

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 Mary Schaefer mschaefer@awaretech.com Palm City, FL 772-283-6540 www.awaretech.com	Beckman Coulter Onyi Nacionales onacionales@beckman.com Brea, CA 800-526-3821 www.beckmancoulter.com
FOR POINT-OF-CARE AND LOW-VOLUME LABORATORIES			
Name of instrument	i-STAT 1 analyzer	ChemWell 2910	Access 2
Type of instrument	combination chemistry/immunoassay	combination chemistry/immunoassay	immunoassay
Operational type/Model type	discrete/handheld	batch, random access, discrete/benchtop	continuous random access/benchtop
List price/First year sold in U.S.	—/2000	\$32,000/1998	—/2001
Targeted hospital bed size/Targeted test volume	all/—	200–500/daily: 200–500; monthly 200–400	—/annual: < 40,000
Company manufactures instrument	yes (also sold by McKesson, Henry Schein, Medline)	yes (also sold by GMI, Monobind, ASI, others)	yes (also sold by McKesson, Henry Schein, Medline)
Other models in this family of analyzers	—	ChemWell Fusion, ChemWell-T, ChemWell 2902	Unicel DxI 600, Unicel DxI 800
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)	—
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.	19.5 × 39 × 24 in./6.5 sq. ft.
Weight empty/Weight fully loaded	< 2 lbs./< 2 lbs.	77 lbs./78 lbs.	200 lbs./—
No. of different measured assays onboard simultaneously	—	15 (12 can be run and calibrated at one time)	24 (24 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.	up to 100/13–55 min.
Chemistry:			
No. of direct ion-selective electrode channels	up to 26	—	—
Detection methods	potentiometry, amperometry, conductometry	photometry	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	2 min./20–25	—	—
• Basic metabolic panel	2 min./20–25	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	none	—	—
Immunoassay:			
Fully automated microplate immunoassay system	yes (up to 26 tests per unit)	yes (27–44 tests per unit; 96 wells per microplate)	no
Methodologies supported	potentiometry, amperometry, conductometry	enzyme immunoassay, colorimetric analysis	chemiluminescence
Separation methodologies	none necessary	none necessary, coated microwell	magnetic particle
Stat time until completion of a β-hCG test	10 min.	—	15 min.
• Typical time delay from test order to aspiration of sample	none	—	36 sec.
Stat time until completion of a cTn test	10 min.	—	17 min.
• Typical time delay from test order to aspiration of sample	none	—	36 sec.
Approximate No. of tests per reagent set/Reagent type	—/self-contained single use	—	50 per pack or 100 per kit/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	no/—	yes (12°–15°C on optional cooling accessory)/yes	yes (2°–8°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)/no	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/yes	no/no
Walkaway capability/Walkaway duration	yes/2–10 min. or 1 specimen or up to 13 tests	yes/—	yes/180 min. or 60 specimens
Design of sample-handling system	—	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/—	no/yes (can store up to 294 cuvettes)
Min.–max. sample volume that can be aspirated at one time	17–95 μL	2–250 μL	5–200 μL
Min. reaction volume/Min. specimen volume/Min. dead volume	—	100 μL/100 μL/100 μL	varies by assay/varies by assay/80 μL
Dedicated pediatric sample cup	no	no	yes (dead volume: 80 μL)
Primary tube sampling	no	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	no/no	yes/yes (13 mm)	yes/no
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	yes	no
Detects clots/liquid level/short sample	yes/yes/yes	no/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for hemolysis, icterus, lipemia, clots	—	detection for clots; hemolysis, icterus, lipemia not available
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	no
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	no
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 are not stored onboard)/yes (recommended avg. frequency: 28 days)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—/—/—/each test/each test	—	—/—/—/28 days
Automatic programmable start/Automatic programmable shutdown	yes/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/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	automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, EAN 8, EAN 13)/—	yes (Code 39)/no	yes (Interleaved 2 of 5, 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	no	no
Data-management capability/LIS or EHR systems interfaced	optional add-on/—	onboard/—	onboard/Cerner, Antrim, CCA, Chemware, Dawning Technologies, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson, more
LIS interface provided/Bidirectional interface capability	yes (additional cost)/no	no/no	yes (included in instrument price)/yes (host query)
Modem servicing provided/Service engineer on-site response time	—/— (product replacement within 24 hrs.)	no/—	yes/< 24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	1.4 down service calls per year (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	—	daily: 8 hrs.	daily: 7 min.; weekly: 12 min.
Maintenance records kept onboard for user/vendor	—	no/no	no/no
Maintenance training demonstration module onboard	—	no	yes
Training included with purchase/Avg. time for basic user training	—/4 hrs. (at customer site)	yes (1 training slot)/4 days (at vendor site)	yes (2 training slots)/2 days (at vendor site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer site)/no	yes (at vendor site)/yes	yes (at vendor site)/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year from date of manufacture)/\$6,000	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> handheld portable analyzer; unit use system can perform chemistry, blood gas, cardiac marker, 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 reagent savings 2-in-1 utility with the ability to run in ELISA mode or biochemistry mode 	<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

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

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FOR POINT-OF-CARE AND LOW-VOLUME LABORATORIES

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Diatron MI
Frank Matuszak frank.matuszak@diatron.com
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Dynex Technologies
Alex Azar aazar@dynex.com
Chantilly, VA
800-288-2354 www.dynex.com

Name of instrument	AU480	Pictus 500 (P500)	DS2 Automated ELISA System
Type of instrument	chemistry	chemistry	immunoassay
Operational type/Model type	continuous random access/floor standing	batch, random access, continuous random access, discrete/benchtop	batch/benchtop
List price/First year sold in U.S.	—/2009	\$42,860/2016	—/2007
Targeted hospital bed size/Targeted test volume	—/annual: 50,000–250,000	20–100/daily; 500–2,500; monthly: 15,000–75,000; annual: 182,500–912,500	—/daily: < 4 microplates (96-well microplates)
Company manufactures instrument	yes (also sold by McKesson, Henry Schein, Medline)	yes	yes
Other models in this family of analyzers	DxC 700 AU, AU 5800	Pictus 700 (P700)	DSX
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)
Dimensions (H × W × D)/Instrument footprint	47.5 × 57 × 30 in./18.5 sq. ft.	24.4 × 35.4 × 26 in./6.4 sq. ft.	26 × 21 × 27 in./3.7 sq. ft.
Weight empty/Weight fully loaded	926 lbs./—	253 lbs./271 lbs.	105 lbs./—
No. of different measured assays onboard simultaneously	63 (63 can be run and calibrated at one time)	72 (999 can be run and calibrated at one time)	up to 12 assays per microplate (up to 12 can be run)
No. of user-definable (open chemistry) channels	18 (76 can be active simultaneously)	—	— (open system; up to 12 can be active simultaneously)
Test throughput per hour/Assay run time	800 (400 photometric, 800 with ISE)/8.5 min.	500/30–1,200 sec. (avg. 300 sec.)	assay dependent (up to 384 tests per run)/assay dependent
Chemistry:			
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.	—
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	200– >1,000 (varies by assay)/self-contained multiuse	50–200 per set, 400–1,800 per pack/self-contained multiuse, open reagent system	—/open reagent system
Reagents refrigerated onboard/Reagents ready to use	yes (4°–12°C)/yes	yes (8°±2°C)/yes	no (23°±4°C)/—
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/no	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/yes
Walkaway capability/Walkaway duration	yes/80 specimens	yes/180 min. or 95 specimens or 1,200 tests/assays	yes/up to 192 specimens or up to 192 tests/assays
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	yes/no	yes/yes (can store up to 80 cuvettes)	no/—
Min.–max. sample volume that can be aspirated at one time	1–25 µL	2–100 µL	10–300 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	90 µL/41 µL or 1 uL with 4 mm above gel barrier/50 µL	180 µL/22 µL/100 µL	10 µL/—/—
Dedicated pediatric sample cup	yes (dead volume: 50 µL)	yes (dead volume: 20 µL)	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (primary, secondary tubes: 11.5–16 × 55–102 mm; nested micro cups)	yes/no	yes/yes (17 × 100 mm)
Pierces caps on primary tubes	no	yes	no
Protects against probe collision	yes	yes	no
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection and quantitation for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available	detection for clots; hemolysis, icterus, lipemia not available
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform sample dilutions prior to analysis)/0.001 parts per million	yes (can be programmed to perform dilutions prior to analysis)/30 parts per million	yes (can be programmed to perform dilutions prior to analysis)/0 parts per million
Automatic rerun capability	yes	yes	no
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	yes	yes	no
Analyzer requires dedicated water supply	yes (20 L/hr. consumption during operation)	no (2 L/hr. consumption during operation)	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 7 days)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	1 day/14 days/14–20 days/30 days/—	8 hrs./—/7 days/14 days/14 days	—/assay dependent/assay dependent/—/assay dependent
Automatic programmable start/Automatic programmable shutdown	no/no	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
Waste management	direct to drain	manually by user, direct to drain	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)/no	yes (UPC, Codabar, Code 39, Code 128, Code 93)/yes
Lab can control analyzer from remote computer	yes	yes	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/Cerner, Antrim, CCA, Chemware, Dawning Technologies, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson, more	onboard/AP Vision, Medicus, Schuyler, LabTrack, CGM LabDaq, Medytox	onboard/Orchard, Cerner
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/yes (host query)
Modem servicing provided/Service engineer on-site response time	yes/< 24 hrs.	no/48 hrs.	no/24 hrs.
Mean time between failures	1.2 down service calls per year (displays error codes for troubleshooting)	1 per year (displays error codes for troubleshooting)	250 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 6 min.; weekly: 10 min.; monthly: 45 min.	daily: 30 min.; weekly: 1 hr.; monthly: 2 hrs.	daily: 10 min.; weekly: 5 min.
Maintenance records kept onboard for user/vendor	yes/no	no/no	no/no
Maintenance training demonstration module onboard	yes	no	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/3 days (at customer and vendor sites)	yes (2 training slots)/3 days (at customer site)	no/3 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/—	yes (at vendor or customer site)/yes	yes (at customer site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/ \$5,500	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • standardization across the AU family of chemistry analyzers • lower total cost of ownership due to fewer consumables and concentrated reagents • commonly replaced parts can be changed in 3 steps or less, in 60 seconds or less, without tools 	<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

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FOR POINT-OF-CARE AND LOW-VOLUME LABORATORIES

HYCOR Biomedical
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Nova Biomedical
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Waltham, MA
800-458-5813 www.novabiomedical.com

Ortho Clinical Diagnostics
Laura Osborne laura.osborne@orthoclinicaldiagnostics.com
Raritan, NJ
800-828-6316 www.orthoclinicaldiagnostics.com

Name of instrument	HYTEC 288 PLUS	Stat Profile Prime Plus	VITROS XT 3400 Chemistry Systems
Type of instrument	immunoassay	chemistry	chemistry
Operational type/Model type	batch/benchtop	random access/benchtop	batch, random access, continuous random access, discrete/floor standing
List price/First year sold in U.S.	\$55,000/1999	—/2018	—/2019
Targeted hospital bed size/Targeted test volume	200/variable	—	—/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	—	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)	> 100/> 200 (Canada, Europe, Middle East, South America)	—	> 140/> 140 (North, Central, and South Americas, more)
Dimensions (H × W × D)/Instrument footprint	29.5 × 42.5 × 27.5 in./8 sq. ft.	18 × 14 × 16 in./1.5 sq. ft.	53 × 58 × 34 in./—
Weight empty/Weight fully loaded	198 lbs./198 lbs.	35 lbs./42 lbs.	1,150 lbs./—
No. of different measured assays onboard simultaneously	up to 288 (up to 288 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	3	30 (30 can be active simultaneously)	—
Test throughput per hour/Assay run time	48 (288 tests in throughput)/6 hrs.	up to 38 (760 tests in throughput)/avg. 60 sec.	1,130/2.5–9 min. (avg. 5 min.)
Chemistry:			
No. of direct ion-selective electrode channels	—	7	3
Detection methods	—	photometry, potentiometry, Severinghaus, amperometry, conductivity, enzyme	photometry, potentiometry, turbidimetry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	1 min./60 specimens per hr.	5 min./126 specimens per hr.
• Basic metabolic panel	—	1 min./60 specimens per hr.	6 min./95 specimens per hr.
• Complete metabolic panel	—	1 min./60 specimens per hr.	7.5 min./74 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	—	3 sec.	1 min.
Immunoassay:			
Fully automated microplate immunoassay system	no	—	—
Methodologies supported	enzyme immunoassay	—	—
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	20 or 10/self-contained multiuse	100, 200, 300, 400, or 500/self-contained multiuse	18–120/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	no/yes	no/yes	yes (10°C)/yes
Reagent lot tracking/Reagent inventory	yes/no	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/no	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	no/no
Walkaway capability/Walkaway duration	yes/288 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 288 cuvettes)	no/yes	no/no
Min.–max. sample volume that can be aspirated at one time	50 µL maximum	135 µL	2–200 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	10 µL/50 µL/100 µL	135 µL/135 µL/—	—/2.5 µL/35 µL
Dedicated pediatric sample cup	no	no	yes (dead volume: 35 µL)
Primary tube sampling	no	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/no	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	no	yes	yes
Detects clots/liquid level/short sample	no/no/yes	yes/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	hemolysis, icterus, lipemia, clots not available	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)/< 1 part per 10,000	no/—	yes/0
Automatic rerun capability	no	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results	no	no	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	no	no	yes
Analyzer requires dedicated water supply	no	no	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: monthly)	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	—/—/—/—/monthly	—	6 months/6 months/6 months/6 months or lot change for most chemistry assays/—
Automatic programmable start/Automatic programmable shutdown	no/yes	yes (5 min. avg. start-up time)/yes	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/no	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	manually by user	automated collection onboard instrument	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Codabar, Code 39)/—	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	yes	yes	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	no	yes	yes
UPS backup power supply	yes	no	yes
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard, optional add-on (NovaNet, more)/—	onboard/—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (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/within 48 hrs.	no/within 8 hrs.	yes/4 hrs.
Mean time between failures	210 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 10–15 min.; weekly: 20–25 min.; monthly: 20–25 min.	weekly: 5 min.; monthly: 30 min.	daily: ~7 min. (incl. automated); weekly: ~10 min.; monthly: ~10 min.
Maintenance records kept onboard for user/vendor	yes/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 training slots)/2 days (at 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	no/—	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"> • menu • ease of use • quality of results 	<ul style="list-style-type: none"> • maintenance-free MicroSensor Card and disposable cartridge technology for sensors and reagents • broad menu including iMg, BUN, creatinine, CO-oximetry, estimated plasma volume • automated, liquid QC and supplemental quality monitoring for EP23A compliance and real-time verification of all analytical components during calibration, sample analysis, QC analysis 	<ul style="list-style-type: none"> • incorporates digital reflectometry to process two unique chemistry tests simultaneously on one XT Microslide • waterless system with single-use disposable tips for sample and reagent metering eliminates sample and reagent carryover • MicroSensor technology detects HIL and turbidity without using reagents or additional sample and time

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Part 5 of 6	Roche Diagnostics Mark Sprunger mark.sprunger@roche.com Indianapolis, IN 800-428-5074 diagnostics.roche.com/us/en/home.html	Roche Diagnostics Mark Sprunger mark.sprunger@roche.com Indianapolis, IN 800-428-5074 diagnostics.roche.com/us/en/home.html	Thermo Fisher Scientific/BRAHMS info.brahms@thermofisher.com Hennigsdorf, Germany +49(0)33028830 www.thermoscientific.com/kryptor
FOR POINT-OF-CARE AND LOW-VOLUME LABORATORIES			
Name of instrument	cobas c 311	cobas e 411	B-R-A-H-M-S KRYPTOR compact PLUS
Type of instrument	chemistry	immunoassay	immunoassay
Operational type/Model type	random access, continuous random access/floor standing	random access, continuous random access/benchtop	batch, random access, continuous random access/benchtop
List price/First year sold in U.S.	—/2009	—/2008	—/2015
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	—/daily: 450; monthly: 9,000; annual: 125,000
Company manufactures instrument	no (manufactured by Hitachi High-Technologies)	no (manufactured by Hitachi High-Technologies)	yes (also sold by distribution partners)
Other models in this family of analyzers	—	—	B-R-A-H-M-S KRYPTOR GOLD
No. of units in clinical use in U.S./Outside U.S. (countries)	> 300/> 2,500 (> 50 countries)	> 800/> 10,000 (> 50 countries)	—/> 900 (worldwide)
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.	24 × 29 × 29 in./4.59 sq. ft.
Weight empty/Weight fully loaded	551 lbs./625 lbs.	disk: 397 lbs./397 lbs.; rack: 551 lbs./551 lbs.	119 lbs./—
No. of different measured assays onboard simultaneously	42 photometrics, 3 ISEs (up to 90 can be run and calibrated at one time)	18 (18 can be run and calibrated at one time)	8 (8 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	up to 300 (300 tests in throughput)/3–10 min. (avg. 7 min.)	86 (86 tests in throughput)/9–27 min. (avg. 18 min.)	up to 60 (up to 60 tests in throughput)/9–59 min.
Chemistry:			
No. of direct ion-selective electrode channels	3	—	—
Detection methods	photometry, potentiometry	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	5 min./150 specimens per hr.	—	—
• Basic metabolic panel	8 min./60 specimens per hr.	—	—
• Complete metabolic panel	11 min./27 specimens per hr.	—	—
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
Separation methodologies	—	magnetic particle	none necessary
Stat time until completion of a β-hCG test	—	~10 min.	14 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.	—
• Typical time delay from test order to aspiration of sample	—	< 1 min.	—
Approximate No. of tests per reagent set/Reagent type	50–800/self-contained multiuse	100–200/self-contained multiuse	50–100/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	yes (5°–15°C)/yes	no (20° ±3°C)/yes	yes (2°–8°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	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/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/max. 220 min. (assay dependent) or up to 64 specimens or up to 96 tests
Design of sample-handling system	ring	disk: ring; rack: rack	sample cassette placed in sample carousel
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)	no/no
Min.–max. sample volume that can be aspirated at one time	1–35 µL	10–50 µL	8–70 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	6 µL/51 µL/50 µL	100 µL/10 µL/100 µL	150 µL/sample tube and assay dependent/150 µL (sample tube dependent)
Dedicated pediatric sample cup	yes (dead volume: 50 µL)	yes (dead volume: 50 µL)	yes (dead volume: 75 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 (11–17 × 60–120 mm)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	yes	yes	no
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots; quantitation for hemolysis, icterus, lipemia	detection for clots; hemolysis, icterus, lipemia not available	detection for hemolysis, icterus, lipemia, 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)/≤ 2 parts per million (no contamination)
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)	no
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)/no
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	24 hrs./per lot/per lot/per lot/—	—/—/—/—/28 days	—/—/—/—/5–15 days
Automatic programmable start/Automatic programmable shutdown	no (5 min. start-up time)/yes	yes (4 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	yes	yes	yes
Waste management	direct to drain	automated collection onboard instrument	manually by user, 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, Codabar, Code 39, Code 128, PDF417)/yes	yes (Interleaved 2 of 5, UPC, 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/SCC Soft Computer, Meditech, Cerner, Epic, Sunquest, more	onboard/SCC Soft Computer, Meditech, Cerner, Epic, Sunquest, more	onboard/—
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 (additional cost)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/< 24 hrs.	yes/< 24 hrs.	yes/Mon.–Fri.: 26 hrs. at total breakdown, 72 hrs. at workaround
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: 3 min.; weekly: 3 min.; monthly: 5 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	no
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 (1 training slot)/1.5–2 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	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"> 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 	<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
<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 AND LOW-VOLUME LABORATORIES

Tosoh Bioscience
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South San Francisco, CA
800-248-6764 www.diagnostics.us.tosohbioscience.com

Name of instrument	AIA-360
Type of instrument	immunoassay
Operational type/Model type	continuous random access/benchtop
List price/First year sold in U.S.	—/2004
Targeted hospital bed size/Targeted test volume	—/monthly: < 500
Company manufactures instrument	yes
Other models in this family of analyzers	AIA-900, AIA-2000
No. of units in clinical use in U.S./Outside U.S. (countries)	~600/> 7,000 (worldwide)
Dimensions (H x W x D)/Instrument footprint	21 x 16 x 16 in./2.1 sq. ft.
Weight empty/Weight fully loaded	61 lbs./—
No. of different measured assays onboard simultaneously	25 (25 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—
Test throughput per hour/Assay run time	36/10 min.
Chemistry:	
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	—
Immunoassay:	
Fully automated microplate immunoassay system	—
Methodologies supported	fluorescence
Separation methodologies	—
Stat time until completion of a β-hCG test	20 min.
• Typical time delay from test order to aspiration of sample	—
Stat time until completion of a cTn test	20 min.
• Typical time delay from test order to aspiration of sample	—
Approximate No. of tests per reagent set/Reagent type	100 (20 tests per tray)/unit dose test cup
Reagents refrigerated onboard/Reagents ready to use	no/yes
Reagent lot tracking/Reagent inventory	yes/no
Reagent form/Reagents barcoded	dry chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	yes/—
Walkaway capability/Walkaway duration	yes/58 min. or 25 specimens or 25 tests/assays
Design of sample-handling system	carousel
Uses washable cuvettes/Uses disposable cuvettes	no/no
Min.–max. sample volume that can be aspirated at one time	10–100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	10 µL/110 µL/100 µL
Dedicated pediatric sample cup	no
Primary tube sampling	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/—
Pierces caps on primary tubes	no
Protects against probe collision	—
Detects clots/liquid level/short sample	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	—
Dilutes patient samples onboard/Susceptibility to carryover	no/none
Automatic rerun capability	no
Sample volume can be diluted to rerun out-of-linear-range high results	no
Sample volume can be concentrated to rerun out-of-linear-range low results	no
Analyzer requires dedicated water supply	no
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—/—/—/—/90 days most assays
Automatic programmable start/Automatic programmable shutdown	no (5 min. start-up time)/no
Onboard real-time QC/Onboard software capability to review QC	no/no
Supports multiple QC lot numbers per analyte	—
Waste management	automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no
Instrument can diagnose its own malfunctions	no
System malfunctions can be diagnosed via remote monitoring	—
UPS backup power supply	yes
Data-management capability/LIS or EHR systems interfaced	Tosoh 501RP+/—
LIS interface provided/Bidirectional interface capability	no/no
Modem servicing provided/Service engineer on-site response time	—
Mean time between failures	888 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 5 min.
Maintenance records kept onboard for user/vendor	no/no
Maintenance training demonstration module onboard	no
Training included with purchase/Avg. time for basic user training	yes/2 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	—
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"> • 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

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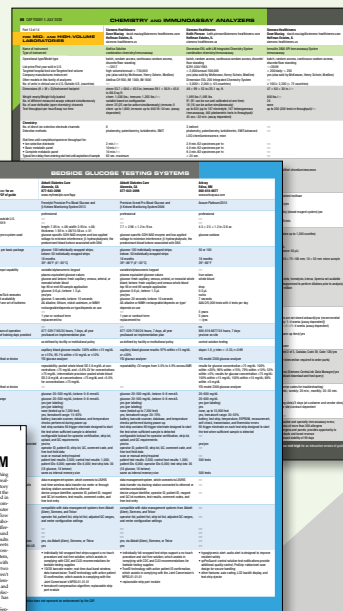
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