-party reagent used                                      | yes<br>DAD/CA/DC   | yes  | yes   |
| walkaway capacity in minutes/Based on No. of specimens/Based on                                     | 240/64/36  | <i>—/—/4</i> 0   | —   |
| NO. OF TESTS-ASSAYS<br>Sustam in liquid abamiatry, dry abamiatry, or reconstituted anhaard          | liquid   | liquid   | liquid  |
| System is inquite chemistry, or y chemistry, or reconstituted onboard                               | nquiu<br>no/60   | ilquiu<br>vee/40   | liquiu  |
| Uses uisposable cuvelles/Maximum No. Storeu   | 110/00<br>voc/40.000 tosts   | yes/40<br>vos/variablo   | yes/12<br>vos/cupplior-dopondont                    |
| Minimum sample volume aspirated precisely at one time   | 2 ul   |  |   |
| System sunnlied with UPS (backup nower)/Requires floor drain  |  |  | 200 μL<br>no/no                                     |
| Requires dedicated water system/Water consumption in L ner hour                                     | no/0.5   | no/  | no/   |
| Noise generated in decidels   | 45   |  | <45   |
| Dedicated nediatric sample cun/Dead volume  | ves/50 ul  | no/—   | < <del>45</del><br>no/—                             |
| Primary tube sampling/Pierces cans on primary tubes   | ves/no   | ves/no   |   |
| Sample bar-code reading capability/Autodiscrimination   | ves/ves  | no/no  | no/—  |
| ••••••••••••••••••••••••••••••••••••••  | ,,   |  |   |
| <ul> <li>Reagent bar-code reading capability</li> </ul>   | ves  | no   | _   |
| Onboard test auto inventory (determines volume in container)  | Ves  | Ves  | _   |
| Measures No. of tests remaining/Short sample detection/   | ves/ves/no   | —/yes/no   | _   |
| Clot detection  | ,,   | .,   |   |
| Automatic detection of adequate reagent for aspiration and analysis                                 | ves  | ves  | _   |
| Hemolysis/Turbidity detection-quantitation  | no/no  | no/no  | _   |
| Dilution of patient samples onboard   | yes  | yes  | _   |
| Automatic rerun capability  | yes  | —  | _   |
| <ul> <li>Sample volume can be reduced to rerun out-of-linear-range high</li> </ul>                  | yes/yes  | yes/yes  | —   |
| results/Increased to rerun out-of-linear-range low results  |  |  |   |
| Autocalibration or autocalibration alert  | yes  | yes  | no  |
| <ul> <li>Calibrants stored onboard/Multipoint calibration supported</li> </ul>                      | yes/yes  | no/yes   | —/yes   |
| Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/                                | autocalibrate/14 days/14 days/14 days  | —  | —   |
| Drugs of abuse  |  |  |   |
| Automatic shutdown/Startup programmable   | no/no  | no/no  | no/no   |
|   |  |  |   |
| Stat time to completion of all analytes/throughput per hour for:                                    | 100  |  |   |
| <ul> <li>Sodium, potassium, chloride, TCO2</li> </ul>   | 122 specimens per hour (first result after   | -  | —   |
|   | / minutes, 12 seconds) namely 488 tests per hour   |  |   |
| <ul> <li>Sodium, potassium, chioride, 1002, glucose, urea, creatinine</li> </ul>                    | 35 specimens per nour (first result after 8 minutes,   | _  | -   |
| Albumin direct and total bilimiting ACT ALT ALD   | o seconos) nanely 240 tests per nour<br>24 anonimeno per bour (first result ofter 0 minut              |  |   |
| - Albannin, un est anu totai bhirubiñ, ASI, ALI, ALP  | 24 specimens per nour (inst result after 9 minutes,<br>20 seconds) namely 144 tests per hour           | —  | -   |
| • Typical time delay from ordering stat tost to assiration of sample                                | 20 3000103/ namely 144 18313 per moul<br>18 seconds  |  | _   |
| Frequency of OC required/Onhoard SW canability to roview OC   | 8–24 hours/ves   | —/ves  | _   |
| Onboard real-time OC/Support multiple OC lot Nos per analyte  | no/ves   | ves/ves  | _   |
| QC results transferred automatically to LIS   | no   | yes  | _   |
| ,,,,  |  | ·  |   |
| Data-management capability/Instrument vendor supplies LIS interface                                 | onboard (AMS)/ves. included  | onboard/—  | no/no   |
| LISs with which system interfaces in active user sites  | Antek, Fletcher, Flora, others   | <u> </u>   | _   |
|   | . , ,  |  |   |
| Bidirectional interface capability  | yes (broadcast download and host querv)  | yes  | no  |
| LIS interface operates simultaneously with running assays   | yes  | yes  | —   |
| Uses LOINC to transmit orders and results   | no   | no   | -   |
| <ul> <li>How labs get LOINC codes for reagent kits</li> </ul>                                       | -  | -  | -   |
|   |  |  |   |
| Lab can control analyzer remotely   | yes  | no   | no  |
|   |  |  |   |
| Modem servicing available/System can diagnose own malfunctions                                      | yes/yes  | yes/yes  | —   |
|   |  |  |   |
| On-site time of service engineer/Onboard error codes for troubleshooting                            | engineers are on standby/yes   | —/yes  | —/yes   |
| Mean time between failures/To repair failures   | 11.5 months/90 minutes   | —  | —   |
| Onboard maintenance records/Maintenance training demo module  | no/—   | yes/no   | -   |
| Iraining provided with purchase/Advanced operator training  | 3 days on site, 1 day at vendor offices/yes  | —/yes  | -   |
| Annual service contract cost (24 h/7 d)   | \$8,900 (M-F), warranty extension  | varies per distributor   | _   |
|   |  |  |   |
| Distinguishing teatures (supplied by company)   | monitors cuvette cleaniness, flags its replace-  | versatile open system, runs biochemistry and   | cost-effective with long-life IAD filters; self-    |
|   | illevietem and notions toote address of the  | urbiametric assays; universal rack for reagent   | prompting touchscreen with mouse-compatible         |
|   | an system and patient tests status on first screen;  | containers, controls, and calibrators for regular,   | interface for easy selections and entries; optional |
|   | at-a-yiance interface design saves time running  | stat, and peutatric samples; user decides which  | punt-in nowcen for reduced sample volumes           |
|   | unonnou y pancio, precioiun uata cumparison; runs<br>three reagent methode, quitable for more conterio | ones and now many rack positions to amocate for<br>each: compact economical instrument designed to |   |
|   | unce reagent methods, suitable for more esoteric<br>testing in development: automatic complex proditiv | caun, compace, economical instrument designed to   |   |
| Note: a dach in liqu of an approver means company did not answer question or such that is not a "   | tion nostdilution and nost-concentration   | use as a backup to larger evetome  |   |
| now, a uaen in nou or an anewer meane company uiu not answer question or question is not applicable | מיהו, הההומוותוות מות ההפרבההוות המותוו  | นอง นง น มนงกนุม เข เนเษยเ องอเซเแอ  |   |

| Part 3 of 10   | Beckman Coulter, Inc.<br>Burcin Ekener bekener@beckman.com<br>250 S. Kraemer Blvd., Brea, CA 92821<br>800-526-3821 www.beckmancoulter.com   | Carolina Liquid Chemistries<br>Patricia Shugart contactsales@carolinachemistries.com<br>391 Technology Way, Suite 2, Winston Salem, NC 27101<br>877-722-8910 www.carolinachemistries.com                         | Carolina Liquid Chemistries<br>Patricia Shugart contactsales@carolinachemistries.com<br>391 Technology Way, Suite 2, Winston Salem, NC 27101<br>877-722-8910 www.carolinachemistries.com                             |
|--|---|--|--|
| Name of instrument/First year sold in U.S./List price<br>No. of units in clinical use in U.S./Outside U.S.<br>Country where designed/Manufactured/Reagents manufactured<br>Operational type/Reagent type   | AU480 Clinical System/2009/—<br>120/>300<br>Japan/Japan/Ireland<br>continuous random access/open reagent system   | BioLis 24i/2008/\$60,000<br>>200/3,000<br>Japan/Japan/U.S.<br>batch, random access, continuous random access/  | CLC 480/—/\$75,000<br>—<br>Japan/Japan/U.S.<br>batch, random access, discrete, continuous random   |
| Sample handling system/Model type  | continuous loading rack feeder holds up to 80   | open reagent system<br>sample ring/benchtop  | access/self-contained single-use cartridges-pack-<br>ages-slides, open reagent system<br>sample ring/benchtop  |
| Dimensions in inches (H $\times$ W $\times$ D)/Instrument footprint  | samples, while 22 samples are accommodated via<br>stat turntable/floor-standing<br>$47.5 \times 57.1 \times 30/11.9$ square feet  | 20 $\times$ 31 $\times$ 25/5 square feet   | $31.5 \times 26.5 \times 20.5/5$ square feet   |
| Tests available on instrument in U.S.  | >125 tests, including complete general chemistry,<br>proteins/serology (including reformulated ferritin<br>assay), thyroid, esoterics (including lithium), TDM<br>(including methotrexate), DAT panels (including<br>oxycodone; multiple cutoffs, qualitative, and semi-<br>quantitative methods available for most assays) | 100, GlycoMark   | >80 different chemistries, including drugs of abuse<br>and adulterants; reads at 10 different wavelengths<br>between 340 and 800 nm  |
| Analytes for which user-defined methods have been implemented  | total open system, unlimited  |  |  |
| Methods supported/Immunoassay methods No. of direct ion selective electrode channels   | photometry, potentiometry (ion-selective<br>electrode), homogenous EIA, turbidimetry, latex<br>agglutination/—<br>3 electrodes, indirect method   | photometry, potentiometry/—<br>3   | photometry, potentiometry, ISE   |
| Must load separate reagent pack for each specimen  | no  | no   | no   |
| <ul> <li>Separate reagent pack for each test run</li> <li>No. of different measured assays onboard simultaneously</li> <li>No. of different assays programmed and calibrated at once</li> <li>No. of user-definable (open) channels/No. active simultaneously</li> <li>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</li> </ul> | no<br>63<br>63<br>60/all<br>up to 60 different assays/50–1,500 (per vial)   | no<br>39<br>39<br>39/39<br>39/3 × 300  | no<br>39<br>39<br>39/39<br>39/3 × 300  |
| Shortest/Median onboard reagent stability/Refrigerated onboard     Multiple reagent configurations supported     Reagent container placed directly on system for use     Instrument hose one constitution when third party respect used  | 5 days/30 days/yes (4°–12°C)<br>yes<br>yes  | 7 days/14 days/yes (2°–8°C)<br>yes<br>yes  | 7 days/14 days/yes (<10°C)<br>yes<br>yes   |
| Walkaway capacity in minutes/Based on No. of specimens/Based on<br>No. of tests-assays   | varies/up to 102/varies   | 4 hours/40/39  | yes<br>4 hours/40/39   |
| System is liquid chemistry, dry chemistry, or reconstituted onboard<br>• Uses disposable cuvettes/Maximum No. stored<br>• Uses washable cuvettes/Replacement frequency   | liquid<br>no/—<br>yes/permanent   | liquid<br>no/—<br>yes/—  | liquid<br>no/<br>yes/annual or as needed   |
| Minimum sample volume aspirated precisely at one time<br>System supplied with UPS (backup power)/Requires floor drain<br>Requires dedicated water system/Water consumption in L per hour   | 1 μL<br>no (optional)/yes (no with optional water pump)<br>yes/20 average peak consumption  | —<br>yes/no<br>yes, water system provided with instrument/—  | 3 μL<br>no/no<br>ves/3.5   |
| Noise generated in decibels<br>Dedicated pediatric sample cup/Dead volume<br>Primary tubo campling/Piercos cans on primary tuboc   | <60<br>no/—   | yes/30 µL  | <60<br>yes/30 μL   |
| Sample bar-code reading capability/Autodiscrimination  | yes, no<br>yes, on sample transport, shortly before sample is<br>aspirated (2 of 5 interl., Codebar, codes 39 and 128)/yes  | yes (on sample transport, shortly before sample is<br>aspirated, codes 39 and 128)/yes   | yes no<br>yes (on sample transport, shortly before sample is<br>aspirated, codes 39 and 128, ITF, NW-7)/yes  |
| Reagent Dat-code reading capability Onboard test auto inventory (determines volume in container)     Measures No. of tests remaining/Short sample detection/     Clot detection  | yes<br>yes<br>yes/yes/yes   | yes<br>yes<br>yes/yes/yes  | yes<br>yes<br>yes/yes/yes  |
| Automatic detection of adequate reagent for aspiration and analysis     Hemolysis/Turbidity detection-quantitation     Dilution of patient camples onboard   | yes<br>yes/yes  | yes<br>yes/yes   | yes<br>yes/yes<br>vec  |
| Automatic rerun capability<br>• Sample volume can be reduced to rerun out-of-linear-range high   | yes<br>yes/yes  | yes<br>yes/yes   | yes<br>yes/no  |
| • Calibrants stored onboard/Multipoint calibration supported   | yes<br>yes/yes  | no<br>yes/yes  | no<br>yes/yes  |
| Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/<br>Drugs of abuse<br>Automatic shutdown/Startup programmable  | 1 day/30 days/14 days/14–20 days<br>ves/ves   | 24 hours/14 days/4–7 days/7 days<br>ves/ves  | 24 hours/14 days/4–7 days/7 days<br>ves/ves  |
| Stat time to completion of all analytes/throughput per hour for:   | A minutes (includes TCO2) 200 specimens   | 12 minutas 160 snacimans   | 12 minutas 160 snacimans   |
| Sodium, potassium, chloride, 1002     Sodium, potassium, chloride, TC02, glucose, urea, creatinine   | <9 minutes (includes 1002); 200 specimens <9 minutes (includes photometric assays), 80 specimens  | 1 hour, 60 specimens   | 1 hour, 60 specimens   |
| <ul> <li>Albumin, direct and total billrubin, AS1, AL1, ALP</li> <li>Typical time delay from ordering stat test to aspiration of sample</li> </ul>   | <9 minutes, 67 specimens<br><2 minutes  | 5 minutes  | 5 minutes  |
| Frequency of QC required/Onboard SW capability to review QC<br>Onboard real-time QC/Support multiple QC lot Nos. per analyte<br>QC results transferred automatically to LIS  | per CLIA and laboratory's decision/yes<br>yes/yes<br>yes  | 8–24 hours/yes<br>yes/yes<br>yes   | 8–24 hours/yes<br>yes/yes<br>yes   |
| Data-management capability/Instrument vendor supplies LIS interface<br>• LISs with which system interfaces in active user sites  | onboard/no (optional)<br>all common interfaces, including Cerner, Antrim, CCA,<br>Chemware, Dawning Technology, ADAC, Dynamic<br>Healthcare, Antek, Siemens, McKesson (Data<br>Innovations). CPSI. Meditech, Misvs, Citation, SCC   | onboard/yes (additional cost)<br>Fletcher Flora, Lab Track, and several other<br>common systems  | onboard/yes (additional cost)<br>Lab Track, Lab DAQ, Fletcher-Flora, Orchard, and<br>other systems   |
| Bidirectional interface capability<br>LIS interface operates simultaneously with running assays  | yes (broadcast download and host query)<br>yes  | yes (broadcast download and host query)<br>yes   | yes (broadcast download and host query)<br>yes   |
| How labs get LOINC codes for reagent kits  |   | =  | by contacting technical support  |
| Lab can control analyzer remotely  | yes<br>   | no   | yes  |
| Modem servicing available/System can diagnose own malfunctions<br>On-site time of service engineer/Onboard error codes for troubleshooting   | yes/yes<br><24 hours/ves  | no/yes<br>24 hours/ves   | yes/no<br>24 hours/ves   |
| • Mean time between failures/To repair failures<br>Onboard maintenance records/Maintenance training demo module<br>Training provided with purchase/Advanced operator training<br>Annual service contract cost (24 h/7 d)   | average two calls per year/<24 hours<br>yes/yes<br>3–5 days on site, 5 days at vendor offices/yes<br>contract-dependent   | yes (includes audit trail)/no<br>5 days on site/yes<br>—   | installation on site, 3.5 days at vendor offices/yes<br>\$8,500  |
| Distinguishing features (supplied by company)  | standardization with family of chemistry and<br>immunoassay systems—the AU680, AU2700,<br>and AU5400; broad test menu of 130 methods<br>provides standardized results for improved patient  | water system eliminates need to purchase, ship,<br>and store cubes of water; HbA1c performed directly<br>onboard w/results equivalent to HPLC, don't need<br>separate HbA1c analyzer; small size, large menu, 39 | comprehensive test menu; cost-effective water sys-<br>tem eliminates need for daily cuvette changes and<br>costs associated with cuvette wash solutions; runs<br>drugs of abuse in a qualitative or semiquantitative |
| Note: a dash in lieu of an answer means company did not answer question or question is not applicable  | management and streamlined operation  | onboard chemistries; runs general and special chem-<br>istries from CMPs to D-dimer, cystatin C, insulin, more   | mode, providing an actual number in ng/mL  |

| Part 4 of 10   | ELITech Clinical Systems<br>Patrice Babineau elitechNA@elitechgroup.com<br>101 College Road East, Princeton, NJ 08540<br>609-216-7360 www.elitechgroup.com   | ELITech Clinical Systems<br>Patrice Babineau elitechNA@elitechgroup.com<br>101 College Road East, Princeton, NJ 08540<br>609-216-7360 www.elitechgroup.com   | HORIBA Medical<br>Jim Knowles jim.knowles@horiba.com<br>34 Bunsen Drive, Irvine, CA 92618<br>888-903-5001 www.horiba.com/us/en/medical   |
|--|--|--|--|
| Name of instrument/First year sold in U.S./List price<br>No. of units in clinical use in U.S./Outside U.S.<br>Country where designed/Manufactured/Reagents manufactured<br>Operational type/Reagent type   | Selectra ProM Chemistry System/2011/\$41,500<br>—/300<br>Netherlands/Netherlands/France<br>continuous random access/self-contained<br>multi-use cartridges-packages-slides<br>ring/henchton  | Selectra ProS Chemistry System/2011/\$34,500<br>—/70<br>Netherlands/Netherlands/France<br>continuous random access/self-contained<br>multi-use cartridges-packages-slides<br>ring/benchton   | ABX Pentra 400/2006/\$95,319<br>176/1,003<br>France/France/France and U.S.<br>batch, random access, discrete, continuous random<br>access/self-contained single-use cartridges-pack-<br>ages-slides, open reagent system<br>rack/benchton  |
| Dimensions in inches ( $H \times W \times D$ )/Instrument footnrint  | $30 \times 48 \times 24$ 4/8 1 square feet   | $30 \times 32.5 \times 24/5.4$ square feet   | $25 \times 40 \times 28$ in/7.7 square feet  |
|  | albumin ALT/GPT ALKP AST/GOT hilirubin (direct and   | albumin ALT/GPT ALKP AST/GOT hilirubin (direct and   | albumin calcium sodium alk nhos AIT carbon di-   |
| Research-use-only assays/Tests in development  | total BUN), calcium, carbon dioxide, chloride choles-<br>terol, cholesterol (HDL and LDL), creatinine, glucose,<br>GGT, hemoglobin A1c, LDH, phosphorus, potassium,<br>sodium, total protein, triglycerides, uric acid<br>—/TxB cardio, hyaluronic acid, D-dimer, TIMP-1,<br>PIIINC, anylase, CK, iron, TIBC, magnesium,<br>muti-range CRP microprotein        | total BUN), calcium, carbon dioxide, chloride choles-<br>terol, cholesterol (HDL and LDL), creatinine, glucose,<br>GGT, hemoglobin A1c, LDH, phosphorus, potassium,<br>sodium, total protein, triglycerides, uric acid<br>—/TxB cardio, hyaluronic acid, D-dimer, TIMP-1,<br>PIIINC, amylase, CK, iron, TIBC, magnesium,<br>multi-range CPB microprotein       | oxide, glucose (PAP), lipase, total protein, chloride,<br>glucose (hexokinase), magnesium, triglycerides,<br>amylase, cholesterol, nitrogen, iron, myoglobin, uric<br>acid, total bilirubin, creatinine, lactic acid, more<br>—/TDMs, DAUs   |
| Analytes for which user-defined methods have been implemented  | APO A1, APO B, CRP, haptoglobin, IgA, IgG, IgM, micro-<br>albumin, microprotein, orosomucoid, prealbumin, more   | APO A1, APO B, CRP, haptoglobin, IgA, IgG, IgM, micro-<br>albumin, microprotein, orosomucoid, prealbumin, more   | alcohol, apolipoprotein A1, apolipoprotien B, beta 2, microglobulin, ferritin, fructosamine, GlycoMark, more   |
| Methods supported/Immunoassay methods  | photometry, potentiometry/turbidimetric  | photometry, potentiometry/turbidimetric  | photometry, potentiometry (ion-selective electrode),   |
| No. of direct ion selective electrode channels   | 4<br>4   | 4<br>po  | an buillieure/   |
| <ul> <li>Must load separate reagent pack for each specimen</li> <li>Separate reagent pack for each test run</li> <li>No. of different measured assays onboard simultaneously</li> <li>No. of different assays programmed and calibrated at once</li> <li>No. of user-definable (open) channels/No. active simultaneously</li> <li>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</li> <li>Shortest/Median onboard reagent stability/Refrigerated onboard</li> <li>Multiple reagent configurations supported</li> </ul> | no<br>no<br>36<br>96<br>10/10<br>36/34–83<br>24 hours/28 days/yes (10°C)<br>yes  | no<br>34<br>90<br>10/10<br>34/34–83<br>24 hours/28 days/yes (10°C)<br>yes  | no<br>55<br>55<br>15/15<br>55/100 to 400<br>8 hours/30 days/yes (15°–32°C)<br>yes  |
| Reagent container placed directly on system for use<br>Instrument has same capabilities when third-party reagent used<br>Walkaway capacity in minutes/Based on No. of specimens/Based on   | yes<br>yes<br>240/62/720   | yes<br>yes<br>120/25/285   | yes<br>yes<br>2 hours/60/—   |
| No. of tests-assays<br>System is liquid chemistry, dry chemistry, or reconstituted onboard<br>• Uses disposable cuvettes/Maximum No. stored<br>• Uses washable cuvettes/Replacement frequency<br>Minimum sample volume aspirated precisely at one time   | liquid<br>no/48 in semi-disposable rotor<br>yes/10,000 tests<br>1 µL   | liquid<br>no/48 in semi-disposable rotor<br>yes/10,000 tests<br>1 µL   | liquid<br>yes/432<br>no/—<br>2 µL  |
| System supplied with UPS (backup power)/Requires floor drain<br>Requires dedicated water system/Water consumption in L per hour<br>Noise generated in decibels<br>Dedicated pediatric sample cup/Dead volume   | yes/no<br>no/up to 0.5<br>62<br>yes/100 μL   | yes/no<br>no/up to 0.9<br>62<br>yes/100 µL   | no/no<br>no/0.5 average<br><66<br>no/—   |
| Primary tube sampling/Pierces caps on primary tubes<br>Sample bar-code reading capability/Autodiscrimination   | yes/no<br>yes, on sample transport, shortly before sample is<br>aspirated (2 of 5 interleaved, Codebar, codes 4, 11,<br>39, 93 and 128)/yes  | yes/no<br>yes, on sample transport, shortly before sample is<br>aspirated (2 of 5 interleaved, Codebar, codes 4, 11,<br>39, 93 and 128)/yes  | yes/no<br>yes/no   |
| <ul> <li>Reagent bar-code reading capability</li> <li>Onboard test auto inventory (determines volume in container)</li> <li>Measures No. of tests remaining/Short sample detection/<br/>Clot detection</li> </ul>  | yes<br>yes<br>yes/yes/no   | yes<br>yes<br>yes/yes/no   | yes<br>yes<br>yes/yes/yes  |
| Automatic detection of adequate reagent for aspiration and analysis     Hemolysis/Turbidity detection-quantitation     Dilution of patient samples onboard     Automatic roum consulting   | yes<br>no/no<br>yes  | yes<br>no/no<br>yes  | yes<br>yes/yes<br>yes  |
| Automatic refuir capability     Sample volume can be reduced to rerun out-of-linear-range high     results/Increased to rerun out-of-linear-range low results     Autocalibration or autocalibration alert     Calibrants stored onboard/Multipoint calibration supported     Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/     Drugs of abuse  | yes<br>yes<br>no/yes<br>4–8 hours/28 days/—/—  | yes<br>yes/no<br>yes<br>no/yes<br>4–8 hours/28 days/—/—  | yes<br>yes/yes<br>yes/yes<br>2 hours/14 days/—/—   |
| Automatic shutdown/Startup programmable  | yes/yes  | yes/yes  | no/yes   |
| Stat time to completion of all analytes/throughput per hour for:<br>• Sodium, potassium, chloride, TCO2<br>• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine  | 5 minutes, 66 specimens<br>12 minutes, 33 specimens  | 5 minutes, 66 specimens<br>12 minutes, 26 specimens  | <5 minutes, —<br>7.5 minutes, 35 specimens   |
| <ul> <li>Albumin, direct and total bilirubin, AST, ALT, ALP</li> <li>Typical time delay from ordering stat test to aspiration of sample</li> </ul>   | 14 minutes, 22 specimens<br>3 minutes  | 14 minutes, 19 specimens<br>3 minutes  | <11 minutes, 23 specimens<br>1–2 minutes   |
| Frequency of QC required/Onboard SW capability to review QC<br>Onboard real-time QC/Support multiple QC lot Nos. per analyte<br>QC results transferred automatically to LIS  | 0.5–1 day/yes<br>yes/no<br>yes   | 0.5–1 day/yes<br>yes/no<br>yes   | 8 hours/yes<br>yes/yes<br>yes  |
| Data-management capability/Instrument vendor supplies LIS interface<br>• LISs with which system interfaces in active user sites  | onboard/no<br>—  | onboard/no<br>—  | onboard/no<br>Antek, Fletcher Flora, Meditech, Orchard, Schuyler<br>House, Sunquest, Technidata  |
| Bidirectional interface capability<br>LIS interface operates simultaneously with running assays<br>Uses LOINC to transmit orders and results<br>• How labs get LOINC codes for reagent kits  | yes<br>broadcast download and host query<br>no<br>—  | yes<br>broadcast download and host query<br>no<br>—  | yes<br>yes<br>no<br>   |
| Lab can control analyzer remotely  | yes  | yes  | no   |
| Modem servicing available/System can diagnose own malfunctions   | no/yes   | no/yes   | yes/yes  |
| On-site time of service engineer/Onboard error codes for troubleshooting<br>• Mean time between failures/To repair failures<br>Onboard maintenance records/Maintenance training demo module<br>Training provided with purchase/Advanced operator training<br>Annual service contract cost (24 h/7 d)   | 24 hours/yes<br>10–12 months/1 hour<br>yes (inludes audit trail)/yes<br>3 days on site/yes<br>\$4,200 (M-F, 9 AM–5 PM)   | 24 hours/yes<br>12–14 months/1 hour<br>yes (inludes audit trail)/yes<br>3 days on site/yes<br>\$3,500 (M-F, 9 AM-5 PM)   | <24 hours/yes<br>—/<24 hours<br>yes/yes<br>4 days at corporate office in California/yes<br>—   |
| Distinguishing features (supplied by company)<br>Note: a dash in lieu of an answer means company did not answer question or question is not applicable   | intuitive software; touchscreen interface guides<br>operator through daily workflow, including onboard<br>checklists that track start and end of daily tasks;<br>combined onboard PSID, host-query LIS, and<br>programmable result checks improve walkaway<br>and reduce errors; liquid-stable, ready-to-use, and<br>packaged to fit benchtop laboratory needs | intuitive software; touchscreen interface guides<br>operator through daily workflow, including onboard<br>checklists that track start and end of daily tasks;<br>combined onboard PSID, host-query LIS, and<br>programmable result checks improve walkaway<br>and reduce errors; liquid-stable, ready-to-use, and<br>packaged to fit benchtop laboratory needs | benchtop design runs more than 53 assays with<br>room for 55 onboard tests; user-friendly, color-coded<br>touchscreen validation station; high throughput<br>(420 tests per hour); clot level and crash protection;<br>auto rerun, autocalibration, autodilution; runs three<br>reagents on a single assay; most reagents in plug-<br>and-play cassettes |

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| Chemistry analyzer   | rs (for low-volume la   | aboratories)   |
|--|---|--|
| Part 5 of 10   | Medica Corp.<br>Charlene Soley csoley@medicacorp.com<br>5 Oak Park Drive, Bedford, MA 01730<br>781-275-7425 www.medicacorp.com  | MedTest DX<br>Randy Rusz rrusz@medtestdx.com<br>510 Furnace Dock Road, Cortlandt Manor, NY 10567<br>866.540.2715 www.medtestdx.com   |
| Name of instrument/First year sold in U.S./List price<br>No. of units in clinical use in U.S./Outside U.S.<br>Country where designed/Manufactured/Reagents manufactured<br>Operational type/Reagent type   | Easy RA/2009/—<br>36/70<br>U.S./U.S./U.S.<br>batch, random access, discrete, continuous<br>random access/self-contained multi-use<br>cartridges-packages_slides   | Poly-Chem/2002/\$58,500<br>153/—<br>Japan/Japan/U.S.<br>batch, random access/open reagent system   |
| Sample handling system/Model type  | two sample rings (up to 48 samples)/benchtop  | rack/benchtop  |
| Dimensions in inches (H $\times$ W $\times$ D)/Instrument footprint  | $15 \times 40 \times 26/7.2$ square feet  | 22 × 30 × 24/—   |
| Tests available on instrument in U.S.<br>Research-use-only assays/Tests in development   | albumin, alk phos, alanine aminotransferase (ALT,<br>SGPT), aspartate aminotransperase (AST, SGOT),<br>calicum, chloride, cholesterol, CK, creatinine<br>(serum & urine), GGT, glucose-trinder, HDL<br>cholesterol, LDH, lithium, potassium, sodium, total<br>protein, microalbumin, many more<br>—/HbA1c, CK-MB, linase, bsCBP LIBC, TIBC, drugs | albumin, ALK, ALT, amylase, apolipoprotein A1,<br>apolipoprotein B, ASO, AST, C3, C4, calcium, full<br>range CRP, cholesterol, C02, creatinine, CRP, direct<br>bilirubin, direct LDL, ferritin, fructosamine, gamma<br>GT, glucose, HbA1C, HDL cholesterol, IGA, IGG, more |
| Analytes for which user-defined methods have been implemented  | of abuse<br>creatinine (iaffe)  | glutamine, glutamate, lactate, ammonia   |
| Methods supported/immunoassav methods  | nhotometry, notentiometry, turbidimetric  | nhotometry, BISF   |
| No. of direct ion selective electrode channels   | immunoassay, enzymatic immunoassay<br>4   | 3  |
| <ul> <li>Must load separate reagent pack for each specimen</li> </ul>  | no  | no   |
| <ul> <li>Separate reagent pack for each test run</li> <li>No. of different measured assays onboard simultaneously</li> <li>No. of different assays programmed and calibrated at once</li> <li>No. of user-definable (open) channels/No. active simultaneously</li> <li>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</li> <li>Shortest/Median onboard reagent stability/Refrigerated onboard</li> </ul>   | no<br>28<br>140<br>6/6<br>28/80–250<br>168 hours/30 days/yes  | no<br>43<br>43<br>60/60<br>40/200<br>4 hours/28 days/yes (8°C)   |
| Multiple reagent configurations supported<br>Reagent container placed directly on system for use<br>Instrument has same capabilities when third-party reagent used<br>Welkewey concerning the maintee (Read on No. of capaciment (Read on No. | yes<br>yes<br>  | yes<br>yes<br>no<br>19 to first result/40/1 000  |
| <ul> <li>Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays</li> <li>System is liquid chemistry, dry chemistry, or reconstituted onboard</li> <li>Uses disposable cuvettes/Maximum No. stored</li> <li>Uses washable cuvettes/Replacement frequency</li> </ul>  | 36/24/28<br>liquid<br>yes/72<br>no/—  | 18 to first result/40/1,000<br>liquid<br>no/—<br>yes/50,000 tests  |
| System supplied with UPS (backup power)/Requires floor drain   | 2 µL<br>no/no   | 2 µL<br>yes/yes  |
| Requires dedicated water system/Water consumption in L per hour<br>Noise generated in decibels   | no/—<br>minimal   | yes/7<br>60  |
| Dedicated pediatric sample cup/Dead volume<br>Primary tube sampling/Pierces caps on primary tubes  | no/—<br>yes/no  | yes/—<br>yes/no  |
| Sample bar-code reading capability/Autodiscrimination <ul> <li>Reagent bar-code reading capability</li> </ul>  | yes<br>no, uses RFID  | on sample transport, shortly before sample is<br>aspirated (2 of 5 interleaved, UPC, Codabar, codes<br>39 and 128)/no<br>yes   |
| Onboard test auto inventory (determines volume in container)  • Measures No. of tests remaining/Short sample detection/ Clot detection  • Automatic detection of adequate reagent for aspiration and analysis  | yes<br>yes/yes/no<br>ves  | yes<br>yes/yes/no<br>ves   |
| Hemolysis/Turbidity detection-quantitation   | no/no   | no/no  |
| Dilution of patient samples onboard<br>Automatic rerun capability<br>• Sample volume can be reduced to rerun out-of-linear-range high  | yes<br>no<br>yes/no   | yes<br>yes<br>yes/yes  |
| results/Increased to rerun out-of-linear-range low results<br>Autocalibration or autocalibration alert<br>• Calibrants stored onboard/Multipoint calibration supported<br>Trained calibration framework for ISC (Matchelitics (Thereportie drugs (   | yes<br>no/yes<br>2 hours (20 dous ( _ /   | no<br>no/yes<br>deik/7_14.deus/_/  |
| Drugs of abuse<br>Automatic shutdown/Startun programmable  | o nours/ 30 days/—/—  | ualiy/7-14 uays/—/—  |
| Stat time to completion of all analytes/throughout per hour for:   | 10/110  | 110/ yes   |
| Sodium, potassium, chloride, TCO2     Sodium, potassium, chloride, TCO2, glucose, urea, creatinine     Albumin, direct and total bilirubin. AST. ALT. ALP  | 3 minutes, 200 specimens<br>8 minutes, 100 specimens<br>9 minutes. —  | 2 minutes, 450 specimens<br>10 minutes, 180 specimens<br>11 minutes, 180 specimens   |
| • Typical time delay from ordering stat test to aspiration of sample<br>Frequency of QC required/Onboard SW capability to review QC  | <1 minute<br>CLIA minimum/yes   | per shift-daily/yes  |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS  | no/yes<br>yes   | yes/no<br>yes  |
| Data-management capability/Instrument vendor supplies LIS interface<br>• LISs with which system interfaces in active user sites  | onboard/yes<br>Orchard, Antek, J&S, Fletcher Flora  | onboard/no<br>LabDAQ, Data Innovations, Soft Computer, Misys   |
| Bidirectional interface capability<br>LIS interface operates simultaneously with running assays<br>Uses LOINC to transmit orders and results<br>• How labs get LOINC codes for reagent kits  | yes<br>yes<br>no<br>  | broadcast download and host query<br>yes<br>no<br>—  |
| Lab can control analyzer remotely  | no  | no   |
| Modem servicing available/System can diagnose own malfunctions   | no/yes  | no/no  |
| On-site time of service engineer/Onboard error codes for troubleshooting   | <24 hours/yes   | 24 hours/yes   |
| • Mean time between failures/To repair failures<br>Onboard maintenance records/Maintenance training demo module<br>Training provided with purchase/Advanced operator training<br>Annual service contract cost (24 h/7 d)   | 1 year/—<br>no/no<br>yes/—<br>varies  | —<br>no/no<br>3 days on site, 3 days at vendor office/yes<br>varies  |
| Distinguishing features (supplied by company) Note: a dash in lieu of an answer means company did not answer question or question is not applicable  | simplified user interface accessed through a<br>touchscreen display; RFID-tagged reagents allow<br>for reading and writing capability; all reagent<br>parameters programmed on the wedge, no data<br>entry; easy-to-replace components all located in a<br>slide-out drawer; comprehensive inventories of all<br>system components                | small benchtop analyzer for physician office<br>laboratory, as primary system in small lab, or<br>back-up system in large lab; onboard reusable<br>cuvettes provide cost savings on disposables;<br>large reagent menu   |

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| Part 6 of 10  | MedTest DX<br>Randy Rusz rrusz@medtestdx.com<br>510 Furnace Dock Road, Cortlandt Manor, NY 10567<br>866-540-2715 www.medtestdx.com  | Nova Biomedical Corp.<br>info@novabiomedical.com<br>200 Prospect St., Waltham, MA 02454-9141<br>800-458-5813 www.novabiomedical.com  | Nova Biomedical Corp.<br>info@novabiomedical.com<br>200 Prospect St., Waltham, MA 02454-9141<br>800-458-5813 www.novabiomedical.com |
|---|---|--|---|
| Name of instrument/First year sold in U.S./List price   | SPOTCHEM EZ/2006/\$12,500<br>95/  | Stat Profile pHOx Ultra/2011/—<br>—/—  | Stat Profile pHOx series/1998/—<br>—/—  |
| Country where designed/Manufactured/Reagents manufactured<br>Operational type/Reagent type  | Japan/Japan/U.S.<br>discrete/single-use strips  | U.S./U.S./U.S.<br>discrete/self-contained multi-use cartridges   | U.S./U.S./U.S.<br>discrete/self-contained multi-use cartridges-<br>packages-slides  |
| Sample handling system/Model type   | tray/benchtop   | sample automatically drawn from syringe, capillary,  | sample automatically drawn from syringe, capillary,   |
| Dimensions in inches (H $\times$ W $\times$ D)/Instrument footprint   | 6.5 × 13.5 × 8/—  | or open tube/benchtop $17.2 \times 17.3 \times 22.3/2.7$ square feet   | or open tube/benchtop $15 \times 15 \times 18/1.9$ square feet  |
| Tests available on instrument in U.S.   | albumin, ALT, amylase, AST, ALP, BUN, calcium, CPK,<br>creatinine, GGT, LDH, magnesium, phosphorous, total<br>bilirubin, total protein, uric acid, panel 1 (BUN, glu,<br>cre, cal, alb), panel 2 (ALP, T-BIL, T-ALT, T-protein,<br>AST), ling panel (chol, trip, HDL, CLDL) | pH, PCO2, PO2, SO2%, hematocrit, hemoglobin,<br>sodium, potassium, chloride, ionized calcium,<br>ionized Mg, glucose, BUN, creatinine, lactate,<br>bilirubin, deoxyhemoglobin, oxyhemoglobin,<br>methemoglobin, carboxyhemoglobin  | pH, PCO2, PO2, SO2%, hematocrit, hemoglobin,<br>sodium, potassium, chloride, ionized calcium,<br>glucose, lactate                   |
| Research-use-only assays/Tests in development   | —/LDL   |  | -   |
| Analytes for which user-defined methods have been implemented   | -   | -  | _   |
| Methods supported/Immunoassay methods   | optical measurement of reflection intensity of  | potentiometry (ISE), optical, reflectance/—  | potentiometry (ISE), optical, reflectance/—   |
| No. of direct ion selective electrode channels  |   | 12   | 5   |
| Must load separate reagent pack for each specimen   | yes   | no   | no  |
| Separate reagent pack for each test run No. of different measured assays onboard simultaneously   | yes<br>9  | no<br>20   | no<br>11  |
| <ul> <li>No. of different assays programmed and calibrated at once</li> <li>No. of user-definable (open) channels/No. active simultaneously</li> </ul>                | card calibration, 21  | 20<br>0/—  | 11<br>0/—   |
| No. of different analytes for which system accommodates reagent<br>containers onboard at once/Tests per container set   | -   | 20/200–500 samples (2,600–6,500 tests),<br>depending on lab  | 11/varies by analyzer and laboratory use pattern  |
| Shortest/Median onboard reagent stability/Refrigerated onboard  | —/—/no  | 45 days/45 days/no   | 45 days/45 days/no  |
| Multiple reagent configurations supported Reagent container placed directly on system for use   | no<br>yes   | yes  | —<br>yes  |
| Instrument has same capabilities when third-party reagent used<br>Walkaway capacity in minutes/Based on No. of specimens/Based on                                     | no<br>up to 15/1/up to 9  | Ξ  | -   |
| No. of tests-assays<br>System is liquid chemistry, dry chemistry, or reconstituted onboard  | dry   | ISE  | ISE   |
| Uses disposable cuvettes/Maximum No. stored     Uses washable cuvettes/Replacement frequency  | no/—<br>no/—  | no/—<br>no/—   | no/   |
| Minimum sample volume aspirated precisely at one time   | 5 μL  | 60 μL  | 45 μL   |
| Requires dedicated water system/Water consumption in L per hour   | no/no<br>no/—   | no (optional)/no<br>no/—   | no (optional)/no<br>no/—  |
| Noise generated in decibels<br>Dedicated pediatric sample cup/Dead volume   | —<br>no/—   | minimal<br>no/   | minimal   |
| Primary tube sampling/Pierces caps on primary tubes   | no/no   | yes/no   | yes/no  |
| Sample bar-code reading capability/Autodiscrimination   | by nandheid scanner as tubes are loaded onto<br>instrument (2 of 5 interleaved, UPC, Codabar, codes<br>39 and 128)/ves  | loaded onto instrument (2 of 5 interleaved, UPC,<br>Codabar, codes 39 and 128)/ves   | yes, by handheid scanner as tubes are loaded onto<br>instrument (2 of 5 interleaved, UPC, Codabar, codes<br>39 and 128)/ves         |
| Reagent bar-code reading capability     Onhoard test auto inventory (determines volume in container)  | yes<br>no   | yes<br>ves   | yes   |
| Measures No. of tests remaining/Short sample detection/     Oldet detection/  | no/yes/no   | yes/yes  | yes/yes   |
| Otor detection     Automatic detection of adequate reagent for aspiration and analysis     Hemolysis/Turbidity detection-quantitation                                 | no<br>no/no   | yes<br>ves (on co-ovimeter module)/ves (on co-ovimeter   | yes<br>no/no  |
| Dilution of nationt samples onboard   | no  | module)<br>wes (on co-oximeter module)   | 10/10   |
| Automatic rerun capability  |   | no   | no  |
| <ul> <li>Sample volume can be reduced to rerun out-of-linear-range high<br/>results/increased to rerun out-of-linear-range low results</li> </ul>                     | no/no   | no/no  | no/no   |
| Autocalibration or autocalibration alert<br>• Calibrants stored oppoard/Multingint calibration supported  | no<br>no/no   | yes<br>ves/ves   | yes<br>ves/ves  |
| Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/  | —/per box/—/—   | 30–120 minutes/30–120 minutes/—/—  | 30–120 minutes/30–120 minutes/—/—   |
| Drugs of abuse<br>Automatic shutdown/Startup programmable   | no/no   | yes/yes  | yes/yes   |
| Stat time to completion of all analytes/throughput per hour for:  |   |  |   |
| <ul> <li>Sodium, potassium, chloride, TCO2</li> <li>Sodium, potassium, chloride, TCO2, glucose, urea, creatinine</li> </ul>   | —<br>9 minutes, 48 samples per hour   | 50 seconds, 26–36, depending on use mode<br>123 seconds, 21–24, depending on use mode  | 50 seconds, 44 specimens<br>—   |
| <ul> <li>Albumin, direct and total bilirubin, AST, ALT, ALP</li> <li>Typical time delay from ordering stat test to aspiration of sample</li> </ul>                    | 9 minutes, 48 samples per hour<br>—   | <br><2 seconds   | <br><2 seconds  |
| Frequency of QC required/Onboard SW capability to review QC   | daily/no  | 8 hours/yes  | 8 hours (CLIA)/yes  |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS   | no/no<br>no   | yes/yes<br>yes   | yes/yes<br>yes  |
| Data-management capability/Instrument vendor supplies LIS interface<br>• LISs with which system interfaces in active user sites                                       | onboard/no  | onboard/no<br>most LIS vendors   | no/no<br>virtually all  |
| Bidirectional interface capability  | -   | yes  | yes (broadcast download and host query)   |
| LIS interface operates simultaneously with running assays<br>Uses LOINC to transmit orders and results<br>• How labs get LOINC codes for reagent kits                 | yes<br>no<br>   | yes<br>no<br>  | yes<br>no<br>   |
| Lab can control analyzer remotely   | no  | yes  | yes   |
| Modem servicing available/System can diagnose own malfunctions  | no/no   | yes/yes  | yes/yes   |
| On-site time of service engineer/Onboard error codes for troubleshooting  | depot service/yes   | <8 business hours/yes  | <8 business hours/yes   |
| Mean time between failures/To repair failures   | _/  | _  | _   |
| Onboard maintenance records/Maintenance training demo module<br>Training provided with purchase/Advanced operator training<br>Annual service contract cost (24 h/7 d) | no/no<br>1 day on site/no<br>—  | yes (includes audit trail of who replaced parts)/yes<br>yes/yes<br>varies  | yes/yes<br>yes/yes<br>—   |
| Distinguishing features (supplied by company)   | small analyzer for stat labs, small POLs, ERs, and  | comprehensive 20-test critical care profile,   | onboard quality control; liquid calibration   |
|   | imaging centers; analyzer and reagent test strips are<br>CLIA-waived; dry chemistry strips, effective stability,<br>and shelf life; single test strips and panel strips avail-<br>able; customizable testing  | including ionized Mg, BUN, and creatinine; color<br>touchscreen; integrated co-oximeter; open<br>software architecture; onboard data management;<br>automated onboard quality control; sealed waste<br>system; auto-monitoring of QC and reagent packs;<br>tankless gas calibration; automated maintenance | eliminates gas tanks; remote control; remote<br>review; space-saving design   |

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Tabulation does not represent an endorsement by the College of American Pathologists.

#### 64 / CAP TODAY

#### Chemistry analyzers (for low-volume laboratories)

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| Part 7 of 10   | Nova Riomedical Corn   | Ortho-Clinical Diagnostics   | Bandox Laboratories   |
|--|--|--|---|
|  | info@novabiomedical.com  | Sales Support  | Graeme McNeill graeme.mcneill@randox.com  |
|  | 800-458-5813 www.novabiomedical.com                                    | <b>800-828-6316</b> www.orthoclinical.com  | 304-728-2890 www.randox.com   |
| Name of instrument/First year sold in U.S./List price  | Nova 16/1995/  | Vitros DT 60 II Chemistry System (DT 60 II DTF   | By Davtona/2005/  |
|  | 10/1355/   | DTSC)/1993/—   |   |
| No. of units in clinical use in U.S./Outside U.S.<br>Country where designed/Manufactured/Reagents manufactured                                     | <br>U.S./U.S./U.S.   | 15,000 units worldwide<br>U.S./U.S./U.S.   | >1,000 units worldwide<br>Japan/Japan/U.K.  |
| Operational type/Reagent type  | batch, random access/self-contained multiuse                           | batch, random access, discrete/self-contained  | random access/self-contained multi-use  |
| Sample handling system/Model type  | 40-position tray, stat sampling directly from sample                   | -/benchtop   | ring/benchtop   |
| Dimensions in inches (H $	imes$ W $	imes$ D)/Instrument footprint  | container/benchtop<br>$20.5 \times 19.2 \times 20.7/2.75$ square feet  | 6.75	imes18.75	imes13.75/1.8 square feet (DT 60 II)  | 30.3 $	imes$ 24.4 $	imes$ 19.7/3.338 square feet  |
| Tacts available on instrument in U.S.  | sodium notassium chlorida total CO2 alucosa                            | ammonia cholesterol HDI cholesterol neonatal   | estic acid acid nhoshatase alhumin aldolase   |
|  | BUN, creatinine, Hct   | bilirubin, total protein, amylase, creatinine, lactate,  | ALK PHOS, alpha 1 acid glycoprotein, alpha 1  |
|  |  | phosphorus, triglycerides, BUN, glucose, Mg, total<br>bilirubin, uric acid, albumin, AST, CK, GGT, lipase. | antitrypsin, ALT, ammonia, amphetamines, amylase,<br>amylase pancreatic, APO A-1, APO AII, APO B, APO           |
|  |  | ALP, calcium, iron, lithium, ALT, cholinesterase,  | CII, APO CIII, APO E, ASO, AST, B2 microglobulin, more  |
| Research-use-only assays/Tests in development  | _  |  | acetic acid, Apo E, apo CIII, apo AII, alpha-1-anti-  |
|  |  |  | trypsin, alpha-1-acid glycoprotein, bile acids, butyryl<br>cholinesterase, enzymatic chloride, glutamate, more/ |
| Analytes for which user defined methods have been implemented  |  |  | haptoglobin, oxycodone, propoxyphene, more  |
| Analytes for which user-defined methods have been implemented  | —  | —  | erol-3-phosphate, oxidase, phospholipids, maltose,  |
|  |  |  | T4, T-uptake, aldehyde, chromate, cyclosporin, more   |
| Methods supported/Immunoassay methods  | potentiometry/—  | potentiometry, colorimetric, enzymatic/—   | photometry, potentiometry (ISE), latex-enhanced   |
| No. of direct ion selective electrode channels   | 8  | 4  | 3   |
| Must load separate reagent pack for each specimen  | no   | yes  | no  |
| Separate reagent pack for each test run  | no   |  | no<br>42  |
| <ul> <li>No. of different measured assays onboard simultaneously</li> <li>No. of different assays programmed and calibrated at once</li> </ul>     | 8  | 5, 1, 1 (D160 II, D1E II, D150 II)<br>>30  | 43<br>60  |
| No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reagent                    | 0/—<br>8/(at 8.000 tests/month): 2 700                                 | none   | 10/10<br>43/50–11.250   |
| containers onboard at once/Tests per container set   |  |  |   |
| <ul> <li>Shortest/Median onboard reagent stability/Refrigerated onboard</li> <li>Multiple reagent configurations supported</li> </ul>              | 21 days/21 days/no<br>—  | —/—/no<br>no   | 8 hours/28 days/yes (8°–15°C)<br>yes  |
| Reagent container placed directly on system for use  | no, requires prehandling (remove clip from sealed                      | no   | yes   |
| Instrument has same capabilities when third-party reagent used   |  | -  | yes   |
| No. of tests-assays  | 60 per tray/40 per tray/280 per tray                                   | —  | 664/40/76,115   |
| System is liquid chemistry, dry chemistry, or reconstituted onboard<br>• Uses disposable cuvettes/Maximum No. stored                               | —<br>no/—  | dry<br>no/—  | liquid<br>no/45   |
| Uses washable cuvettes/Replacement frequency   |  | no/—   | yes/minimum 5 years   |
| System supplied with UPS (backup power)/Requires floor drain   | no/no  | no/no  | 2 μL<br>no/no   |
| Requires dedicated water system/Water consumption in L per hour<br>Noise generated in decibels   | no/—<br>minimal  | no/none  | yes/7.5<br>60   |
| Dedicated pediatric sample cup/Dead volume   | —  | —  | yes/50 μL   |
| Sample bar-code reading capability/Autodiscrimination  | yes/no<br>handheld scanner as tubes loaded onto instrument (2          | no/no<br>no/—  | yes/no<br>on sample transport, shortly before sample is aspirated   |
| Reagent har-code reading canability  | of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes alternate method | Ves  | (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes  |
| Onboard test auto inventory (determines volume in container)   | yes  | _  | yes<br>yes  |
| Measures No. of tests remaining/short sample detection/<br>Clot detection  | no/yes/yes   | —  | yes/yes/no  |
| <ul> <li>Automatic detection of adequate reagent for aspiration and analysis</li> <li>Hemolysis/Turbidity detection-quantitation</li> </ul>        | yes<br>no/no   | —<br>no/no   | yes<br>ves/ves  |
| Dilution of patient samples onboard  | yes  | no   | yes   |
| Sample volume can be reduced to rerun out-of-linear-range high   | yes<br>no/no   | no<br>no/no  | yes<br>yes/yes  |
| results/Increased to rerun out-of-linear-range low results<br>Autocalibration or autocalibration alert   | ves  | 10   | ves   |
| Calibrants stored onboard/Multipoint calibration supported   | yes/—  | no/yes   | yes/yes   |
| Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/<br>Drugs of abuse   | 2 hours/2 hours/—/—  | reagent lot changes  | dally/28 days/7 days/28 days  |
| Automatic shutdown/Startup programmable  | _  | no/no  | yes/yes   |
| Stat time to completion of all analytes/throughput per hour for:   | 52 coopeds 60 anosimons  | 15 tasts   | 12 minutes 50 cocordo   |
| Sodium, potassium, chloride, TCO2     Sodium, potassium, chloride, TCO2, glucose, urea, creatinine   | 85 seconds, 45 specimens   | 75 tests   | 14 minutes, 50 seconds, —   |
| <ul> <li>Albumin, direct and total bilirubin, AST, ALT, ALP</li> <li>Typical time delay from ordering stat test to aspiration of sample</li> </ul> |  | 20 tests<br>none   | 14 minutes, 30 seconds, —<br>30 seconds   |
| Frequency of QC required/Onboard SW capability to review QC  | CLIA minimum/yes   | every 24 hours/no  | shortest: daily; longest: customer discretion/yes   |
| QC results transferred automatically to LIS  | yes  | yes  | yes   |
| Data-management capability/Instrument vendor supplies LIS interface  | onboard and optional add-on/no   | —/no   | onboard/no  |
| LISs with which system interfaces in active user sites   | most LIS vendors including Cerner. Misss                               | _  | _   |
|  | McKesson, Soft, others   |  | Noo (hoot guory)  |
| LIS interface operates simultaneously with running assays  | yes<br>no  | yes  | yes (nost query)<br>yes   |
| Uses LOINC to transmit orders and results<br>• How labs get LOINC codes for reagent kits   | no<br>   | _  | no<br>  |
| Lab can control angluzor remotely  | Vas  | 10   | 10  |
|  | ,  |  |   |
| Modem servicing available/System can diagnose own malfunctions   | no/yes   | no/yes   | yes/yes   |
| On-site time of service engineer/Onboard error codes for troubleshooting <ul> <li>Mean time between failures/To repair failures</li> </ul>         | <8 business hours/yes<br>—   | —/yes<br>—   | within 24 hours/yes<br>2 per 3 years/within 8 working hours   |
| Onboard maintenance records/Maintenance training demo module   | no/no  | no/no  | no/no   |
| raining provided with purchase/Advanced operator training<br>Annual service contract cost (24 h/7 d)   | yes/yes<br>—   | yes/—<br>—   | 3 days on site/yes<br>varies on level   |
| Distinguishing features (supplied by company)  | whole blood analyzer for creatinine and TCO2; can                      | disposable tips eliminate sample carryover: random   | benchtop analyzer provides consolidation of testing   |
|  | analyze whole blood, serum, plasma, urine, CSF, and dialysate          | access testing (runs in any order, with no reagent<br>preparation); individual packaged test slides elimi- | in an established compact platform; dedicated multi-speed paddle mixers allow optimum mixing                    |

nate waste and facilitate rapid analysis; dry-slide technology minimizes the effects of interferences

for each assay; direct ISE module prevents pseudohyponatremia

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| Part 8 of 10   | Roche Diagnostics Corp.<br>Adam Sterle adam.sterle@roche.com<br>9115 Hague Rd.<br>Indianapolis, IN 46256   | Roche Diagnostics Corp.<br>Adam Sterle adam.sterle@roche.com<br>9115 Hague Road<br>Indianapolis, IN 46256  | SDI Biomed<br>Robert Silverberg rs@sdibiomed.com<br>23679 Calabasas Road, #241<br>Calabasas, CA, 91302  |
|--|--|--|---|
|  | 317-521-3099 www.mylabonline.com   | 317-521-3099 www.mylabonline.com   | 818-349-4464 www.sdibiomed.com  |
| Name of instrument/First year sold in U.S./List price<br>No. of units in clinical use in U.S./Outside U.S.<br>Country where designed/Manufactured/Reagents manufactured<br>Operational type/Reagent type<br>Sample handling system/Model type<br>Dimensions in inches (H × W × D)/Instrument footprint | cobas c311/2009/\$125,000<br>>100/>750<br>Japan/Japan/Germany<br>continuous random access/self-contained multi-use<br>cassettes<br>sample rotor/floor-standing<br>50 × 52 × 34/8 5 square feet | COBAS INTEGRA 400 Plus/1999/\$145,000<br>550/>2,000<br>Switzerland/Switzerland/U.S. and Germany<br>continuous random access/self-contained<br>multi-use cassettes<br>rack/benchtop<br>28.5 × 53 × 26/0.6 square feet | SDI CA 480 Clinical Chemistry System/2004/\$65,000<br>>50/>600<br>Europe/Europe/U.S.<br>random access/self-contained single-use<br>cartridges-packages-slides<br>wheel, with 4 independent segments/benchtop<br>40 5 × 25.4 × 17.7/7.2 survare feet   |
| Dimensions in inches (H × W × D)/ instrument lootprint   | $50 \times 52 \times 34/6.5$ square reel   | 28.5 × 53 × 20/9.6 square leet   | 40.5 × 25.4 × 17.1/7.2 Square leet  |
| Tests available on instrument in U.S.<br>Research-use-only assays/Tests in development   | >90 tests available for anemia, diabetes, cardiac<br>markers, TDM, DAT, general chemistries, ISE, and<br>D-dimer   | >100 tests available for anemia, diabetes, cardiac<br>markers, TDM, DAT, general chemistries, ISE,<br>thyroid function and D-dimer   | albumin, alkaline phosphatase, ALT, amylase,<br>AST, CO2, direct bilirubin, total bilirubin, calcium,<br>cholesterol, CK, creatinine, Gamma-GT, glucose-HK,<br>D-HDL, iron, phosphorus, LDH-L, magnesium, total<br>protein, triglycerides, urea nitrogen, uric acid, more<br>—/drugs of abuse |
|  | lidocaine  |  |   |
| Analytes for which user-defined methods have been implemented  | _  | _  | none  |
| Methods supported/Immunoassay methods  | photometry, potentiometry  | photometry, potentiometry, fluorescence polariza-  | photometry, poteniometry/selected methodologies   |
| No. of direct ion selective electrode channels<br>• Must load separate reagent pack for each specimen  | no<br>no   | tion/turbidimetric, latex particle enhanced<br>4<br>no   | 3<br>no   |
| a Consusta vacuum tuncel fau acab taat wun   |  |  |   |
| • Separate reagent pack for each test run<br>No. of different measured assays onboard simultaneously   | <br>45   | 40   | 33  |
| No. of different assays programmed and calibrated at once     No. of user-definable (open) channels (No. active simultaneously   | >130<br>10/10  | up to 999<br>10/10   | 33  |
| No. of different analytes for which system accommodates reagent  | 42 cassettes plus 3 ISE/75-800 tests each,   | 36 cassettes plus 4 ISE/75-800 tests each,   | 30/150 per container  |
| containers onboard at once/Tests per container set   | depending on reagent   | depending on reagent   | 14  days/30  days/yes (14°C)  |
| Multiple reagent configurations supported  | yes  | yes  | yes   |
| Reagent container placed directly on system for use  | yes<br>ves   | yes<br>ves   | yes<br>ves  |
| Walkaway capacity in minutes/Based on No. of specimens/Based on  | 173/108/45   | 176/90/40  | 165/40/33   |
| No. of tests-assays<br>System is liquid chemistry, dry chemistry, or reconstituted onboard   | liquid   | liquid   | liquid  |
| Uses disposable cuvettes/Maximum No. stored  | no/66  | yes/1,000  | no  |
| <ul> <li>Uses washable cuvettes/Replacement frequency</li> <li>Minimum sample volume aspirated precisely at one time</li> </ul>  | yes/monthly<br>1 uL  | no/—<br>2 uL   | yes/analyzer uses permanent quartz cuvettes<br>3 uL   |
| System supplied with UPS (backup power)/Requires floor drain   | yes/yes  | yes/no   | yes/no  |
| Requires dedicated water system/Water consumption in L per hour<br>Noise generated in decibels   | yes/12<br><65  | no/2 maximum<br><61  | no/1<br>  |
| Dedicated pediatric sample cup/Dead volume   | yes/50 μL  | yes/50 μL  | no/—  |
| Primary tube sampling/Pierces caps on primary tubes<br>Sample bar-code reading capability/Autodiscrimination   | yes/no<br>yes (2 of 5 interleaved, Codabar, codes 39 and<br>128)/yes   | yes/no<br>yes (2 of 5 interleaved, Codabar, codes 39 and 128)/<br>yes  | yes/no<br>yes/yes   |
| Reagent bar-code reading capability  | yes  | yes  | yes   |
| Onboard test auto inventory (determines volume in container)  • Measures No. of tests remaining/Short sample detection/ Clot detection   | yes<br>yes/yes/yes   | yes<br>yes/yes/yes   | yes<br>yes/yes/no   |
| Automatic detection of adequate reagent for aspiration and analysis     Hemolysis/Turbidity detection-guantitation   | yes<br>vos/vos   | yes<br>ves/ves   | yes<br>no/no  |
| Dilution of patient samples onboard  | yes  | yes  | yes   |
| Automatic rerun capability<br>• Sample volume can be reduced to rerun out-of-linear-range high   | yes<br>ves/ves   | yes<br>ves/ves   | yes<br>ves/no   |
| results/Increased to rerun out-of-linear-range low results   | ,,   | ,,   | ,   |
| Autocalibration or autocalibration alert     • Calibrants stored onboard/Multipoint calibration supported  | yes<br>no/yes  | yes<br>yes/yes   | yes<br>yes/yes  |
| Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/   | 24 hours/lot/lot/lot   | 5 hours/lot/lot plus 20–26 weeks/lot plus  | 30 minutes/once per week/once per week/once   |
| Automatic shutdown/Startup programmable  | yes/yes  | yes/yes  | no/no   |
| Stat time to completion of all analytes/throughout per hour for  |  |  |   |
| Sodium, potassium, chloride, TCO2  | 5 minutes, 150 specimens   | 5 minutes  | 1.5 minutes, 60 specimens   |
| Sodium, potassium, chloride, TCO2, glucose, urea, creatinine     Albumin_direct and total bilirubin_AST_ALT_ALP  | 8 minutes, 38 specimens  | 8 minutes<br>11 minutes  | 6 minutes, 48 seconds, 60 specimens<br>7 minutes, 12 seconds, 50 specimens  |
| • Typical time delay from ordering stat test to aspiration of sample   | <1 minute  | <1 minute  | 3 minutes   |
| Frequency of QC required/Onboard SW capability to review QC<br>Onboard real-time QC/Support multiple QC lot Nos, per analyte   | daily/yes<br>ves/ves   | daily/yes<br>ves/ves   | 8 hours/yes<br>ves/ves  |
| QC results transferred automatically to LIS  | yes  | yes  | yes   |
| Data-management capability/Instrument vendor supplies LIS interface <ul> <li>LISs with which system interfaces in active user sites</li> </ul>   | onboard/no<br>all major LIS providers  | onboard/no<br>all major LIS vendors  | onboard/—<br>SchuyLab, LabDaq, Fletcher Flora, Medcom   |
| Bidirectional interface capability   | yes (broadcast download and host querv)  | yes (broadcast download and host querv)  | yes   |
| LIS interface operates simultaneously with running assays  | yes  | yes  | yes   |
| How labs get LOINC codes for reagent kits  | yes<br>Web site (MyLab Online)   | _  | no<br>  |
| Lab can control analyzer remotely  | no   | no   | no  |
| Modem servicing available/System can diagnose own malfunctions   | yes/yes  | yes/yes  | yes/yes   |
| On-cite time of convine and non/Onhand away and a fee travelast action   | ~8 hours/ves   | ~8 hours/ves   | ves guaranteed within 34 hours/use  |
| Mean time between failures/To repair failures  | 190 days/3 hours   | 130 days/<3 hours  | 10,000 hours/2 hours  |
| Onboard maintenance records/Maintenance training demo module   | yes (includes audit trail of who replaced parts)/no  | yes (includes audit trail of who replaced parts)/yes   | yes/no<br>4 days on site or 4 days at yonder offices (yes   |
| Annual service contract cost (24 h/7 d)  | 2 days on site, 5 days at vendor onices/yes<br>varies  | o days at vehicle offices/yes<br>varies  | 4 days on site of 4 days at vendor offices/yes<br>\$7,500   |
| Dictinguishing fosturos (sumplied by someony)  | convenience and stability of sales a mark manual   | unique reagent econotte eliminates second aver   | normanont ouvettee, onheard ist week (dry system  |
| visunguisining reatures (supplied by company)  | standardized operator interface and reagents,<br>other cobas chemistry platforms, Hitachi reliability  | ration; menu consolidates testing, including direct LDL, whole blood, HbA1c, and lithium   | permanent cuvertes, onboard jet wash/dry system,<br>six minutes to first result, notebook-like operator<br>interface, small footprint   |

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#### Chemistry analyzers (for low-volume laboratories)

October 2011

| Part 9 of 10   | Siemens Healthcare Diagnostics<br>Jason Ong jason.f.ong@siemens.com<br>1717 Deerfield Road<br>Deerfield, IL 60015<br>800-242-3233 www.usa.siemens.com/diagnostics   | Siemens Healthcare Diagnostics<br>Jason Ong jason.f.ong@siemens.com<br>1717 Deerfield Road<br>Deerfield, IL 60015<br>800-242-3233 www.usa.siemens.com/diagnostics  | Vital Diagnostics<br>Dianna Poissant USsales@vitaldiagnostics.com<br>27 Wellington Road<br>Lincoln, RI 02865<br>800-345-2822 www.vitaldiagnostics.com   |
|--|---|--|---|
| Name of instrument/First year sold in U.S./List price  | Dimension Xpand Plus Integrated Chemistry   | Dimension EXL 200/2011/—   | Envoy 500 Chemistry Analyzer/2005/—   |
| No. of units in clinical use in U.S./Outside U.S.<br>Country where designed/Manufactured/Reagents manufactured   | System/2004/—<br>U.S./U.S./U.S.<br>bath random coccor continuous random coccor/   | U.S./U.S./U.S.   | 270/—<br>Italy/Italy/Australia  |
| Sample handling system/Model type  | batch, random access, continuous random access/<br>self-contained single-use and multi-use cartridges<br>racks/floor-standing   | batch, random access, continuous random access/<br>self-contained multi-use cartridges<br>segmented sample wheel<br>$56 \times 40 \times 41/46$ equate foot  | random access/self-contained multi-use cartridges-<br>packages-slides<br>rotor/benchtop<br>27 × 40 × 22/6 square foot   |
| Tests available on instrument in II S  | thyronine untake total T4/thyroxine trijodothyronine  |  | ceneral chemistry albumin bilinubin direct HbA1c  |
| Research-use-only assays/Tests in development  | cardiac troponin I, ferritin, free PSA, free T4/thyroxine,<br>human chorionic gonadotropin hormone, mass CK-MB,<br>myoglobin, NT-pro BNP, thyroid stimulating hormone,<br>total PSA CardioPhase hsCRP, complement C3, more<br>—/mycophenolic acid | —/LOCI free T3, LOCI B12, LOCI folate, mycophenolic acid   | bilirubin, total, calcium, creatinine, glucos, ribAro,<br>total, magnesium, phosphorus, protein, total,<br>urea nitrogen (BUN), uric acid, enzyme, alanine<br>aminoTransferase (ALT), alkaline phosphatase, more<br>— |
| Analytes for which user-defined methods have been implemented  | _   |  | CRP wide range, hsCRP, digoxin, ferritin, fructos-<br>amine, lipase, phenobarbital, UIBC, glyoMark, cystatin<br>C, valproic acid, carbamazepine, IgA, IgG, IgM, ethanol   |
| Methods supported/Immunoassay methods  | photometry, potentiometry (ISE)/colorimetric,<br>immunoturbidimetric, potentiometric, EMIT<br>(homoneous IA) ACMIA (heterogeneous IA)   | photometry, potentiometry, LOCI, ACMIA, EMIT,<br>PETINIA, turbidimetric  | photometry, potentiometry, turbidimetric  |
| No. of direct ion selective electrode channels<br>• Must load separate reagent pack for each specimen  | 3<br>no   | 3<br>no  | 4<br>no   |
| <ul> <li>Separate reagent pack for each test run</li> <li>No. of different measured assays onboard simultaneously</li> </ul>   | no<br>47  | no<br>47   | no<br>40  |
| <ul> <li>No. of different assays programmed and calibrated at once</li> <li>No. of user-definable (open) channels/No. active simultaneously</li> </ul>                             | >90<br>10/10  | 47<br>10/47  | 40<br>500/40  |
| No. of different analytes for which system accommodates reagent<br>containers onboard at once/Tests per container set  | 47/72–1,440   | 47/15–240  | 40/150  |
| <ul> <li>Shortest/Median onboard reagent stability/Refrigerated onboard</li> <li>Multiple reagent configurations supported</li> </ul>  | 72 hours/30 days/yes (2°–8°C)<br>yes  | 24 hours/30 days/yes (2°–8°C)<br>yes   | 80 hours/21 days/yes (12°–15°C)<br>yes  |
| Reagent container placed directly on system for use<br>Instrument has same capabilities when third-party reagent used  | yes<br>yes  | yes<br>yes   | yes<br>no   |
| Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays  | can be hours/60/>1,000  | can be hours/60/<2,000   | 240/52/> 1,000  |
| System is liquid chemistry, dry chemistry, or reconstituted onboard<br>• Uses disposable cuvettes/Maximum No. stored   | liquid, reconstitutes onboard<br>yes/12,000   | liquid, reconstitutes onboard<br>yes/12,000  | liquid<br>no  |
| Uses washable cuvertes/heplacement frequency Minimum sample volume aspirated precisely at one time   | no/—<br>2 μL  | no/—<br>2 μL   | yes/never<br>1 μL   |
| System supplied with UPS (backup power)/Requires floor drain<br>Requires dedicated water system/Water consumption in L per hour  | yes/no<br>yes/up to 2 maximum   | yes/no<br>yes/5<br>  | yes/no<br>no/2  |
| Noise generated in deciders<br>Dedicated pediatric sample cup/Dead volume  | 0<br no/20 μL   | 5<br yes/30 μL   | >60<br>no/  |
| Sample bar-code reading capability/Autodiscrimination  | yes/no<br>on sample transport, shortly before sample is<br>aspirated (2 of 5 interleaved, Codabar, codes 39 and<br>128)/yes   | yes/no<br>shortly after tubes are loaded onto instruments (2<br>of 5 interleaved, Codabar, codes 39 and 128)/—   | yes/no<br>sample loaded on the analyzer by internal bar-code<br>scanner (2 of 5 interleaved, UPC, Codabar, codes 39<br>and 128)/no  |
| <ul> <li>Reagent bar-code reading capability</li> <li>Onboard test auto inventory (determines volume in container)</li> </ul>  | yes<br>yes  | yes<br>yes   | yes<br>yes  |
| Measures No. of tests remaining/Short sample detection/<br>Clot detection  | yes/yes/no  | yes/yes/yes  | yes/yes/no  |
| Automatic detection of adequate reagent for aspiration and analysis     Hemolysis/Turbidity detection-quantitation   | yes<br>yes/yes  | yes<br>yes/yes   | yes<br>no/no  |
| Dilution of patient samples onboard<br>Automatic rerun capability  | yes<br>yes  | yes<br>yes   | yes<br>yes  |
| Sample volume can be reduced to rerun out-of-linear-range high<br>results/increased to rerun out-of-linear-range low results   | yes/no  | yes/no   | yes/yes   |
| Autocalibration or autocalibration alert     Calibrants stored onboard/Multipoint calibration supported  | yes<br>yes/yes  | yes<br>yes/yes   | yes<br>no/yes   |
| Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/<br>Drugs of abuse   | every 2 hours, autocalibrate/—/60–90 days/30<br>days  | —/90 days/30 days/30 days  | 4 hours/7–31 days/—/—   |
| Automatic snutdown/startup programmable  | n0/n0   | N0/N0  | yes/yes   |
| Stat time to completion of all analytes/throughput per nour for:     Sodium, potassium, chloride, TCO2     Sodium, potassium, chloride, TCO2     Sodium, potassium, chloride, TCO2 | 2 minutes, 62 specimens   | _  | 3 minutes, 45 seconds, 37 specimens   |
| Albumin, direct and total bilirubin, AST, ALT, ALP     Twicel time data from refering a characteristic and control of complexity   | 8 minutes, 40 specimens<br>60 spoond staady state 2 minutes from standby  | Ξ  | 9 minutes, 10 seconds, 45 specimens<br>9 minutes, 26 seconds, 26 specimens  |
| Frequency of QC required/Onboard SW capability to review QC  | daily/yes   | 24 hours/yes   | 4–24 hours  |
| QC results transferred automatically to LIS  | yes<br>yes  | yes/yes<br>yes   | yes<br>yes  |
| Data-management capability/Instrument vendor supplies LIS interface  | optional add-on/yes (additional cost)   | onboard (EasyLink data management system<br>ontional add-on)/ves (additional cost)   | no/no   |
| LISs with which system interfaces in active user sites   | interfaces available for all major LIS vendors  |  | Antek, Fletcher Flora, Orchard, Skyler Lab, Data<br>Innovations. Sunquest   |
| Bidirectional interface capability<br>LIS interface operates simultaneously with running assays  | yes (broadcast download and host query)<br>ves  | yes (broadcast download and host query)<br>ves   | broadcast download<br>ves   |
| Uses LOINC to transmit orders and results<br>• How labs get LOINC codes for reagent kits   | no<br>  | yes<br>—   | no<br>e-mail inquiry  |
| Lab can control analyzer remotely  | no  | _  | no  |
| Modem servicing available/System can diagnose own malfunctions   | yes/yes   | yes/yes  | yes/yes   |
| On-site time of service engineer/Onboard error codes for troubleshooting<br>• Mean time between failures/To repair failures  | 2–8 hours/yes<br>—  | 2–8 hours/—<br>—   | within 24 hours/yes<br>—  |
| Onboard maintenance records/Maintenance training demo module<br>Training provided with purchase/Advanced operator training<br>Annual service contract cost (24 h/7 d)              | no/no<br>5 days on site, 4 days at vendor offices/no<br>multiple types  | <br>3 days at vendor offices/yes<br>   | yes/yes<br>yes/yes<br>\$8,995 (M-F, 8 am-8 pm)  |
| Distinguishing features (supplied by company)  | integrated chemistry, specialty, and immunoassay  | integrates general chemistry with homogeneous  | C02 performed as an electrolye; four-parameter  |
| Note: a dash in lieu of an answer means company did not answer question or question is not applicable  | systems; niche testing platform for no pre-treat<br>immuno-suppressive drug testing; no reagent<br>preparation; minimal operator maintenance  | allows a single platform for >95 percent of most<br>requested tests; eliminates sample splitting between<br>general chemistry tests and immunoassays; fully<br>automated onboard ISD assays; QCC PowerPak<br>onboard; reagent management system standard | cuvettes; small footprint   |

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

| Chemistry and  | alyzers   |
|--|---|
| Part 10 of 10  | Vital Diagnostics   |
|  | Dianna Poissant USsales@vitaldiagnostics.com  |
|  | 27 Wellington Road<br>Lincoln, RI 02865   |
|  | 800-345-2822 www.vitaldiagnostics.com   |
| Name of instrument/First year sold in U.S./List price  | Eon 100 Automated Chemistry Analyzer/2011/—   |
| No. of units in clinical use in U.S./Outside U.S.<br>Country where designed/Manufactured/Reagents manufactured   | 21/15<br>Italy/Italy/Australia  |
| Operational type/Reagent type  | random access, continuous random access/self-   |
| Sample handling system/Model type  | ring/benchtop<br>$30 \times 20 \times 255(10 \text{ square feet})$  |
|  |   |
| lests available on instrument in 0.5.  | (total), calcium, carbon dioxide, creatinine, glucose,  |
|  | iron (total), magnesium, phosphorus, protein (total),<br>urea nitrogen (BUN), uric acid, direct LDL, triglycerides, |
|  | direct HDL, cholesterol, alanine aminotransferase (ALT),<br>alkaline phosphatase (ALP), amylase (AMY), aspartate    |
| Research-use-only assays/Tests in development  | transaminase (AST), creatine phosphokinase (CPK), more<br>—/CRP wide range, CRP high sensitivity,                   |
|  | hemoglobin A1c, microalbumin, UIBC  |
| Analytes for which user-defined methods have been implemented  | _   |
|  |   |
| Mathode sunnarted/immunoassay mathods  | nhotometry notentiometry  |
| methous supporteu/mininunoassay methous  | protomen y, potentiomen y   |
| No. of direct ion selective electrode channels   | 3   |
| Must road separate reagent pack for each specimen  |   |
| Separate reagent pack for each test run     No. of different measured assays onboard simultaneously  | 28  |
| <ul> <li>No. of different assays programmed and calibrated at once</li> <li>No. of user-definable (open) channels/No. active simultaneously</li> </ul> | 28<br>—   |
| No. of different analytes for which system accommodates reagent<br>containers onboard at once/Tests per container set                                  | 28/100  |
| Shortest/Median onboard reagent stability/Refrigerated onboard   | 168 hours/21 days/yes (12°–14°C below room<br>temperature)  |
| Multiple reagent configurations supported Reagent container placed directly on system for use  | yes   |
| Instrument has same capabilities when third-party reagent used   | no<br>03/0/17   |
| No. of tests-assays  |   |
| Uses disposable cuvettes/Maximum No. stored  | no  |
| Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time   | yes/1 year<br>1 μL  |
| System supplied with UPS (backup power)/Requires floor drain<br>Requires dedicated water system/Water consumption in L per hour                        | yes/no<br>no/—  |
| Noise generated in decibels<br>Dedicated pediatric sample cup/Dead volume  | >60<br>no/—   |
| Primary tube sampling/Pierces caps on primary tubes<br>Sample bar-code reading capability/Autodiscrimination   | yes/no<br>yes, after loading samples and immediately prior to   |
|  | execution of run (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/no  |
| Reagent bar-code reading capability Onboard test auto inventory (determines volume in container)   | yes   |
| Measures No. of tests remaining/Short sample detection/     Clet detection/  | yes/yes/no  |
| Automatic detection of adequate reagent for aspiration and analysis     Momentum (Turkidity detection guaratitation)                                   | yes   |
| Hemolysis/ lurbidity detection-quantitation     Dilution of patient samples onboard  | no/no<br>yes  |
| Sample volume can be reduced to rerun out-of-linear-range high   | yes<br>yes/no   |
| results/Increased to rerun out-of-linear-range low results<br>Autocalibration or autocalibration alert   | yes   |
| Calibrants stored onboard/Multipoint calibration supported<br>Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/                     | no/yes<br>8 hours/7–28 days/—/—   |
| Drugs of abuse<br>Automatic shutdown/Startup programmable  | yes/yes   |
| Stat time to completion of all analytes/throughput per hour for:   |   |
| Sodium, potassium, chloride, TCO2     Sodium, potassium, chloride, TCO2     Sodium, potassium, chloride, TCO2, glucose, urea, creatinine               | 35 seconds, 90 specimens<br>5 minutes, 21 seconds, 20 specimens   |
| Albumin, direct and total bilirubin, AST, ALT, ALP     Tynical time delay from ordering stat test to assiration of cample                              | 7 minutes, 18 specimens   |
| Frequency of QC required/onboard SW capability to review QC  | 4–24 hours/yes  |
| QC results transferred automatically to LIS  | yes   |
| Data-management capability/Instrument vendor supplies LIS interface  | onboard/no<br>Antek's LabDAO  |
| Ridirectional interface canability   | hroadcast download and bost query   |
| LIS interface operates simultaneously with running assays  | yes   |
| How labs get LOINC codes for reagent kits  | e-mail inquiry  |
| Lab can control analyzer remotely  | no  |
| Modem servicing available/System can diagnose own malfunctions   | yes/yes   |
| On-site time of service engineer/Onboard error codes for troubleshooting   | <24 hours/yes   |
| Onboard maintenance records/Maintenance training demo module   | no/no   |
| Annual service contract cost (24 h/7 d)  | yes/yes<br>via distributor  |
| Distinguishing features (supplied by company)  | long-use cuvettes eliminate waste; intuitive  |
| Note: a dash in lieu of an answer means company did not answer question or question is not applicable  | software; fast, accurate ISE's; small footprint;<br>virtually maintenance free                                      |
|  |   |

Tabulation does not represent an endorsement by the College of American Pathologists.