

Part 1 of 6	<b>Abbott Point of Care</b> Jeff Abney jeff.abney@abbott.com Princeton, NJ 609-454-9000 www.pointofcare.abbott/us/en/home	<b>Awareness Technology</b> Rafael Castillo rcastillo@awaretech.com Palm City, FL 772-283-6540 www.awaretech.com	<b>Awareness Technology</b> Rafael Castillo rcastillo@awaretech.com Palm City, FL 772-283-6540 www.awaretech.com
<b>FOR POINT-OF-CARE AND LOW-VOLUME LABORATORIES</b>			
Name of instrument	i-STAT 1 analyzer	ChemWell 2910	ChemWell-T
Type of instrument	combination chemistry/immunoassay	combination chemistry/immunoassay	chemistry
Operational type/Model type	discrete/handheld	batch, random access, discrete/benchttop	batch, random access, discrete/benchttop
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)	yes (also sold by GMI, Monobind, ASI, others)	yes (also sold by distribution partners)
Other models in this family of analyzers	—	ChemWell Fusion, ChemWell-T, 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)	380/6,000 (worldwide)	150/4,000 (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	—/2–10 min.	200 (27 tests in throughput)/6–120 min.	100/—
<b>Chemistry:</b>			
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	—
• Complete metabolic panel	—	assay dependent	—
Typical time delay from ordering stat test until aspiration of sample	none	assay dependent	—
<b>Immunoassay:</b>			
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	10 min.	assay dependent	—
• Typical time delay from test order to aspiration of sample	none	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
Reagents refrigerated onboard/Reagents ready to use	no/—	yes (12°–15°C on optional cooling accessory)/yes	yes (8°–15°C)/variable; reagent specific
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)/no	liquid chemistry (open reagent system)/no
Separate reagent pack for each specimen/for each test run	no/no	no/yes	—
Walkaway capability/Walkaway duration	yes/2–10 min. or 1 specimen or up to 13 tests	yes/480 min.	yes/120 min. or ~16–20 specimens or up to 40 tests
Design of sample-handling system	—	rack (custom reagent and sample rack)	rack
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 (custom reagent and sample racks available)
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	—
Dilutes patient samples onboard/Susceptibility to carryover	no/—	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	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)/no	yes (Code 39)/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/no	no/no
Modem servicing provided/Service engineer on-site response time	—/— (product replacement within 24 hrs.)	no/—	no/—
Mean time between failures	— (displays error codes for troubleshooting)	400 days (displays error codes for troubleshooting)	400 days (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)/—
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"> <li>handheld portable analyzer; unit use system can perform chemistry, blood gas, cardiac marker, and coagulation tests</li> <li>CLIA-waived tests, including glucose and creatinine</li> <li>uses 2–3 drops of whole blood or plasma</li> </ul>	<ul style="list-style-type: none"> <li>vertical plate reading for biochemistries</li> <li>2-in-1 utility with the ability to run in ELISA mode or biochemistry mode</li> <li>low-cost analyzer that saves on reagent use; open system; remote access; software included (free)</li> </ul>	<ul style="list-style-type: none"> <li>compact low-cost analyzer that saves on reagent use</li> <li>flexibility of hardware/software</li> <li>software included (free)</li> </ul>

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

Part 2 of 6	<b>Beckman Coulter</b> <b>Onyi Nacionales</b> onacionales@beckman.com <b>Brea, CA</b> <b>800-526-3821</b> www.beckmancoulter.com	<b>Beckman Coulter</b> <b>Onyi Nacionales</b> onacionales@beckman.com <b>Brea, CA</b> <b>800-526-3821</b> www.beckmancoulter.com	<b>Diatron MI</b> <b>Frank Matuszak</b> frank.matuszak@diatron.com <b>Medley, FL</b> <b>833-228-7931</b> www.diatron.com
Name of instrument	Access 2	AU480	Pictus 500 (P500)
Type of instrument	immunoassay	chemistry	chemistry
Operational type/Model type	continuous random access/benchtop	continuous random access/floor standing	batch, random access, continuous random access, discrete/benchtop
List price/First year sold in U.S.	—/2001	—/2009	\$42,860/2016
Targeted hospital bed size/Targeted test volume	—/annual: < 40,000	—/annual: 50,000–250,000	20–100/daily: 500–2,500; monthly: 15,000–75,000; annual: 182,500–912,500
Company manufactures instrument	yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific)	yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific)	yes
Other models in this family of analyzers	Unicel Dxl 600, Unicel Dxl 800	DxC 700 AU, AU 5800	Pictus 700 (P700)
No. of units in clinical use in U.S./Outside U.S. (countries)	—	—	> 40/≤ 200 (Europe, Latin America, Africa, Middle East, Asia)
Dimensions (H × W × D)/Instrument footprint	19.5 × 39 × 24 in./6.5 sq. ft.	47.5 × 57 × 30 in./18.5 sq. ft.	24.4 × 35.4 × 26 in./6.4 sq. ft.
Weight empty/Weight fully loaded	200 lbs./—	926 lbs./—	253 lbs./271 lbs.
No. of different measured assays onboard simultaneously	24 (24 can be run and calibrated at one time)	63 (63 can be run and calibrated at one time)	72 (999 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	18 (76 can be active simultaneously)	—
Test throughput per hour/Assay run time	up to 100/13–55 min.	800 (400 photometric, 800 with ISE)/8.5 min.	500/30–1,200 sec. (avg. 300 sec.)
<b>Chemistry:</b>			
No. of direct ion-selective electrode channels	—	3	3
Detection methods	—	photometry, potentiometry	photometry, potentiometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	4.5 min./400 specimens per hr.	2 min./60 specimens per hr.
• Basic metabolic panel	—	12.5 min./133 specimens per hr.	7.5 min./45 specimens per hr.
• Complete metabolic panel	—	14.5 min./72 specimens per hr.	9 min./25 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	—	60 sec.	24 sec.
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	no	—	—
Methodologies supported	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	200–>1,000 (varies by assay)/self-contained multiuse	50–200 per set, 400–1,800 per pack/self-contained multiuse, open reagent system
Reagents refrigerated onboard/Reagents ready to use	yes (2°–8°C)/yes	yes (4°–12°C)/yes	yes (8°±2°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/no
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/80 specimens	yes/180 min. or 95 specimens or 1,200 tests/assays
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 294 cuvettes)	yes/no	yes/yes (can store up to 80 cuvettes)
Min.–max. sample volume that can be aspirated at one time	5–200 µL	1–25 µL	2–100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	varies by assay/varies by assay/80 µL	90 µL/41 µL or 1 µL with 4 mm above gel barrier/50 µL	180 µL/22 µL/100 µL
Dedicated pediatric sample cup	yes (dead volume: 80 µL)	yes (dead volume: 50 µL)	yes (dead volume: 20 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/no	yes/yes (primary, secondary tubes: 11.5–16 × 55–102 mm; nested micro cups)	yes/no
Pierces caps on primary tubes	no	no	yes
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 and quantitation for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform sample dilutions prior to analysis)/0.001 parts per million	yes (can be programmed to perform dilutions prior to analysis)/30 parts per million
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)	no (2 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 (recommended avg. frequency: assay dependent)	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 7 days)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/—/—/—/28 days	1 day/14 days/14–20 days/30 days/—	8 hrs./—/7 days/14 days/14 days
Automatic programmable start/Automatic programmable shutdown	no (< 5 min. start-up time)/no	no/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	manually by user, direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/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	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/Cerner, Antrim, CCA, Chemware, Dawning Technologies, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson, more	onboard/AP Vision, Medicus, Schuyler, LabTrack, CGM LabDaq, Medytox
LIS interface provided/Bidirectional interface capability	yes (included in instrument price)/yes (host query)	yes (included in instrument price)/yes (broadcast download and host query)	yes (additional cost)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/< 24 hrs.	yes/< 24 hrs.	no/48 hrs.
Mean time between failures	1.4 down service calls per year (displays error codes for troubleshooting)	1.2 down service calls per year (displays error codes for troubleshooting)	1 per year (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 7 min.; weekly: 12 min.	daily: 6 min.; weekly: 10 min.; monthly: 45 min.	daily: 30 min.; weekly: 1 hr.; monthly: 2 hrs.
Maintenance records kept onboard for user/vendor	no/no	yes/no	no/no
Maintenance training demonstration module onboard	yes	yes	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/2 days (at vendor site)	yes (2 training slots)/3 days (at customer and vendor sites)	yes (2 training slots)/3 days (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 or customer site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/ \$5,500
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>offers the robustness of a reference laboratory immunoassay analyzer in convenient size of a benchtop system</li> <li>standardization of results and reagents across all volume segments</li> <li>reliable benchtop system providing the same high-quality results as the core lab</li> </ul>	<ul style="list-style-type: none"> <li>standardization across the AU family of chemistry analyzers</li> <li>lower total cost of ownership due to fewer consumables and concentrated reagents</li> <li>commonly replaced parts can be changed in 3 steps or less, in 60 seconds or less, without tools</li> </ul>	<ul style="list-style-type: none"> <li>uninterrupted workflow</li> <li>Windows-based, intuitive, user-friendly software</li> <li>high-quality components for long stability and result reliability</li> </ul>
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			



Part 4 of 6	<b>HORIBA Medical</b> Susan Behnke medical-marketing.us@horiba.com Irvine, CA 888-903-5001 www.horiba.com/us/en/medical/	<b>Nova Biomedical</b> info@novabio.com Waltham, MA 800-458-5813 www.novabiomedical.com	<b>QuidelOrtho</b> Laura Osborne laura.osborne@quidelortho.com Raritan, NJ 800-828-6316 www.quidelortho.com
Name of instrument	Pentra C400 chemistry	Stat Profile Prime Plus chemistry	Vitros XT 3400 Chemistry Systems chemistry
Type of instrument	batch, random access, continuous random access, discrete/benchtop	random access/benchtop	batch, random access, continuous random access, discrete/floor standing
Operational type/Model type	batch, random access, continuous random access, discrete/benchtop	random access/benchtop	batch, random access, continuous random access, discrete/floor standing
List price/First year sold in U.S.	\$100,000/2006	—/2018	—/2019
Targeted hospital bed size/Targeted test volume	≤ 250/daily; 1,200; monthly; 24,000; annual: 288,000	—	—/annual: 50,000–4 million
Company manufactures instrument	yes (also sold by distribution partners)	yes (also sold by distribution partners)	no (manufactured by JABIL; also sold by Cardinal, McKesson, more)
Other models in this family of analyzers	Pentra 400	Stat Profile Prime CCS, Stat Profile Prime, Stat Profile Prime ES	Vitros 4600 Chemistry System, Vitros 350 Chemistry System
No. of units in clinical use in U.S./Outside U.S. (countries)	650/1,900	—	> 140/> 225 (North, Central, and South Americas, more)
Dimensions (H × W × D)/Instrument footprint	25 × 40 × 28 in./7.7 sq. ft.	18 × 14 × 16 in./1.5 sq. ft.	53 × 58 × 34 in./—
Weight empty/Weight fully loaded	264 lbs./266 lbs.	35 lbs./42 lbs.	1,150 lbs./—
No. of different measured assays onboard simultaneously	55 (55 can be run and calibrated at one time)	20 (20 can be run and calibrated at one time)	89 (89 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	40 (40 can be active simultaneously)	30 (30 can be active simultaneously)	—
Test throughput per hour/Assay run time	420 (4 tests in throughput)/1–10 min. (avg. 5 min.)	up to 38 (760 tests in throughput)/avg. 60 sec.	1,130/2.5–9 min. (avg. 5 min.)
<b>Chemistry:</b>			
No. of direct ion-selective electrode channels	3	7	3
Detection methods	photometry, potentiometry, enzyme immunoassay immunoturbidimetry	photometry, potentiometry, Severinghaus, amperometry, conductivity, enzyme	photometry, potentiometry, turbidimetry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	< 5 min./37 specimens per hr.	1 min./60 specimens per hr.	5 min./126 specimens per hr.
• Basic metabolic panel	7.5 min./35 specimens per hr.	1 min./60 specimens per hr.	6 min./95 specimens per hr.
• Complete metabolic panel	< 11 min./23 specimens per hr.	1 min./60 specimens per hr.	7.5 min./74 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	< 1 min.	3 sec.	1 min.
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	—	—	—
Methodologies supported	—	—	—
Separation methodologies	—	—	—
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	100–400/self-contained multiuse, open reagent system	100, 200, 300, 400, or 500/self-contained multiuse	18–120/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	yes (2°–8°C)/variable; reagent specific	no/yes	yes (10°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
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/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/180 min. or 60 specimens or > 800 tests/assays	yes/1 min. or 1 specimen or 20 tests/assays	yes/—
Design of sample-handling system	rack	probe	universal sample tray, continuous load and unload, circular routine sample center
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 432 cuvettes)	no/yes	no/no
Min.–max. sample volume that can be aspirated at one time	2–60 µL	60–135 µL	2–200 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	180 µL/2 µL/100 µL	135 µL/135 µL/—	—/2.5 µL/35 µL
Dedicated pediatric sample cup	yes (dead volume: 100 µL)	no	yes (dead volume: 35 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes	yes/yes	yes/yes (micro sample cups, micro collection containers, 10.25 × 45 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, more)
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, hemolysis, icterus, lipemia	detection for hemolysis, icterus, lipemia, clots	detection for clots; detection and quantitation for hemolysis, icterus, lipemia
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/—	no/—	yes/0
Automatic rerun capability	yes	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results	yes	no	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	yes	no	yes
Analyzer requires dedicated water supply	no (average of 0.5 L/hr. consumption during operation)	no	no
Autocalibration/Multipoint calibration supported	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 14 days)	yes (calibrants can be stored onboard)/yes	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 6 months or lot change)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	2 hrs. (automatic)/—/—/avg. 14 days/—	—	6 months/6 months/6 months/6 months or lot change for most chemistry assays/—
Automatic programmable start/Automatic programmable shutdown	yes (5 min. start-up time)/no	yes (5 min. avg. start-up time)/yes	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	no	yes	yes
Waste management	direct to drain or container if no drain available	automated collection onboard instrument	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/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	no	yes (optional)	yes
Data-management capability/LIS or EHR systems interfaced	onboard/CGM LabDaq, Orchard, Cerner, Sunquest, Meditech, Schuyler House	onboard, optional add-on (NovaNet, more)/—	onboard/—
LIS interface provided/Bidirectional interface capability	no/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	no/< 24 hrs.	no/within 8 hrs.	yes/4 hrs.
Mean time between failures	avg. 250 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: < 5 min.; weekly: < 15 min.; monthly: < 30 min.	—	daily: ~7 min. (incl. automated); weekly: ~10 min.; monthly: ~10 min.
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/no	yes (includes audit trail of who replaced parts)/yes (includes audit trail of who replaced parts)	yes (includes audit trail of who replaced parts)/yes (includes audit trail of who replaced parts)
Maintenance training demonstration module onboard	no	yes	no
Training included with purchase/Avg. time for basic user training	yes/2.5 days (at vendor or customer site)	yes/30 min. (at customer site)	yes (1 training slot)/4 days (at both vendor and customer sites)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/yes	yes/no	yes (at both vendor and customer sites)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (5 years)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>full menu of moderately complex drugs of abuse and general chemistry assays; can run up to 55 assays onboard with 420 results/hr.</li> <li>no requirement for external water system, no drain or special electrical required; remote diagnostics available for real-time troubleshooting</li> <li>flexible, open-channel system capable of running ≤ 40 third-party reagents onboard</li> </ul>	<ul style="list-style-type: none"> <li>maintenance-free MicroSensor Card and disposable cartridge technology for sensors and reagents</li> <li>broad menu including iMg, BUN, creatinine, CO-oximetry, estimated plasma volume</li> <li>automated, liquid QC and supplemental quality monitoring for EP23A compliance and real-time verification of all analytical components during calibration, sample analysis, QC analysis</li> </ul>	<ul style="list-style-type: none"> <li>incorporates digital reflectometry to process two unique chemistry tests simultaneously on one XT Microslide</li> <li>waterless system with single-use disposable tips for sample and reagent metering eliminates sample and reagent carryover</li> <li>MicroSensor technology detects HIL and turbidity without using reagents or additional sample and time</li> </ul>
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 5 of 6	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	Roche Diagnostics John Kleinschmidt john.kleinschmidt@roche.com Indianapolis, IN 800-428-5074 diagnostics.roche.com/us/en/home.html
FOR POINT-OF-CARE AND LOW-VOLUME LABORATORIES			
Name of instrument	cobas c 311	cobas e 411	cobas pure integrated solutions
Type of instrument	chemistry	immunoassay	combination chemistry/immunoassay
Operational type/Model type	random access, continuous random access/floor standing	random access, continuous random access/benchtop	random access, continuous random access/floor standing
List price/First year sold in U.S.	—/2009	—/2008	—/2022
Targeted hospital bed size/Targeted test volume	< 100/daily; < 200; monthly: < 40,000; annual: < 500,000	< 100/daily; < 200; monthly: < 40,000; annual: < 500,000	< 200/daily: 410–2,054; monthly: 12,500–62,500; annual: 150,000–750,000
Company manufactures instrument	no (manufactured by Hitachi High-Technologies)	no (manufactured by Hitachi High-Technologies)	no (manufactured by Hitachi High-Technologies)
Other models in this family of analyzers	—	—	chem: cobas c 303; immuno: cobas c 402
No. of units in clinical use in U.S./Outside U.S. (countries)	> 300/> 2,500 (> 50 countries)	> 800/> 10,000 (> 50 countries)	< 1,000/> 1,000 (> 50 countries)
Dimensions (H × W × D)/Instrument footprint	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.	5.8 × 8 × 2.6 ft./21 sq. ft.
Weight empty/Weight fully loaded	551 lbs./625 lbs.	disk: 397 lbs./397 lbs.; rack: 551 lbs./551 lbs.	2,205 lbs./2,205 lbs.
No. of different measured assays onboard simultaneously	42 photometric, 3 ISEs (up to 90 can be run and calibrated at one time)	18 (18 can be run and calibrated at one time)	up to 73 (up to 73 can be run and calibrated at one time [chem: 42, immuno: 28, ISE: 3])
No. of user-definable (open chemistry) channels	10 (10 can be active simultaneously)	0	10 (10 can be active simultaneously)
Test throughput per hour/Assay run time	up to 300 (300 tests in throughput)/3–10 min. (avg. 7 min.)	86 (86 tests in throughput)/9–27 min. (avg. 18 min.)	870 (up to 300 photometric, 450 ISE tests in throughput)/chem: 4–10 min. (avg. 10 min.); immuno: 9–27 min. (avg. 18 min.)
<b>Chemistry:</b>			
No. of direct ion-selective electrode channels	3	—	3
Detection methods	photometry, potentiometry	—	photometry, potentiometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	5 min./150 specimens per hr.	—	4.5 min. for ISE, 10 min. with CO <sub>2</sub> /ISE: 150 specimens per hr.
• Basic metabolic panel	8 min./60 specimens per hr.	—	10 min./—
• Complete metabolic panel	11 min./27 specimens per hr.	—	10 min./—
Typical time delay from ordering stat test until aspiration of sample	< 1 min.	—	< 1 min.
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	—	no	no
Methodologies supported	—	electrochemiluminescence	electrochemiluminescence
Separation methodologies	—	magnetic particle	magnetic particle
Stat time until completion of a β-hCG test	—	~10 min.	~10 min.
• Typical time delay from test order to aspiration of sample	—	< 1 min.	< 1 min.
Stat time until completion of a cTn test	—	~10 min.	~10 min.
• Typical time delay from test order to aspiration of sample	—	< 1 min.	< 1 min.
Approximate No. of tests per reagent set/Reagent type	50–800/self-contained multiuse	100–200/self-contained multiuse	up to 3,300 (chem), 300 (immuno)/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (5°–15°C)/yes	no (20° ±3°C)/yes	yes (5°–15°C [chemistry], 6°–10°C [immunoassay])/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/yes
Walkaway capability/Walkaway duration	yes/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	yes/30–45 min.
Design of sample-handling system	ring	disk: ring; rack: rack	5-position rack
Uses washable cuvettes/Uses disposable cuvettes	yes/yes (can store up to 66 cuvettes)	no/yes (can store up to 360 assay tips, 180 assay cups)	yes/yes (can store up to 210 cuvettes)
Min.–max. sample volume that can be aspirated at one time	1–35 µL	10–50 µL	1–60 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	6 µL/51 µL/50 µL	100 µL/10 µL/100 µL	75 µL/1.5 µL (chemistry), 4 µL (immunoassay)/50 µL
Dedicated pediatric sample cup	yes (dead volume: 50 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 (12 × 100 mm)	yes/yes (12 × 100 mm)	yes/yes (11 × 102 mm [chem], 13 × 102 mm [immuno])
Pierces caps on primary tubes	no	no	no
Protects against probe collision	yes	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots; quantitation for hemolysis, icterus, lipemia	detection for clots; hemolysis, icterus, lipemia not available	quantitation for hemolysis, icterus, lipemia; detection for clots
Dilutes patient samples onboard/Susceptibility to carryover	yes (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)	yes (can be programmed to perform dilutions prior to analysis)/< 1 part per million (chemistry), no carryover (immunoassay)
Automatic rerun capability	yes	yes	yes
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	yes	yes	yes
Analyzer requires dedicated water supply	yes (12 L/hr. consumption during operation)	no (3 L consumption for 250 tests)	yes (12 L/hr. consumption during operation for chemistry, 16 L/hr. for immunoassay)
Autocalibration/Multipoint calibration supported	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)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: once per lot [chem], up to 84 days per lot [immuno])
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	24 hrs./per lot/per lot/per lot/—	—/—/—/—/28 days	once per lot/once per lot/once per lot/once per lot/up to 84 days per lot
Automatic programmable start/Automatic programmable shutdown	no (5 min. start-up time)/yes	yes (4 min. avg. start-up time)/yes	yes (6.5 min. avg. start-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	direct to drain	automated collection onboard instrument	direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, PDF417)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	yes	no	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/SCC Soft Computer, Meditech, Cerner, Epic, Sunquest, more	onboard/SCC Soft Computer, Meditech, Cerner, Epic, Sunquest, more	onboard, optional add-on (Bio-Rad MAS)/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/< 24 hrs.	yes/< 24 hrs.	yes/—
Mean time between failures	279 days (displays error codes for troubleshooting)	368 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 5 min.; weekly: 18 min.; monthly: 38 min.	daily: 5 min.; weekly: 6 min.; monthly: 11 min.	daily: < 5 min.; weekly: 30 min.; monthly: 59 min.
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/yes (includes audit trail of who replaced parts)	some records/some records	yes (includes audit trail of who replaced parts)/yes (includes audit trail of who replaced parts)
Maintenance training demonstration module onboard	yes	yes	yes
Training included with purchase/Avg. time for basic user training	yes (1 training slot)/1 week (at both vendor and customer sites)	yes (1 training slot)/1 week (at both vendor and customer sites)	yes (~2 training slots per module)/4–5 days (at both vendor and customer sites)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor 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)/configuration dependent	yes (1 year)/configuration dependent	yes (1 year)/contract dependent
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>drives lab efficiency with standardized instrumentation, reference ranges, consumables, and usage</li> <li>minimizes downtime with industry-leading service; 213-day mean time between repair visits (average)</li> <li>speeds up turnaround time for high-volume stat assays</li> </ul>	<ul style="list-style-type: none"> <li>drives lab efficiency with standardized instrumentation, reference ranges, consumables, and usage</li> <li>minimizes downtime with industry-leading engineering and service; 325-day mean time between repair visits (average)</li> <li>speeds up turnaround time for high-volume stat assays</li> </ul>	<ul style="list-style-type: none"> <li>minimal operator intervention with automated maintenance, automated calibration, and continuous loading of reagents</li> <li>maximizes reagent use; long onboard reagent (up to 6 months) and calibration stabilities</li> <li>increases revenue through expanded testing services</li> </ul>
<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	Thermo Fisher Scientific/BRAHMS info.brahms@thermofisher.com Hennigsdorf, Germany +49(0)33028830 www.thermoscientific.com/kryptor	Tosoh Bioscience Karen Wrona karen.wrona@tosoh.com South San Francisco, CA 800-248-6764 www.diagnostics.us.tosohbioscience.com
FOR POINT-OF-CARE AND LOW-VOLUME LABORATORIES		
Name of instrument Type of instrument	B-R-A-H-M-S KRYPTOR compact PLUS immunoassay	AIA-360 immunoassay
Operational type/Model type	batch, random access, continuous random access/ benchtop	continuous random access/benchtop
List price/First year sold in U.S. Targeted hospital bed size/Targeted test volume Company manufactures instrument Other models in this family of analyzers No. of units in clinical use in U.S./Outside U.S. (countries)	—/2015 —/daily: 450; monthly: 9,000; annual: 125,000 yes (also sold by distribution partners) B-R-A-H-M-S KRYPTOR GOLD —/> 900 (worldwide)	—/2004 —/monthly: < 500 yes AIA-900, AIA-2000 ~600/> 7,000 (worldwide)
Dimensions (H × W × D)/Instrument footprint Weight empty/Weight fully loaded No. of different measured assays onboard simultaneously No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	24 × 29 × 29 in./4.59 sq. ft. 119 lbs./— 8 (8 can be run and calibrated at one time) — up to 60 (up to 60 tests in throughput)/9–59 min.	21 × 16 × 16 in./2.1 sq. ft. 61 lbs./— 25 (25 can be run and calibrated at one time) — 36/10 min.
<b>Chemistry:</b> No. of direct ion-selective electrode channels Detection methods Stat time until completion/specimen throughput for: • Ion-selective electrode • Basic metabolic panel • Complete metabolic panel Typical time delay from ordering stat test until aspiration of sample	— — — — —	— — — — —
<b>Immunoassay:</b> Fully automated microplate immunoassay system Methodologies supported Separation methodologies 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	no fluorescence, enzyme immunoassay none necessary 14 min. 2 min. — —	— fluorescence — 20 min. — 20 min. —
Approximate No. of tests per reagent set/Reagent type Reagents refrigerated onboard/Reagents ready to use Reagent lot tracking/Reagent inventory Reagent form/Reagents barcoded Separate reagent pack for each specimen/for each test run Walkaway capability/Walkaway duration	50–100/self-contained single use yes (2°–8°C)/yes yes/yes liquid chemistry (closed reagent system)/yes no/no yes/max. 220 min. (assay dependent) or up to 64 specimens or up to 96 tests	100 (20 tests per tray)/unit dose test cup no/yes yes/no dry chemistry (closed reagent system)/yes yes/— yes/58 min. or 25 specimens or 25 tests/assays
Design of sample-handling system Uses washable cuvettes/Uses disposable cuvettes Min.–max. sample volume that can be aspirated at one time Min. reaction volume/Min. specimen volume/Min. dead volume	sample cassette placed in sample carousel no/no 8–70 µL 150 µL/sample tube and assay dependent/150 µL (sample tube dependent)	carousel no/no 10–100 µL 10 µL/110 µL/100 µL
Dedicated pediatric sample cup Primary tube sampling Accommodates most standard tube sizes/Accepts nonstandard tube sizes Pierces caps on primary tubes Protects against probe collision Detects clots/liquid level/short sample Detection or quantitation for hemolysis, icterus, lipemia, clots Dilutes patient samples onboard/Susceptibility to carryover	yes (dead volume: 75 µL) yes yes/yes (11–17 × 60–120 mm) no no yes/yes/yes detection for hemolysis, icterus, lipemia, clots yes (can be programmed to perform dilutions prior to analysis)/ ≤ 2 parts per million (no contamination)	no yes yes/— no — yes/yes/yes — no/none
Automatic rerun capability Sample volume can be diluted to rerun out-of-linear-range high results Sample volume can be concentrated to rerun out-of-linear-range low results	yes yes yes	no no no
Analyzer requires dedicated water supply Autocalibration/Multipoint calibration supported Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays Automatic programmable start/Automatic programmable shutdown Onboard real-time QC/Onboard software capability to review QC Supports multiple QC lot numbers per analyte Waste management	no yes (calibrants are not stored onboard)/no —/—/—/—/5–15 days no/no yes/yes yes manually by user, automated collection onboard instrument	no no (calibrants are not stored onboard)/yes —/—/—/—/90 days most assays no (5 min. start-up time)/no no/no — automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination Lab can control analyzer from remote computer Instrument can diagnose its own malfunctions System malfunctions can be diagnosed via remote monitoring UPS backup power supply Data-management capability/LIS or EHR systems interfaced LIS interface provided/Bidirectional interface capability Modem servicing provided/Service engineer on-site response time	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes no yes (operator intervention required to order parts) yes yes onboard/— yes (additional cost)/yes (broadcast download and host query) yes/Mon.–Fri.: 26 hrs. at total breakdown, 72 hrs. at workaround	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes no no — yes Tosoh 501RP+/— no/no —
Mean time between failures Average scheduled maintenance time by lab personnel Maintenance records kept onboard for user/vendor	— (displays error codes for troubleshooting) daily: 3 min.; weekly: 3 min.; monthly: 5 min. yes (includes audit trail of who replaced parts)/yes (includes audit trail of who replaced parts)	888 days (displays error codes for troubleshooting) daily: 5 min. no/no
Maintenance training demonstration module onboard Training included with purchase/Avg. time for basic user training Advanced operator training/Extra charge for follow-up or advanced training Warranty provided/Cost of annual service contract (24 h/7 d)	no yes (1 training slot)/1.5–2 days (at customer site) yes (at vendor site)/yes yes (1 year)/contract dependent	no yes/2 days (at customer site) — yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>fully automated random-access immunoanalyzer with unique Nobel Prize-winning TRACE technology</li> <li>automated timely onboard dilution in less than 5 minutes with integrated self-determining dilution factor</li> <li>no biotin interferences of the assays</li> </ul>	<ul style="list-style-type: none"> <li>unit dose test cup; dry reagent, no premixing or reagent preparation</li> <li>immunoassay method free from biotin interference; compact size, broad menu with fast results</li> <li>90-day calibration stability for most assays</li> </ul>

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

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