

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

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

Part 2 of 6

FOR POINT-OF-CARE USE AND LOW-VOLUME LABORATORIES

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Name of instrument	Access 2 immunoassay	DxC 500 AU Clinical Chemistry Analyzer chemistry	DxC 500i Clinical Analyzer combination chemistry/immunoassay
Type of instrument			
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)	—	11/0	—/— (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/—
Chemistry:			
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	—	—	—
Immunoassay:			
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	no/no	—
Onboard real-time QC/Onboard software capability to review QC	no/yes	yes/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/Cerner, Antrim, CCA, Chemware, Dawning Technologies, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson, more	onboard/Medicus, Orchard, Evident, CGM LabDaq, Cerner, Sunquest	onboard/Medicus, Orchard, Evident, CGM LabDaq, Cerner, Sunquest
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)	<ul style="list-style-type: none"> offers the robustness of a reference laboratory immunoassay analyzer in convenient size of a benchtop system standardization of results and reagents across all volume segments reliable benchtop system providing the same high-quality results as the core lab 	<ul style="list-style-type: none"> intuitive user interface with user-friendly software that guides workflow and anticipates laboratory needs commonly replaced parts can be changed in 3 steps, in 60 seconds, and without tools standardization across the AU family of chemistry analyzers 	<ul style="list-style-type: none"> independent and integrated operations, reagent load on the fly, rapid throughput single point of sample loading, intuitive interface and guided workflows, easy to maintain parts offers a menu of more than 170 assays for complete disease state management

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

Part 3 of 6	Diatron MI Frank Matuszak frank.matuszak@diatron.com Medley, FL 833-228-7931 www.diatron.com	Dynex Technologies Global Customer Service customerservice@dynex.com Chantilly, VA 800-288-2354 www.dynex.com	ELITechGroup Trish Worman p.worman@elitechgroup.com Logan, UT 435-752-6011 www.elitechgroup.com
FOR POINT-OF-CARE USE AND LOW-VOLUME LABORATORIES			
Name of instrument	Pictus 500 (P500)	DS2 Automated ELISA System	Selectra Pro M [†]
Type of instrument	chemistry	immunoassay	chemistry
Operational type/Model type	batch, random access, continuous random access, discrete/benchtop	batch/benchtop	batch, random access, continuous random access, discrete/benchtop
List price/First year sold in U.S.	\$42,860/2016	—/2007	\$64,375/2012
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)	—/daily: 10–40 patients; monthly: 3,333–8,333 tests; annual: 40,000–100,000 tests
Company manufactures instrument	yes	yes	yes (also sold by McKesson, Medline, RedByrd)
Other models in this family of analyzers	Pictus 700 (P700)	DSX	Selectra Pro S
No. of units in clinical use in U.S./Outside U.S. (countries)	> 40/≤ 200 (Europe, Latin America, Africa, Middle East, Asia)	—/4,510 (worldwide)	35/7,000
Dimensions (H × W × D)/Instrument footprint	24.4 × 35.4 × 26 in./6.4 sq. ft.	26 × 21 × 27 in./3.9 sq. ft.	30 × 48 × 24.4 in./8.1 sq. ft.
Weight empty/Weight fully loaded	253 lbs./271 lbs.	105 lbs./—	210 lbs./—
No. of different measured assays onboard simultaneously	72 (999 can be run and calibrated at one time)	up to 12 assays per microplate (up to 12 can be run)	36 (96 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	— (open system; up to 12 can be active simultaneously)	10 (10 can be active simultaneously)
Test throughput per hour/Assay run time	500/30–1,200 sec. (avg. 300 sec.)	assay dependent (up to 384 tests per run)/assay dependent	180 (180 tests in throughput)/—
Chemistry:			
No. of direct ion-selective electrode channels	3	—	4
Detection methods	photometry, potentiometry	—	photometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	2 min./60 specimens per hr.	—	5 min./66 specimens per hr.
• Basic metabolic panel	7.5 min./45 specimens per hr.	—	—/27 specimens per hr.
• Complete metabolic panel	9 min./25 specimens per hr.	—	13 min., 35 sec./12 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	24 sec.	—	3 min.
Immunoassay:			
Fully automated microplate immunoassay system	—	yes (up to 12 tests per unit; 96 wells per microplate)	—
Methodologies supported	—	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	50–200 per set, 400–1,800 per pack/self-contained multiuse, open reagent system	—/open reagent system	varies/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (8°±2°C)/yes	no (23°±4°C)/—	yes (10°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/no	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/yes	no/no
Walkaway capability/Walkaway duration	yes/180 min. or 95 specimens or 1,200 tests/assays	yes/up to 192 specimens or up to 192 tests/assays	yes/240 min. or 62 specimens or 720 tests/assays
Design of sample-handling system	rack	rack	ring
Uses washable cuvettes/Uses disposable cuvettes	yes/yes (can store up to 80 cuvettes)	no/—	yes/no (can store up to 48 cuvettes)
Min.–max. sample volume that can be aspirated at one time	2–100 µL	10–250 µL	1–30 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	180 µL/22 µL/100 µL	10 µL/—/—	220 µL/1 µL/250 µL
Dedicated pediatric sample cup	yes (dead volume: 20 µL)	no	yes (dead volume: 100 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/no	yes/yes (17 × 100 mm)	yes/no
Pierces caps on primary tubes	yes	no	no
Protects against probe collision	yes	no	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	no/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	hemolysis, icterus, lipemia, clots not available
Dilutes patient samples onboard/Susceptibility to 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	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	yes	no	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	no	no
Analyzer requires dedicated water supply	no (2 L/hr. consumption during operation)	no	no
Autocalibration/Multipoint calibration supported	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 7 days)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	8 hrs./—/7 days/14 days/14 days	—/assay dependent/assay dependent/—/assay dependent	4–8 hrs./2 weeks minimum/when indicated (if QC fails)/28 days/—
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	yes (15 min. 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, direct to drain	automated collection onboard instrument	automated collection onboard instrument, direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no	yes (UPC, Codabar, Code 39, Code 128, Code 93)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	yes	no	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/AP Vision, Medicus, Schuyler, LabTrack, CGM LabDaq, Medytox	onboard/Orchard, Cerner	onboard/CGM LabDaq, Schuyler House SchuyLab, McKesson Horizon Lab, Medicus Solutions, more
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	no/yes (host query)	no/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/48 hrs.	no/24 hrs.	no/24 business hrs.
Mean time between failures	1 per year (displays error codes for troubleshooting)	250 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 30 min.; weekly: 1 hr.; monthly: 2 hrs.	daily: 10 min.; weekly: 5 min.	daily: 5 min.; weekly: 5 min.; monthly: 15 min.
Maintenance records kept onboard for user/vendor	no/no	no/no	yes/no
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/3 days (at customer site)	no/3 days (at customer site)	yes (2 training slots)/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	yes (at customer site)/no
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/ \$5,500	yes (1 year)/—	yes (1 year)/\$4,500 (Mon.–Fri., 8 AM–7 PM)
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> uninterrupted workflow Windows-based, intuitive, user-friendly software high-quality components for long stability and result reliability 	<ul style="list-style-type: none"> run any assay from any vendor—fully automated open system reliable workload scheduling—more than 98 percent mean time between failures saves space—less than 4 sq. ft. of linear counter space to process up to two 96-well microplates and 100 specimens 	<ul style="list-style-type: none"> cost-efficient benchtop chemistry system for small to mid-size labs TouchPro software with smart icons guides operator through daily workflow, including configurable daily checklists 4-parameter (Na⁺, K⁺, Cl⁻, CO₂) dry electrodes reduce costs and maintenance time, increase reliability of results

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

†all information listed was provided to CAP TODAY in 2024; company did not provide updated information by 2025 entry deadline

Part 5 of 6	QuidelOrtho Laura Osborne laura.osborne@quidelortho.com Raritan, NJ 800-828-6316 www.quidelortho.com	Roche Diagnostics Claire Rhodes claire.rhodes@roche.com Indianapolis, IN 800-428-5074 diagnostics.roche.com/us/en/home.html	Roche Diagnostics Claire Rhodes claire.rhodes@roche.com Indianapolis, IN 800-428-5074 diagnostics.roche.com/us/en/home.html
FOR POINT-OF-CARE USE AND LOW-VOLUME LABORATORIES			
Name of instrument	VITROS XT 3400 Chemistry Systems	cobas c 311	cobas e 411
Type of instrument	chemistry	chemistry	immunoassay
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	random access, continuous random access/floor standing	random access, continuous random access/benchtop
List price/First year sold in U.S.	—/2019	—/2009	—/2008
Targeted hospital bed size/Targeted test volume	—/annual: 50,000–4 million	< 100/daily: < 200; monthly: < 40,000; annual: < 500,000	< 100/daily: < 200; monthly: < 40,000; annual: < 500,000
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	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	> 140/> 225 (North, Central, and South Americas, more)	> 300/> 2,500 (> 50 countries)	> 800/> 10,000 (> 50 countries)
Dimensions (H × W × D)/Instrument footprint	53 × 58 × 34 in./—	50 × 52 × 34 in./8.5 sq. ft.	disk: 31.4 × 47.2 × 28.7 in./9.4 sq. ft.; rack: 31.4 × 67 × 37.4 in./17.4 sq. ft.
Weight empty/Weight fully loaded	1,150 lbs./—	551 lbs./625 lbs.	disk: 397 lbs./397 lbs.; rack: 551 lbs./551 lbs.
No. of different measured assays onboard simultaneously	89 (89 can be run and calibrated at one time)	42 photometric, 3 ISE (up to 90 can be run and calibrated at one time)	18 (18 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	10 (10 can be active simultaneously)	0
Test throughput per hour/Assay run time	1,130/2.5–9 min. (avg. 5 min.)	up to 300 (300 tests in throughput)/3–10 min. (avg. 7 min.)	86 (86 tests in throughput)/9–27 min. (avg. 18 min.)
Chemistry:			
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.	5 min./150 specimens per hr.	—
• Basic metabolic panel	6 min./95 specimens per hr.	8 min./60 specimens per hr.	—
• Complete metabolic panel	7.5 min./74 specimens per hr.	11 min./27 specimens per hr.	—
Typical time delay from ordering stat test until aspiration of sample	1 min.	< 1 min.	—
Immunoassay:			
Fully automated microplate immunoassay system	—	—	no
Methodologies supported	—	—	electrochemiluminescence
Separation methodologies	—	—	magnetic particle
Stat time until completion of a β-hCG test	—	—	~10 min.
• Typical time delay from test order to aspiration of sample	—	—	< 1 min.
Stat time until completion of a cTn test	—	—	~10 min.
• Typical time delay from test order to aspiration of sample	—	—	< 1 min.
Approximate No. of tests per reagent set/Reagent type	18–120/self-contained single use	50–800/self-contained multiuse	100–200/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (10°C)/yes	yes (5°–15°C)/yes	no (20° ±3°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	dry chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/—	yes/60–180 min. or 108 specimens or 45 tests/assays	yes/30–60 min. or 30 specimens (disk), 75 specimens (rack) or 2,000–3,000 tests/assays
Design of sample-handling system	universal sample tray, continuous load and unload, circular routine sample center	ring	disk: ring; rack: rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	yes/yes (can store up to 66 cuvettes)	no/yes (can store up to 360 assay tips, 180 assay cups)
Min.–max. sample volume that can be aspirated at one time	2–200 µL	1–35 µL	10–50 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—/2.5 µL/35 µL	6 µL/51 µL/50 µL	100 µL/10 µL/100 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 (12 × 100 mm)
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; quantitation for hemolysis, icterus, lipemia	detection for clots; hemolysis, icterus, lipemia not available
Dilutes patient samples onboard/Susceptibility to carryover	yes/0	yes (can be programmed to perform sample dilutions prior to analysis)/< 1 part per million	yes (can be programmed to perform sample dilutions prior to analysis)/0 (uses disposable tips)
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	yes (12 L/hr. consumption during operation)	no (3 L consumption for 250 tests)
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: 24 hrs. [ISE]; once per lot [chemistry])	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)
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/—	24 hrs./per lot/per lot/per lot/—	—/—/—/—/28 days
Automatic programmable start/Automatic programmable shutdown	no/no	no (5 min. start-up time)/yes	yes (4 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	direct to drain	automated collection onboard instrument
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)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, PDF417)/yes
Lab can control analyzer from remote computer	no	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/—	onboard/SCC Soft Computer, Meditech, Cerner, Epic, Sunquest, more	onboard/SCC Soft Computer, Meditech, Cerner, Epic, Sunquest, 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/< 24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	279 days (displays error codes for troubleshooting)	368 days (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: 18 min.; monthly: 38 min.	daily: 5 min.; weekly: 6 min.; monthly: 11 min.
Maintenance records kept onboard for user/vendor	yes/yes (both include audit trail of who replaced parts)	yes/yes (both include audit trail of who replaced parts)	some records/some records
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 (1 training slot)/1 week (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)/configuration dependent
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> XT Microslide performs two tests on one slide, which doubles testing output, increases productivity, and fulfills more requests from difficult draws designed to use single-patient consumables without the need for water, eliminating risk of carryover MicroSensor technology automates detection of HIL interferences 	<ul style="list-style-type: none"> drives lab efficiency with standardized instrumentation, reference ranges, consumables, and usage minimizes downtime with industry-leading service; 213-day mean time between repair visits (average) speeds up turnaround time for high-volume stat assays 	<ul style="list-style-type: none"> drives lab efficiency with standardized instrumentation, reference ranges, consumables, and usage minimizes downtime with industry-leading engineering and service; 325-day mean time between repair visits (average) speeds up turnaround time for high-volume stat assays
<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

FOR POINT-OF-CARE USE AND LOW-VOLUME LABORATORIES

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Name of instrument	cobas pure integrated solutions	B-R-A-H-M-S KRYPTOR compact PLUS	AIA-360
Type of instrument	combination chemistry/immunoassay	immunoassay	immunoassay
Operational type/Model type	random access, continuous random access/floor standing	batch, random access, continuous random access/benchtop	continuous random access/benchtop
List price/First year sold in U.S.	—/2022	—/2015	—/2004
Targeted hospital bed size/Targeted test volume	< 200/daily: 410–2,054; monthly: 12,500–62,500; annual: 150,000–750,000	—/daily: 450; monthly: 9,000; annual: 125,000	—/monthly: < 500
Company manufactures instrument	no (manufactured by Hitachi High-Technologies)	yes (also sold by distribution partners)	yes
Other models in this family of analyzers	chem: cobas c 303; immuno: cobas c 402	B-R-A-H-M-S KRYPTOR GOLD	AIA-900, AIA-2000
No. of units in clinical use in U.S./Outside U.S. (countries)	< 1,000/> 1,000 (> 50 countries)	—/> 900 (worldwide)	~600/> 7,000 (worldwide)
Dimensions (H × W × D)/Instrument footprint	5.8 × 8 × 2.6 ft./21 sq. ft.	24 × 29 × 29 in./4.59 sq. ft.	21 × 16 × 16 in./2.1 sq. ft.
Weight empty/Weight fully loaded	2,205 lbs./2,205 lbs.	119 lbs./—	61 lbs./—
No. of different measured assays onboard simultaneously	up to 73 (up to 73 can be run and calibrated at one time [chem: 42, immuno: 28, ISE: 3])	8 (8 can be run and calibrated at one time)	25 (25 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	10 (10 can be active simultaneously)	—	—
Test throughput per hour/Assay run time	870 (up to 300 photometric, 450 ISE tests in throughput)/chem: 4–10 min. (avg. 10 min.); immuno: 9–27 min. (avg. 18 min.)	up to 60 (up to 60 tests in throughput)/9–59 min.	36/10 min.
Chemistry:			
No. of direct ion-selective electrode channels	3	—	—
Detection methods	photometry, potentiometry	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	4.5 min. for ISE, 10 min. with CO ₂ /ISE: 150 specimens per hr.	—	—
• Basic metabolic panel	10 min./—	—	—
• Complete metabolic panel	10 min./—	—	—
Typical time delay from ordering stat test until aspiration of sample	< 1 min.	—	—
Immunoassay:			
Fully automated microplate immunoassay system	no	no	—
Methodologies supported	electrochemiluminescence	fluorescence, enzyme immunoassay	fluorescence
Separation methodologies	magnetic particle	none necessary	—
Stat time until completion of a β-hCG test	~10 min.	14 min.	20 min.
• Typical time delay from test order to aspiration of sample	< 1 min.	2 min.	—
Stat time until completion of a cTn test	~10 min.	—	20 min.
• Typical time delay from test order to aspiration of sample	< 1 min.	—	—
Approximate No. of tests per reagent set/Reagent type	up to 3,300 (chem), 300 (immuno)/self-contained multiuse	50–100/self-contained single use	100 (20 tests per tray)/unit dose test cup
Reagents refrigerated onboard/Reagents ready to use	yes (5°–15°C [chemistry], 6°–10°C [immunoassay])/yes	yes (2°–8°C)/yes	no/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/no
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/yes	dry chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/yes	no/no	yes/—
Walkaway capability/Walkaway duration	yes/30–45 min.	yes/max. 220 min. (assay dependent) or up to 64 specimens or up to 96 tests	yes/58 min. or 25 specimens or 25 tests/assays
Design of sample-handling system	5-position rack	sample cassette placed in sample carousel	carousel
Uses washable cuvettes/Uses disposable cuvettes	yes/yes (can store up to 210 cuvettes)	no/no	no/no
Min.–max. sample volume that can be aspirated at one time	1–60 µL	8–70 µL	10–100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	75 µL/1.5 µL (chemistry), 4 µL (immunoassay)/50 µL	150 µL/sample tube and assay dependent/150 µL (sample tube dependent)	10 µL/110 µL/100 µL
Dedicated pediatric sample cup	yes (dead volume: 50 µL)	yes (dead volume: 75 µL)	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (11 x 102 mm [chem], 13 x 102 mm [immuno])	yes/yes (11–17 × 60–120 mm)	yes/—
Pierces caps on primary tubes	no	no	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	quantitation for hemolysis, icterus, lipemia; detection for clots	detection for hemolysis, icterus, lipemia, clots	—
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/< 1 part per million (chemistry), no carryover (immunoassay)	yes (can be programmed to perform dilutions prior to analysis)/≤ 2 parts per million (no contamination)	no/none
Automatic rerun capability	yes	yes	no
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	no
Sample volume can be concentrated to rerun out-of-linear-range low results	yes	yes	no
Analyzer requires dedicated water supply	yes (12 L/hr. consumption during operation for chemistry, 16 L/hr. for immunoassay)	no	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: once per lot [chem], up to 84 days per lot [immuno])	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	once per lot/once per lot/once per lot/once per lot/up to 84 days per lot	—/—/—/—/5–15 days	—/—/—/—/90 days most assays
Automatic programmable start/Automatic programmable shutdown	yes (6.5 min. avg. start-up time)/yes	no/no	no (5 min. start-up time)/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	no/no
Supports multiple QC lot numbers per analyte	yes	yes	—
Waste management	direct to drain	manually by user, automated collection onboard instrument	automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	yes	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	no
System malfunctions can be diagnosed via remote monitoring	yes	yes	—
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard, optional add-on (Bio-Rad MAS)/SCC Soft Computer, Mediatech, Cerner, Epic, Sunquest, more	onboard/—	Tosoh 501RP+ /—
LIS interface provided/Bidirectional interface capability	yes (included in instrument price)/yes (broadcast download and host query)	yes (additional cost)/yes (broadcast download and host query)	no/no
Modem servicing provided/Service engineer on-site response time	yes/—	yes/Mon.–Fri.: 26 hrs. at total breakdown, 72 hrs. at workaround	—
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	888 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: < 5 min.; weekly: 30 min.; monthly: 59 min.	daily: 3 min.; weekly: 3 min.; monthly: 5 min.	daily: 5 min.
Maintenance records kept onboard for user/vendor	yes/yes (both include audit trail of who replaced parts)	yes/yes (both include audit trail of who replaced parts)	no/no
Maintenance training demonstration module onboard	yes	no	no
Training included with purchase/Avg. time for basic user training	yes (~2 training slots per module)/4–5 days (at both vendor and customer sites)	yes (1 training slot)/1.5–2 days (at customer site)	yes/2 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/yes	yes (at vendor site)/yes	—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/contract dependent	yes (1 year)/contract dependent	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> minimal operator intervention with automated maintenance, automated calibration, and continuous loading of reagents maximizes reagent use; long onboard reagent (up to 6 months) and calibration stabilities increases revenue through expanded testing services 	<ul style="list-style-type: none"> fully automated random-access immunoanalyzer with unique Nobel Prize–winning TRACE technology automated timely onboard dilution in less than 5 minutes with integrated self-determining dilution factor no biotin interferences of the assays 	<ul style="list-style-type: none"> unit dose test cup; dry reagent, no premixing or reagent preparation immunoassay method free from biotin interference; compact size, broad menu with fast results 90-day calibration stability for most assays

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