

Part 1 of 16	Abbott US Marketing Core Diagnostics ats@abbott.com Abbott Park, IL 800-323-9100 corelaboratory.abbott	Aesku us.sales@aesku.com Des Plaines, IL 844-544-5044 www.aesku.com	Alfa Wassermann Diagnostic Technologies info@alfawassermannus.com West Caldwell, NJ 800-220-4488 www.alfawassermannus.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	Alinity ci-series	HELIOS HTC	ACE Excel
Type of instrument	combination chemistry/immunoassay	immunoassay	chemistry
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	batch/benchtop	batch, random access, continuous random access, discrete/benchtop
List price/First year sold in U.S.	—/2018	\$175,000/2017	\$34,500/2012
Targeted hospital bed size/Targeted test volume	all/—	200–1,000/daily; > 25; monthly: > 500; annual: > 5,000	—/daily: ~15–50 comprehensive metabolic panels and lipids
Company manufactures instrument	yes	yes	yes (also sold by McKesson, Henry Schein, Medline, AvMedical)
Other models in this family of analyzers	—	HELIOS, HELMED	ACE Alera
No. of units in clinical use in U.S./Outside U.S. (countries)	~1,700/~11,300 (154 countries)	—/> 350 (> 35 countries)	—
Dimensions (H × W × D)/Instrument footprint	4.4 × 3.9 × 3.84 for standalone module; up to 4.4 × 11.81 × 3.84 for 4-module system/14.98–45.31 sq. ft. for 1- to 4-module system	22.5 × 25.6 × 29.6 in./5.25 sq. ft.	33 × 28 × 26 in./10 sq. ft.
Weight empty/Weight fully loaded	chem: 1,556 lbs.; immuno: 1,371 lbs./—	73 lbs./—	150 lbs./150 lbs.
No. of different measured assays onboard simultaneously	chem: up to 280 (up to 280 can be run and calibrated at one time); immuno: up to 188 (up to 188 can be run and calibrated at one time)	4 (4 can be run and calibrated at one time)	40 (200 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	10 (10 can be active simultaneously)	—	15 (15 can be active simultaneously)
Test throughput per hour/Assay run time	up to 5,400 for Alinity c 4-module system; up to 800 for Alinity i 4-module system/depends on configuration	—	165/—
<b>Chemistry:</b>			
No. of direct ion-selective electrode channels	3	—	3
Detection methods	photometry, potentiometry	—	photometry, potentiometry, turbidimetric homogeneous enzyme immunoassay
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	4 min./35 specimens per hr.
• Basic metabolic panel	—	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	< 30 sec.	—	10 sec.
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	no	—	—
Methodologies supported	chemiluminescence	fluorescence, indirect fluorescent antibody	—
Separation methodologies	magnetic particle	coated IFA slide	—
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	up to 1,500 (chem), up to 600 (immuno)/self-contained multiuse	120/—	30–900/closed reagent system with open reagent channels
Reagents refrigerated onboard/Reagents ready to use	yes (2°–10°C [chemistry], 2°–12°C [immunoassay])/yes	no/yes	yes (10°–14°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/no	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/no	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/240 min. or up to 600 specimens (150 specimens per module)	yes/190 specimens or 240 tests	yes/75 min. or 75 specimens or 248 tests
Design of sample-handling system	6-position rack	rack	ring
Uses washable cuvettes/Uses disposable cuvettes	chem: yes/immuno: yes (can store up to 1,000 cuvettes)	no/no	no/yes (can store up to 248 cuvettes)
Min.–max. sample volume that can be aspirated at one time	1.5–35 µL (chemistry), 2–200 µL (immunoassay)	—	3–200 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	80 µL/assay dependent/50 µL	—/assay dependent/tube dependent	150 µL/53 µL/50 µL
Dedicated pediatric sample cup	no	no	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (10–16.1 × 72–102 mm)	yes/yes (11–16 × 55–100 mm)	—
Pierces caps on primary tubes	no	no	yes
Protects against probe collision	yes	yes	no
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; quantitation for hemolysis, icterus, lipemia	hemolysis, icterus, lipemia, clots not available	hemolysis, icterus, lipemia, clots not available
Dilutes patient samples onboard/Susceptibility to carryover	yes/≤ 0.1 parts per million	yes/no carryover	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
Analyzer requires dedicated water supply	yes (27 L/hr. consumption during operation for chemistry, <10 L/hr. for immunoassay)	no	no
Autocalibration/Multipoint calibration supported	yes (calibrants are stored onboard)/yes	no (calibrants are not stored onboard)/—	yes (calibrants are not stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	1 day/new lot or 7–45 days/new lot or 13 days/new lot or 30 days/new lot or 30 days	—	3 hrs./—/—/30 days/—
Automatic programmable start/Automatic programmable shutdown	—/no	no/no	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	no/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	—	yes
Waste management	automated collection onboard instrument or 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, Code 39, Code 128, Matrix 2/5, Code 11, EAN/JAN, more)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 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)
System malfunctions can be diagnosed via remote monitoring	yes	yes	no
UPS backup power supply	yes	yes	no
Data-management capability/LIS or EHR systems interfaced	onboard/—	optional add-on (AESKU.LAB)/Sunquest, Orchard	onboard/CGM LabDaq, Orchard, CGM SchuyLab, LabTrak, more
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download and host query)	no/yes (host query)	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	—/based on contract	no/—	yes/24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	240 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 0 (chem and immuno); weekly: 30 min. (chem), 16 min. (immuno); monthly: 2 min. (chem), 0 (immuno)	daily: 5 min.; weekly: 20 min.	daily: 15 min.; weekly: 20–30 min.; monthly: 30–40 min.
Maintenance records kept onboard for user/vendor	some records (includes audit trail of who replaced parts)/no	no/no	yes (includes audit trail of who replaced parts)/no
Maintenance training demonstration module onboard	yes	no	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/12 hrs. (at customer site)	yes (1 training slot)/—	yes (1 training slot)/4.5 days (at customer and vendor sites [depends on sales agreement])
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer or vendor site)/yes	yes/—	no/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (varies by contract)/varies by contract	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>compact, flexible, and scalable up to four modules and 14 configurations</li> <li>harmonized family of systems across key lab disciplines leading to easier cross-training for lab staff</li> <li>broad menu of high-quality assays aligned to CLSI guidelines</li> </ul>	<ul style="list-style-type: none"> <li>provides all-in-one IFA ANA, ANCA, and nDNA slide processing and reading on one instrument</li> <li>FDA cleared to identify seven HEp-2 patterns plus negative results</li> <li>utilizes pattern-recognition software and can estimate the endpoint titer</li> </ul>	<ul style="list-style-type: none"> <li>self-contained analyzer; closed-tube sampling; stat interrupt capability; onboard sample, reagent refrigeration; ready-to-use reagents; onboard reagent inventory management</li> <li>integrated ISE module; no external water source or waste drainage</li> <li>Internet connectivity allows for external technical support, remote access, and laboratory integration</li> </ul>
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 2 of 16	<b>Arlington Scientific</b> <b>Mike Ladow</b> mladow@arlingtonscientific.com <b>Springville, UT</b> <b>801-489-8911</b> www.arlingtonscientific.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>Beckman Coulter</b> <b>Onyi Nacionales</b> onacionales@beckman.com <b>Brea, CA</b> <b>800-526-3821</b> www.beckmancoulter.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	ASI Evolution RPR Syphilis Analyzer	AU 5800	DxC 700 AU
Type of instrument	immunoassay	chemistry	chemistry
Operational type/Model type	batch/benchtop	continuous random access/floor standing	continuous random access/floor standing
List price/First year sold in U.S.	\$50,995/2018	—/2011	—/2016
Targeted hospital bed size/Targeted test volume	—/daily: 100; monthly: 3,100; annual: 37,200	—/annual: ≥ 1.5 million	—/annual: 500,000–1.5 million
Company manufactures instrument	yes (also sold by Fisher Scientific, Cardinal, McKesson, VWR)	yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific)	yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific)
Other models in this family of analyzers	—	DxC 700 AU, AU480	AU480, AU 5800
No. of units in clinical use in U.S./Outside U.S. (countries)	—	—	—
Dimensions (H × W × D)/Instrument footprint	19 × 36 × 22 in./6 sq. ft.	50 × 168 × 62 in./72 sq. ft.	51 × 78 × 41 in./40.1 sq. ft.
Weight empty/Weight fully loaded	78 lbs./—	2,300–6,375 lbs. (model dependent)/—	1,046 lbs./—
No. of different measured assays onboard simultaneously	1 (0 can be run and calibrated at one time)	54–216 (54–216 can be run and calibrated at one time) (model dependent)	63 (63 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	18 (76 can be active simultaneously)	18 (120 can be active simultaneously)
Test throughput per hour/Assay run time	190 (1 test in throughput)/—	2,000–9,800/8 min. 30 sec.	1,200 (800 photometric, 400 ISE tests in throughput)/8 min. 30 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./model dependent	4.5 min./400 specimens per hr.
• Basic metabolic panel	—	12.5 min./model dependent	12.5 min./133 specimens per hr.
• Complete metabolic panel	—	14.5 min./model dependent	14.5 min./72 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	—	1 min.	1 min.
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	yes (48 wells per microplate)	—	—
Methodologies supported	agglutination	—	—
Separation methodologies	none necessary	—	—
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	varies/self-contained multiuse	200–6,000 (varies by assay)/self-contained multiuse	200–2,000 (varies by assay)/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	no/yes	yes (4°–12°C)/yes	yes (4°–12°C)/yes
Reagent lot tracking/Reagent inventory	yes/no	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)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/62 min. or 192 specimens or 192 tests	yes/400 specimens	yes/2 hrs. avg. or 150 specimens or 7,200 tests
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/—	yes/no	yes/no
Min.–max. sample volume that can be aspirated at one time	2–500 µL	1–25 µL	1–25 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	110 µL/300 µL/150 µL	120 µL/41 µL or 1 µL with 4 mm above gel barrier/50 µL	120 µL/41 µL or 1 µL with 4 mm above gel barrier/40 µL or 4 mm above gel barrier
Dedicated pediatric sample cup	no	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/no	yes/yes (primary, secondary tubes: 11.5–16 × 55–102 mm; nested micro cups)	yes/yes (primary, secondary tubes: 11.5–16 × 55–102 mm; nested micro cups)
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 not available	detection and quantitation for hemolysis, icterus, lipemia, clots	detection and quantitation for hemolysis, icterus, lipemia, clots
Dilutes patient samples onboard/Susceptibility to carryover	no/—	yes (can be programmed to perform dilutions prior to analysis)/0.001 parts per million	yes (can be programmed to perform dilutions prior to analysis)/0.001 parts per million
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 (0.03 L/hr. consumption during operation)	yes (62–248 L/hr. consumption during operation) (model dependent)	yes (28 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/no	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)	yes (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/—	1 day/14 days/14–20 days/30 days/—
Automatic programmable start/Automatic programmable shutdown	no/no	yes (90 sec. warm-up time)/yes	yes (90 sec. warm-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	no/no	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	no	yes	yes
Waste management	manually by user	direct to drain	direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (UPC, Code 39, Code 128)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no	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/—	onboard/Cerner, Antrim, CCA, Chemware, Dawning Technologies, SCC, Dynamic Healthcare, Antek, more	onboard/Cerner, Antrim, CCA, Chemware, Dawning Technologies, SCC, Dynamic Healthcare, Antek, more
LIS interface provided/Bidirectional interface capability	no/no	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/48 hrs.	yes/within 24 hrs.	yes/within 24 hrs.
Mean time between failures	365 days (displays error codes for troubleshooting)	1.2 down service calls per year (displays error codes for troubleshooting)	1.1 down service calls per year (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 10 min.; weekly: 10 min.; monthly: 10 min.	daily: 8 min.; weekly: 15 min.; monthly: 45 min.	daily: 6 min.; weekly: 10 min.; monthly: 45 min.
Maintenance records kept onboard for user/vendor	no/no	yes/no	yes/no
Maintenance training demonstration module onboard	no	yes	yes
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/0.5 days (at customer site)	yes (2 training slots)/3 days (combination of vendor and customer sites; includes vendor training and in-lab operator training)	yes (2 training slots)/3 days (combination of vendor and customer sites; includes vendor training and in-lab operator training)
Advanced operator training/Extra charge for follow-up or advanced training	no/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 limited, service contract required)/varies by tier of service	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>• 190 RPR syphilis tests per hour</li> <li>• low-cost, automated syphilis test</li> <li>• can provide titers up to 1:2048</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>• most common parts can be changed in three steps in less than 60 seconds and without tools</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>• most common parts can be changed in three steps in less than 60 seconds and without tools</li> </ul>
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Part 3 of 16	Beckman Coulter Onyi Nacionales onacionales@beckman.com Brea, CA 800-526-3821 www.beckmancoulter.com	Beckman Coulter Onyi Nacionales onacionales@beckman.com Brea, CA 800-526-3821 www.beckmancoulter.com	Binding Site Haley Braffett haley.braffett@bindingsite.com San Diego, CA 858-291-4556 www.us.bindingsite.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	Dxl 9000 Access Immunoassay Analyzer	Unicel Dxl 600	Optilite
Type of instrument	immunoassay	immunoassay	chemistry
Operational type/Model type	continuous random access/floor standing	continuous random access/floor standing	continuous random access/benchtop
List price/First year sold in U.S.	—/2023	—/2006	\$111,521/2015
Targeted hospital bed size/Targeted test volume	—	—	> 100/daily; > 50; monthly: ~1,000; annual: ~12,000
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)	no (manufactured by Thermo Fisher)
Other models in this family of analyzers	Access 2, Unicel Dxl 600, Unicel Dxl 800	Access 2, Unicel Dxl 800	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—	—	282/596 (Spain, Germany, France, UK, Italy, Denmark, more)
Dimensions (H × W × D)/Instrument footprint	63 × 79 × 41 in./22.5 sq. ft.	67 × 61.5 × 37.5 in./16 sq. ft.	24.4 × 37 × 27.6 in./7.09 sq. ft.
Weight empty/Weight fully loaded	1,785 lbs./—	1,065 lbs./—	242 lbs./~260 lbs.
No. of different measured assays onboard simultaneously	50 (50 can be run and calibrated at one time)	50 (50 can be run and calibrated at one time)	34 (34 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	0	10
Test throughput per hour/Assay run time	up to 450/8–50 min.	up to 200/13–55 min.	108 (108 tests in throughput)/8–23 min. (avg. 13 min.)
<b>Chemistry:</b>			
No. of direct ion-selective electrode channels	—	—	—
Detection methods	—	—	photometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	—
• Basic metabolic panel	—	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	—	—	—
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	no	no	—
Methodologies supported	chemiluminescence	chemiluminescence	—
Separation methodologies	magnetic particle	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	16 sec.	18 sec.	—
Stat time until completion of a cTn test	12 min.	17 min.	—
• Typical time delay from test order to aspiration of sample	16 sec.	18 sec.	—
Approximate No. of tests per reagent set/Reagent type	50, 100, or 200 per kit/self-contained multiuse	50 per pack or 100 per kit/self-contained multiuse	100/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (4°–10°C)/yes	yes (4°–10°C)/yes	yes (8°–10°C below ambient)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed 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/yes	no/no	no/no
Walkaway capability/Walkaway duration	yes/240 min. or 140 specimens	yes/180 min. or 60 specimens	yes/90 min. or 54 specimens or 180 tests
Design of sample-handling system	rack or direct track sampling when connected to automation	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/yes	no/yes (can store > 1,000 cuvettes)	no/yes (can store up to 360 cuvettes)
Min.–max. sample volume that can be aspirated at one time	2–200 µL	5–200 µL	2–200 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	10 µL/150 µL/80 µL	10 µL/150 µL/140 µL	120 µL/assay dependent/150 µL
Dedicated pediatric sample cup	yes (dead volume: 150 µL)	yes (dead volume: 100 µL)	yes (dead volume: 150 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/no	yes/—	yes/yes (13 × 75 mm, 12 × 75 mm)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	no	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	hemolysis, icterus, lipemia, clots not available	detection for clots; hemolysis, icterus, lipemia not available	detection for hemolysis, clots; 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 dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/—
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	no	no	yes
Analyzer requires dedicated water supply	no	no	no (2 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: per lab protocol and every new lot)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—/—/—/—/28 days	—/—/—/—/28 days	—
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	no/no
Onboard real-time QC/Onboard software capability to review QC	no/yes	no/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	no
Waste management	direct to drain	direct to drain	automated collection onboard instrument
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)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no
Lab can control analyzer from remote computer	yes	yes	no
Instrument can diagnose its own malfunctions	yes (instrument can order parts without operator intervention)	yes (operator intervention required to order parts)	no (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	no
UPS backup power supply	no	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/Cerner, Antrim, CCA, Chemware, Dawning Technologies, SCC, Dynamic Healthcare, Antek, more	onboard/Epic, Sunquest, Orchard, Cerner, SCC Soft Computer
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/within 24 hrs.	yes/within 24 hrs.	no/next business day
Mean time between failures	— (displays error codes for troubleshooting)	3.1 down service calls per year (displays error codes for troubleshooting)	240 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	weekly: < 15 min.; monthly: 7 min.	daily: < 10 min.; weekly: 15 min. at 5,000 tests; monthly: 35 min. at 10,000 tests	daily: 10 min.; weekly: 15 min.; monthly: 30 min.
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/no	yes/no	some records (log)/no
Maintenance training demonstration module onboard	yes	yes	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/3 days (at vendor site)	yes (2 training slots)/3 days (at vendor site)	yes (2 training slots)/2 days (primarily at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	no/yes	yes (at vendor site)/yes	yes (at customer site)/\$2,500
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/\$12,950
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>• ZeroDaily Maintenance eliminates daily maintenance; less than 15 minutes of cleaning per week</li> <li>• PrecisionVision Technology uses multiple cameras with defined algorithms to detect processing errors in real time</li> <li>• SimpleSolve provides instrument-guided troubleshooting 24/7 with step-by-step instructions</li> </ul>	<ul style="list-style-type: none"> <li>• onboard aliquoting quickly frees samples for other analyses</li> <li>• scalable results across all immunoassay systems</li> <li>• liquid, ready-to-use reagents</li> </ul>	<ul style="list-style-type: none"> <li>• reduced carryover due to disposable cuvettes</li> <li>• dilution cascade to final result</li> <li>• intuitive software that includes three different antigen excess protection methods, optimized by assay</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 16	<b>Bio-Rad Laboratories Clinical Diagnostics Group</b> <b>Maria Crisostomo</b> maria_crisostomo@bio-rad.com <b>Hercules, CA</b> <b>800-224-6723</b> www.bio-rad.com	<b>Bio-Rad Laboratories Clinical Diagnostics Group</b> <b>Mbithe Nguku</b> mbithe_nguku@bio-rad.com <b>Hercules, CA</b> <b>800-224-6723</b> www.bio-rad.com	<b>Bio-Rad Laboratories Clinical Diagnostics Group</b> <b>Maria Crisostomo</b> maria_crisostomo@bio-rad.com <b>Hercules, CA</b> <b>800-224-6723</b> www.bio-rad.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	BioPlex 2200 System	EVOLIS	PhD Ix
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	continuous random access/floor standing	batch, random access/benchtop	batch/benchtop
List price/First year sold in U.S.	—/2006	—/2001	—/2012
Targeted hospital bed size/Targeted test volume	—/daily: ~800 samples	> 50/up to 360 samples per shift	—/daily: 50–200 samples
Company manufactures instrument	yes	no (manufactured by Stratec)	yes
Other models in this family of analyzers	—	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—/— (Australia, Canada, China, Europe, Hong Kong, Israel, Japan, Korea, New Zealand, Russia, Saudi Arabia)	—	—
Dimensions (H × W × D)/Instrument footprint	53 × 72 × 34 in./12.9 sq. ft.	37 × 44 × 30 in./10 sq. ft.	30 × 36 × 27 in./7 sq. ft.
Weight empty/Weight fully loaded	1,032 lbs./—	209 lbs./—	112 lbs./—
No. of different measured assays onboard simultaneously	51 (51 can be run and calibrated at one time)	4–8 (4–8 can be run and calibrated at one time)	—
No. of user-definable (open chemistry) channels	—	—	—
Test throughput per hour/Assay run time	up to 2,200 (up to 22 tests in throughput)/avg. 45 min. (assay dependent)	—	—
<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	no	yes (96 wells per microplate)	yes (96 tests per unit containing up to 8 different assays; 96 wells per microplate)
Methodologies supported	multiplex flow (cytometric)	enzyme immunoassay	fluorescence, enzyme immunoassay
Separation methodologies	magnetic particle	coated microwell	none necessary
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 (assay panel dependent), 200 (HIV, vitamin D, Lyme total), 150 (ToRC IgM)/self-contained multiuse	192/self-contained multiuse	192/open reagent system
Reagents refrigerated onboard/Reagents ready to use	yes (2°–8°C)/yes	no/yes	no/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/no	yes/no
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/480 min. or 800 specimens or 9,600 tests	yes/180 specimens or 4 tests	yes/192 specimens or 8 EIA or 4 IFA assays
Design of sample-handling system	rack	—	benchtop, reagent rack
Uses washable cuvettes/Uses disposable cuvettes	no/—	no/yes	no/no
Min.–max. sample volume that can be aspirated at one time	3–150 µL	10–100 µL	1–100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	3 µL/350 µL (tube size dependent)/250 µL	10 µL/10 µL/100 µL	1 µL/1 µL/150 µL
Dedicated pediatric sample cup	no	no	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/no	yes/no	yes/yes (12–13 × 100 mm, 75 × 100 mm)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	yes	no	no
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	hemolysis, icterus, lipemia, clots 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)/<1 part per million	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	no	no	no
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	no	no	no
Analyzer requires dedicated water supply	no (0.5 L/hr. consumption during operation)	no (0.5 L/hr. consumption during operation)	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 30 days [assay dependent])	no (calibrants are not stored onboard)/yes (recommended avg. frequency: each run)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: each run)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/—/—/—/30 days (assay dependent)	—/—/—/—/each run	—/—/—/—/each run
Automatic programmable start/Automatic programmable shutdown	yes/—	no/no	no/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	no
Waste management	manually by user or automated collection onboard instrument or direct to drain	manually by user or automated collection onboard instrument	manually by user or 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)/yes	yes (Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	no (operator intervention required to order parts)	no (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	no	no
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/Antrim, CCA, Cerner, Sunquest, CGM Schuyllab, Data Innovations, SCC Soft Computer, Meditech, Orchard, more	onboard/—	onboard/—
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download and host query)	no/yes (broadcast download)	no/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/< 24 hrs.	yes/24 hrs.	no/24 hrs.
Mean time between failures	— (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: 30 min.; monthly: ~60 min.	daily: 5 min.; monthly: < 60 min.	daily: < 5 min.; < weekly: 15 min.; monthly: < 30 min.
Maintenance records kept onboard for user/vendor	yes/yes (both include audit trail of who replaced parts)	yes/yes (includes audit trail of who replaced parts)	no/no
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/5 days (at vendor site)	yes (2 training slots)/5 days (at customer site)	yes (2 training slots)/2 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	no/yes	no/yes	no/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>• full random-access automation with innovative multiplex chemistry; internal QC beads for monitoring test performance; 51 assays: 26 autoimmune, 24 infectious disease, vitamin D</li> <li>• compatible track line connectivity option</li> <li>• CylancePROTECT Antivirus program provides digital protection against malware</li> </ul>	<ul style="list-style-type: none"> <li>• fully automated system that performs EIA assays with positive sample identification</li> <li>• network workstations for higher throughput</li> <li>• semi-open system with bidirectional LIS and comprehensive range of assays</li> </ul>	<ul style="list-style-type: none"> <li>• open platform with assay programming wizard and capability to run IFA and EIA methods on a single instrument</li> <li>• accurate delivery of volumes as low as 1 µL</li> <li>• unique IFA hyperwash, resulting in lower background fluorescence</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 16	Bio-Rad Laboratories Clinical Diagnostics Group Mbithe Nguku mbithe_nguku@bio-rad.com Hercules, CA 800-224-6723 www.bio-rad.com	bioMérieux Kara Hardin kara.hardin@biomerieux.com Salt Lake City, UT 800-682-2666 www.biomerieux-usa.com	DiaSorin Technical Support tech.support@diasorin.com Stillwater, MN 800-328-1482 or 651-439-9710 www.diasorin.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	PR4100 Microplate Reader	VIDAS 3	LIAISON XL
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	batch/benchtop	batch, random access, continuous random access/ benchtop	batch, random access, continuous random access, discrete/ floor standing
List price/First year sold in U.S.	—/2012	—/2015	—/2010
Targeted hospital bed size/Targeted test volume	—	—	> 300/≥ 50,000
Company manufactures instrument	yes	yes	no
Other models in this family of analyzers	—	VIDAS, MINI VIDAS	LIAISON XS
No. of units in clinical use in U.S./Outside U.S. (countries)	—	> 500/—	> 600/> 4,100
Dimensions (H × W × D)/Instrument footprint	5.3 × 13.7 × 7.4 in./—	24 × 29.5 × 25.5 in./5.2 sq. ft.	59 × 59 × 36 in./14.6 sq. ft.
Weight empty/Weight fully loaded	5.7 lbs./—	154 lbs./—	—/661 lbs.
No. of different measured assays onboard simultaneously	—	12 (several different lots of assays can be stored at one time)	25 (25 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	—	0
Test throughput per hour/Assay run time	—	up to 36/assay dependent	up to 171/16–65 min. (avg. 35 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	no	no	no
Methodologies supported	enzyme immunoassay	enzyme-linked fluorescent assay (ELFA) technology	chemiluminescence
Separation methodologies	none necessary	—	magnetic particle
Stat time until completion of a β-hCG test	—	25 min. (measures intact molecule)	—
• Typical time delay from test order to aspiration of sample	—	—	—
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approximate No. of tests per reagent set/Reagent type	—	30–60 per kit/self-contained single use	50, 100, 200 (assay dependent)/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	no/—	no/yes	yes (12°C)/yes
Reagent lot tracking/Reagent inventory	no/no	yes/—	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/—	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	—	yes/yes	no/no
Walkaway capability/Walkaway duration	no/—	yes/27 specimens or 12 tests	yes/360 min. or 120 specimens or 1,000 tests
Design of sample-handling system	batch, benchtop	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/—	no/yes (can store up to 1,000 cuvettes)
Min.–max. sample volume that can be aspirated at one time	—	100–300 µL	50–1,000 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—	100 µL/100 µL/125 µL for aliquot tubes	—/5 µL/150 µL
Dedicated pediatric sample cup	no	yes	yes (dead volume: 50 µL)
Primary tube sampling	no	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	no (microplate reader)/no (microplate reader)	yes/—	yes/yes
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	—	yes
Detects clots/liquid level/short sample	yes/yes/no	yes/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	hemolysis, icterus, lipemia, clots not available	—	detection for clots; hemolysis, icterus, lipemia not available
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)/—
Automatic rerun capability	no	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results	no	yes	no
Sample volume can be concentrated to rerun out-of-linear-range low results	no	no	no
Analyzer requires dedicated water supply	no	no	no
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/no	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 14 or 28 days)	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 4 weeks [assay dependent])
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—	—/—/—/—/every 14–28 days	—
Automatic programmable start/Automatic programmable shutdown	no/no	yes (5 min. warm-up time)/yes	no/no
Onboard real-time QC/Onboard software capability to review QC	no/no	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	no	yes	yes
Waste management	manually by user	manually by user or automated collection onboard instrument	automated collection onboard instrument or direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no
Lab can control analyzer from remote computer	no	yes	no
Instrument can diagnose its own malfunctions	no (operator intervention required to order parts)	yes (operator intervention required to order parts)	no (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	no	yes	yes
UPS backup power supply	no	yes	yes
Data-management capability/LIS or EHR systems interfaced	no/—	onboard/Cerner, SCC Soft Computer, Meditech, Epic, more	onboard/Cerner, Epic, Sunquest, Vistar, SCC Soft Computer, Orchard, Meditech, Comtron, ApolloLIMS, LabWare, more
LIS interface provided/Bidirectional interface capability	no/no	yes (additional cost)/yes (broadcast download and host query)	no/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/—	no/< 24 hrs.	yes/24 hrs.
Mean time between failures	—	> 1 year (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	—	weekly: 10–15 min.	daily: 10 min.; weekly: 20 min.; monthly: 30 min.
Maintenance records kept onboard for user/vendor	no/no	yes/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)/1 day (at customer site)	yes/— (at customer site)	yes (3 training slots)/— (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	no/yes	—	yes (at vendor site)/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes/—	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>comprehensive data-analysis software for full traceability</li> <li>LIS connectivity</li> <li>compact size—space saver</li> </ul>	<ul style="list-style-type: none"> <li>VIDAS NEPHROCHECK, an assay to aid in the risk assessment of acute kidney injury, is now part of the specialty critical care and infectious disease menu</li> <li>easy-to-use benchtop immunoassay system with ready-to-use assay format</li> <li>mean time between failure &gt; 370 days</li> </ul>	<ul style="list-style-type: none"> <li>secure traceability of all processes, status of reagents, and consumables</li> <li>disposable pipette tips prevent sample carryover</li> <li>no daily maintenance—instrument monitors maintenance needs</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 16	<b>Diatron</b> <b>Frank Matuszak</b> frank.matuszak@diatron.com <b>Medley, FL</b> <b>833-228-7931</b> www.diatron.com	<b>Diazyme Laboratories</b> <b>Ericka Borges</b> marketing@diayzme.com <b>Poway, CA</b> <b>858-455-4768</b> www.diazyme.com	<b>Dynex Technologies</b> <b>Global Customer Service</b> customerservice@dynex.com <b>Chantilly, VA</b> <b>800-288-2354</b> www.dynex.com
Name of instrument	Pictus 700 (P700)	DZ-Lite 3000 Plus	Agility Automated ELISA System
Type of instrument	chemistry	immunoassay	immunoassay
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	batch, random access/floor standing	batch/benchtop
List price/First year sold in U.S.	\$60,190/2013	\$60,000/2017	—/2012
Targeted hospital bed size/Targeted test volume	50–250/daily; 1,000–4,000; monthly: 30,000–120,000; annual: 365,000–1,460,000	—/daily; 1,000; monthly: 30,000; annual: 350,000	—
Company manufactures instrument	—	no (manufactured by SNIBE Diagnostics)	yes
Other models in this family of analyzers	Pictus 500 (P500)	—	DSX
No. of units in clinical use in U.S./Outside U.S. (countries)	< 100/> 750 (Europe, Latin America, Africa, Middle East, Asia)	55/1 (Philippines, Netherlands)	—/425 (worldwide)
Dimensions (H × W × D)/Instrument footprint	39.4 × 38.1 × 26.4 in./7.1 sq. ft.	59.8 in. × 56.7 in. × 30 ft./—(3.5 ft. recommended clearance)	49 × 50 × 36 in./12.5 sq. ft.
Weight empty/Weight fully loaded	418 lbs./478 lbs.	502 lbs./—	469 lbs./—
No. of different measured assays onboard simultaneously	72 (up to 72 can be run and calibrated at one time)	25 (25 can be run and calibrated at one time)	up to 16 SmartKit reagent packs (up to 16 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	0	— (up to 16 can be active simultaneously)
Test throughput per hour/Assay run time	720/30–1,200 sec. (avg. 300 sec.)	180 (180 tests in throughput, assay dependent)/15–45 min. (avg. 30 min.)	assay dependent (up to 1,536 tests per run)/assay dependent
<b>Chemistry:</b>			
No. of direct ion-selective electrode channels	3	—	—
Detection methods	photometry, potentiometry	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	2 min./60 specimens per hr.	—	—
• Basic metabolic panel	7.5 min./60 specimens per hr.	—	—
• Complete metabolic panel	9 min./50 specimens per hr.	—	—
Typical time delay from ordering stat test until aspiration of sample	24 sec.	—	—
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	—	no	yes (up to 12 tests per unit; 96 wells per microplate)
Methodologies supported	—	chemiluminescence	enzyme immunoassay
Separation methodologies	—	magnetic particle	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	100/self-contained multiuse	—/open system with self-contained multiuse SmartKit
Reagents refrigerated onboard/Reagents ready to use	yes (8° ±2°C)/yes	yes (10°)/yes	no (23° ±4°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/no	no/yes
Walkaway capability/Walkaway duration	yes/180 min. or 95 specimens or 1,800 tests	yes/144 specimens or 1,500 tests	yes/up to 1,152 specimens or up to 1,152 tests
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	yes/yes (can store up to 160 cuvettes)	no/yes (can store up to 700 cuvettes)	no/no
Min.–max. sample volume that can be aspirated at one time	2–100 µL	5–300 µL	10–300 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	180 µL/22 µL/100 µL	200 µL/120 µL/100 µL	10 µL/—/—
Dedicated pediatric sample cup	yes (dead volume: 20 µL)	no	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/no	yes/no	yes/yes (17 × 100 mm)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	yes	no	no
Detects clots/liquid level/short sample	yes/yes/yes	—/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available	detection for clots; hemolysis, icterus, lipemia not available	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)/30 parts per million	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/no carryover
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	no	no
Analyzer requires dedicated water supply	no (< 3 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 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	8 hr./—/7 days/14 days/14 days	—/—/—/7 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	yes
Waste management	manually by user or direct to drain	manually by user or direct to drain	automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, EAN 8/13, Code 93, UPCA/UPCE)/yes	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 (instrument can order parts without operator intervention)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	no	yes
Data-management capability/LIS or EHR systems interfaced	onboard/AP Visions, Medicus, CGM Schuyllab, Labtrack, CGM LabDaq, Medytox	onboard/—	onboard/Orchard, Cerner
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	no/yes (host query)	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	no/48 hrs.	no/24 hrs.	no/24 hrs.
Mean time between failures	1 year (displays error codes for troubleshooting)	1 year (displays error codes for troubleshooting)	200 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 30 min.; weekly: 1 hr.; monthly: 2 hr.	daily: 20 min.; weekly: 20 min.; monthly: 90 min.	daily: 10 min.; weekly: 5 min.
Maintenance records kept onboard for user/vendor	no/no	no/no	no/no
Maintenance training demonstration module onboard	no	yes	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/3 days (at customer site)	yes (as many training slots as needed)/2 hours (at customer site)	no/3 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer or vendor site)/yes	yes (at customer site)/no	yes (at customer site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/\$5,500	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>uninterrupted workflow</li> <li>Windows-based, intuitive, user-friendly software</li> <li>high-quality components for long stability and result reliability</li> </ul>	<ul style="list-style-type: none"> <li>unique menu</li> <li>advanced chemiluminescent technology</li> <li>for clinical and research applications</li> </ul>	<ul style="list-style-type: none"> <li>increases productivity—full walkaway processing from beginning of testing with up to 16 SmartKit carriers stored</li> <li>practical automation—assesses testing requirements, develops efficient work list, continuous sample loading</li> <li>value—frees up labor time, allows for multitasking by eliminating most of ELISA labor</li> </ul>
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 7 of 16	<b>ELITechGroup</b> Trish Worman p.worman@elitechgroup.com Logan, UT 435-752-6011 www.elitechgroup.com	<b>EUROIMMUN Medizinische Labordiagnostika</b> Product Management Auto. automation-pm@euroimmun.de Luebeck, Germany +49 451 2032-0 www.euroimmun.com	<b>EUROIMMUN Medizinische Labordiagnostika</b> Product Management Auto. automation-pm@euroimmun.de Luebeck, Germany +49 451 2032-0 www.euroimmun.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	Envoy 500/Envoy 500+ Chemistry Analyzer	EUROLabWorkstation ELISA	EUROLabWorkstation IFA
Type of instrument	chemistry	immunoassay	immunoassay
Operational type/Model type	batch, random access, continuous random access, discrete/benchtop	batch/benchtop	batch/benchtop
List price/First year sold in U.S.	\$85,000/2004 (Envoy 500), 2014 (Envoy 500+)	—/2017	—/2019
Targeted hospital bed size/Targeted test volume	—/daily: 20–80 patients; monthly: 4,200–17,000; annual: 50,000–200,000	—/> 3,000	—/up to 3,000
Company manufactures instrument	no (also sold by McKesson, RedByrd, Henry Schein)	yes (also sold by EUROIMMUN US)	yes (also sold by EUROIMMUN US)
Other models in this family of analyzers	—	—	—
(No. of units in clinical use in U.S./Outside U.S. (countries))	250/—	—	—
Dimensions (H × W × D)/Instrument footprint	27 × 40 × 23 in./10 sq. ft.	~34 × 129 × 32 in./—	~34 × 115 × 32 in./—
Weight empty/Weight fully loaded	209 lbs./219 lbs.	~760 lbs./~990 lbs.	~760 lbs./~990 lbs.
No. of different measured assays onboard simultaneously	40 (40 can be run and calibrated at one time)	180 (180 can be run and calibrated at one time)	75 (75 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	500 (40 can be active simultaneously)	—	—
Test throughput per hour/Assay run time	490/—	> 200 (assay dependent)/—	> 200 (assay dependent)/—
<b>Chemistry:</b>			
No. of direct ion-selective electrode channels	4	—	—
Detection methods	photometry	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	3 min., 45 sec./37 specimens per hr.	—	—
• Basic metabolic panel	10 min./588 specimens per hr.	—	—
• Complete metabolic panel	15 min./266 specimens per hr.	—	—
Typical time delay from ordering stat test until aspiration of sample	< 1 min.	—	—
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	—	yes (180 tests per unit; 96 wells per microplate)	no
Methodologies supported	—	enzyme immunoassay	fluorescence
Separation methodologies	—	coated microwell	BIOCHIPS on indirect immunofluorescence slides
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	varies/open reagent system	96/open reagent system	up to 1,200/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (10°–15°C)/yes	no/yes	no/yes
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)/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/240 min. or 52 specimens or > 1,000 tests/assays	yes/up to 480 min. or 800 specimens or 1,440 tests	yes/up to 360 min. or ~700 specimens or 750 tests
Design of sample-handling system	ring	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	yes/no (can store up to 34 cuvettes)	no/yes (can store up to 1,440 cuvettes)	no/no
Min.–max. sample volume that can be aspirated at one time	1–100 µL	5–1,100 µL	5–1,100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	300 µL/1 µL/100 µL	100 µL/5 µL/75 µL	100 µL/5 µL/75 µL
Dedicated pediatric sample cup	no	yes (dead volume: 75 µL)	yes (dead volume: 75 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes	yes/yes (10–16 × 100 mm)	yes/yes (10–16 × 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	no/yes/yes	no/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available	detection for clots	detection for 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)/1.3 parts per million	yes (can be programmed to perform dilutions prior to analysis)/1.3 parts per million
Automatic rerun capability	yes	no	no
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	no	no	no
Analyzer requires dedicated water supply	no (1 L/hr. consumption during operation)	no	no
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes	no/yes (recommended avg. frequency: each run)	no/—
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	4 hrs./—/—/7–31 days/—	—/—/—/—/each run	—/—/—/—/assay dependent
Automatic programmable start/Automatic programmable shutdown	yes (7 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	—	—
Waste management	automated collection onboard instrument or direct to drain	automated collection onboard instrument or direct to drain	automated collection onboard instrument or 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, Data Matrix)/—	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Data Matrix)/—
Lab can control analyzer from remote computer	no	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	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/CGM LabDag, CGM SchuyLab, McKesson Horizon Lab, Medicus Solutions, more	onboard/—	onboard/—
LIS interface provided/Bidirectional interface capability	no/yes (host query)	yes (additional cost)/yes (host query)	yes (additional cost)/yes (host query)
Modem servicing provided/Service engineer on-site response time	no/24 business hrs.	yes/—	yes/—
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	weekly: 15 min.; monthly: 15 min.	—	—
Maintenance records kept onboard for user/vendor	yes/no	yes/yes	yes/yes
Maintenance training demonstration module onboard	no	yes	yes
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/3 days (at customer site)	yes (1 training slot)/1 day (at customer site)	yes (1 training slot)/1 day (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer site)/no	yes (at customer or vendor site)/—	yes (at customer or vendor site)/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/\$8,995 (M–F, 8 AM–7 PM)	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>fast benchtop chemistry system</li> <li>reusable glass cuvettes eliminate cost of disposable cuvettes</li> <li>4-parameter (Na+, K+, Cl-, CO2) dry electrodes reduce costs and maintenance time, increase reliability of results</li> </ul>	<ul style="list-style-type: none"> <li>high-throughput system: more than 200 tests per hour for up to 15 ELISA plates in one run</li> <li>flexible and fully code-tracked loading for patient samples, reagents, and labware without predefined positioning</li> <li>convenient and intuitive operation of hardware and software with QC conformant tracking of actions and real walkaway time</li> </ul>	<ul style="list-style-type: none"> <li>high-throughput system: more than 200 tests per hour for up to 750 reaction fields in one run</li> <li>flexible and fully code-tracked loading for patient samples, reagents, and labware without predefined positioning</li> <li>fully automated IIFT processing from primary sample to cover-slipped slide with real walkaway time</li> </ul>

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

Part 8 of 16	<b>FUJIFILM Healthcare Americas Corp.</b> <b>Amador Alejo</b> amador.alejo@fujifilm.com <b>Lexington, MA</b> <b>877-714-1924</b> www.ivd.fujimed.com	<b>Fujirebio US</b> <b>Amanze Orusakwe</b> amanze.orusakwe@fujirebio-us.com <b>Malvern, PA</b> <b>844-544-3787</b> www.fujirebio.com	<b>Gold Standard Diagnostics</b> <b>Christina Brusca</b> christina.brusca@us.goldstandarddiagnostics.com <b>Davis, CA</b> <b>530-759-8000</b> www.gsdx.us
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	µTASWako i30	LUMIPULSE G1200	AIX1000 Agglutination Instrument
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	random access/benchtop	continuous random access/floor standing	batch/benchtop
List price/First year sold in U.S.	—/2011	\$118,000/2016	—/2016
Targeted hospital bed size/Targeted test volume	—	> 50/daily; 80; monthly: 16,000; annual: 200,000	—
Company manufactures instrument	no (manufactured by FUJIFILM Wako Pure Chemical Corp.)	no (manufactured by Otsuka)	yes (also sold by Cardinal Health, Thermo Fisher Scientific, WWR)
Other models in this family of analyzers	—	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	25/400 (Canada, Germany, Japan, China, South Korea, Vietnam, Thailand, Malaysia, Philippines)	18/> 1,000 (Japan, Germany, France, Italy, Belgium, more)	—
Dimensions (H × W × D)/Instrument footprint	21.5 × 20.5 × 23.4 in./3.34 sq. ft.	57.6 × 47.2 × 31.5 in./14.2 sq. ft.	17.7 × 25.3 × 22.5 in./4.1 sq. ft.
Weight empty/Weight fully loaded	157 lbs./—	727 lbs./794 lbs.	62 lbs./~110 lbs.
No. of different measured assays onboard simultaneously	6 (6 can be run and calibrated at one time)	36 (36 can be run and calibrated at one time)	1 (1 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	—	—
Test throughput per hour/Assay run time	25/—	120 (120 tests in throughput)/avg. 25 min.	128 (128 tests in throughput)/75 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	no	no	no
Methodologies supported	fluorescence	chemiluminescence	agglutination
Separation methodologies	microcapillary gel electrophoresis	magnetic particle	none necessary
Stat time until completion of a β-hCG test	—	30 min.	—
• Typical time delay from test order to aspiration of sample	—	none	—
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/self-contained multiuse	42/self-contained single use	480/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (2°–10°C)/yes	yes (2°–8°C)/no	no/—
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	no/no
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/no	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	—/yes	no/no
Walkaway capability/Walkaway duration	yes/190 min. or 50 specimens or 80 tests	yes/100 specimens	yes/90 min. or 192 specimens or 1 test
Design of sample-handling system	rack	rack	universal slide-in racks
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/no	no/no
Min.–max. sample volume that can be aspirated at one time	3 µL minimum	10–140 µL	1–150 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—/75 µL/72 µL	150 µL/110 µL/100 µL	105 µL/300 µL/150 µL
Dedicated pediatric sample cup	no	no	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes	yes/yes	yes/yes (12–16 × up to 100 mm)
Pierces caps on primary tubes	no	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	hemolysis, icterus, lipemia, clots not available	detection for clots; hemolysis, icterus, lipemia not available	detection for hemolysis, icterus, lipemia, clots not available
Dilutes patient samples onboard/Susceptibility to carryover	no/0.1 parts per million	yes (can be programmed to perform dilutions prior to analysis)/1 part per million	yes/—
Automatic rerun capability	yes	no	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	no	no	no
Analyzer requires dedicated water supply	no	no (2.1 L/hr. consumption during operation)	no (0.045 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/—	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 30 days)	—
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—	—/—/—/—/30 days	—
Automatic programmable start/Automatic programmable shutdown	no/no	yes (5 min. warm-up time)/yes	no (< 5 min. warm-up time)/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	no
Waste management	automated collection onboard instrument	manually by user or direct to drain	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ITF, EAN/JAN-13, EAN/JAN-18, STF(5BER), EAN-128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Standard 2 of 5)/no	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, 1D, 2D)/no
Lab can control analyzer from remote computer	no	no	no
Instrument can diagnose its own malfunctions	no (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	no	yes
UPS backup power supply	no	yes	no
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/SCC Soft Computer, more	onboard/—
LIS interface provided/Bidirectional interface capability	no/yes (host query)	yes (included in instrument price)/yes (broadcast download and host query)	no/no
Modem servicing provided/Service engineer on-site response time	no/based on contract	no/24 hrs.	—
Mean time between failures	— (displays error codes for troubleshooting)	400 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 0; weekly: 0; monthly: 15 min.	daily: 15 min.; weekly: 30 min.; monthly: 45 min.	daily: < 5 min.; weekly: < 20 min.
Maintenance records kept onboard for user/vendor	no/—	no/no	yes/yes
Maintenance training demonstration module onboard	no	yes (2 training slots per module)	no
Training included with purchase/Avg. time for basic user training	yes/~2 days (at customer site)	yes/6 hrs. (at customer site)	yes (minimum 1 training slot)/2 days (at customer site or online)
Advanced operator training/Extra charge for follow-up or advanced training	—	yes (at customer site)/yes	yes/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/\$14,375	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>microfluidics technology; small footprint–tabletop; liver cancer risk markers</li> <li>small sample volume</li> <li>fast turnaround time</li> </ul>	<ul style="list-style-type: none"> <li>unitized immunoreaction cartridge eliminates open bottle stability concerns and waste due to dead volume</li> <li>30-min. time to result for all assays</li> <li>uninterrupted productivity—replenishes samples, reagents, and consumables on the fly</li> </ul>	<ul style="list-style-type: none"> <li>universal slide-in racks accommodate a variety of tube sizes for easier and faster sample loading</li> <li>ability to add SMS and email alerts for notification of errors or test completion</li> <li>automated processing, analysis, interpretation, and result archiving</li> </ul>
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			





Part 10 of 16	<b>HYCOR Biomedical</b> <b>Erik van Megen</b> marketingdept@hycorbiomedical.com <b>Garden Grove, CA</b> <b>800-382-2527</b> www.hycorbiomedical.com	<b>Mindray North America</b> <b>Anna Chen</b> a.chen@mindray.com <b>Redmond, WA</b> <b>416-826-1663</b> www.mindraynorthamerica.com	<b>QuidelOrtho</b> <b>Laura Osborne</b> laura.osborne@quidelortho.com <b>Raritan, NJ</b> <b>800-828-6316</b> www.quidelortho.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	NOVEOS Immunoassay Analyzer	BA-800M	Vitros 3600 Immunodiagnostic System
Type of instrument	immunoassay	chemistry	immunoassay
Operational type/Model type	batch/floor standing	batch, random access, discrete/floor standing	batch, random access, continuous random access, discrete/floor standing
List price/First year sold in U.S.	—	\$211,000/2017	—/2008
Targeted hospital bed size/Targeted test volume	—/daily: 180; monthly: 5,417; annual: 65,000	—/daily: 1,600–6,000	150–4,500/daily; > 200; monthly: > 5,000; annual: > 60,000
Company manufactures instrument	yes (also sold by Sysmex, Axon Laboratories, Diagnostica Longwood, Aris Mantzoros S.A.)	yes (also sold by MedTest)	no (manufactured by Nypro Engineering and Technology group service; also sold by Cardinal, McKesson, more)
Other models in this family of analyzers	—	BS-480	Vitros ECI/ECIQ Immunodiagnostic System
No. of units in clinical use in U.S./Outside U.S. (countries)	—/— (France, Germany, Netherlands, Switzerland, Greece, Spain, China)	—/> 2,000 (49 countries)	> 150/> 690 (North, Central, and South Americas, more)
Dimensions (H × W × D)/Instrument footprint	51 × 61.5 × 32.5 in./15 sq. ft.	47 × 91 × 40 in./25.19 sq. ft.	65 × 84 × 35 in./19.4 sq. ft.
Weight empty/Weight fully loaded	881 lbs./960 lbs.	1,430 lbs./1,654 lbs.	1,740 lbs./—
No. of different measured assays onboard simultaneously	1,200 (9 can be run and calibrated at one time)	68 (68 can be run and calibrated at one time)	31 (31 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	—	0
Test throughput per hour/Assay run time	~100 tests per hour after first test result (~100 tests in throughput)/107 min.— approx. 8 hrs.	800–1,200 with ISE (68 tests in throughput)/1–15 min.	189/16–73 min. (avg. 30 min.)
<b>Chemistry:</b>			
No. of direct ion-selective electrode channels	—	3 indirect	—
Detection methods	—	photometry, potentiometry, turbidimetry	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	1 min./56 specimens per hr.	—
• Basic metabolic panel	—	10.45 min./80 specimens per hr.	—
• Complete metabolic panel	—	13.08 min./48 specimens per hr.	—
Typical time delay from ordering stat test until aspiration of sample	—	~135 sec.	—
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	no	—	no
Methodologies supported	chemiluminescence	—	chemiluminescence, enzyme immunoassay, direct enhanced chemiluminescence
Separation methodologies	magnetic particle	—	coated microwell
Stat time until completion of a β-hCG test	—	—	24 min.
• Typical time delay from test order to aspiration of sample	—	—	1 min.
Stat time until completion of a cTn test	—	—	18 min.
• Typical time delay from test order to aspiration of sample	—	—	1 min.
Approximate No. of tests per reagent set/Reagent type	75/self-contained multiuse	133–500 per reagent bottle/self-contained single use	50–100/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (2°–15°C)/yes	yes (2°–8°C)/yes	yes (10°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 (closed reagent system)/yes	— (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/96 min. or 51 specimens or 1,200 tests	yes/~462 min. or 300 specimens or 12 test panels	yes/120 min. or 90 specimens or 3,100 tests
Design of sample-handling system	ring	rack and ring	circular routine sampling center
Uses washable cuvettes/Uses disposable cuvettes	yes (can store up to 20 cuvettes)/no	yes (can store up to 165 cuvettes)/no	no/no
Min.–max. sample volume that can be aspirated at one time	6–50 µL	1.5–35 µL	2–200 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	50 µL/4 µL/100 µL	100 µL/1.5 µL/50 µL	—/10 µL/35 µL
Dedicated pediatric sample cup	no	yes (dead volume: 50 µL)	yes (dead volume: 35 µL)
Primary tube sampling	no	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes	yes/—	yes/yes (micro sample cups, 10.25 × 45 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, 13 × 100 mm, 16 × 75 mm, 16 × 100 mm)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	yes	yes
Detects clots/liquid level/short sample	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 and quantitation for hemolysis, icterus, lipemia; detection for 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)/< 1,000 parts per million	yes (can be programmed to perform dilutions prior to analysis)/0
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	no
Analyzer requires dedicated water supply	no	yes (35 L/hr. consumption during operation)	no (no water consumption during operation)
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)	yes (calibrants can be stored onboard)/yes	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/—	—/—/—/28 days
Automatic programmable start/Automatic programmable shutdown	no (1–5 min. warm-up time)/yes	yes/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	automated collection onboard instrument or direct to drain	direct to drain	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no	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	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	no	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/—	onboard/—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	no/yes (broadcast download and host query)	yes (additional cost)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/contract dependent	no/24 hrs.	yes/4 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	2,400 hrs. (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 5 min.; weekly: 50 min.; monthly: 20 min.	daily: < 10 min.; weekly: < 1 hr.; monthly: < 1 hr.	daily: < 10 min.; weekly: 30 min.; monthly: 20 min.
Maintenance records kept onboard for user/vendor	yes/no	yes (includes audit trail of who replaced parts)/some records	yes (includes audit trail of who replaced parts)/no
Maintenance training demonstration module onboard	no	yes	yes
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/3 days (at vendor or customer site)	yes (1+ training slot)/3 days (at customer site)	yes (2 training slots)/5 days (at customer and vendor sites)
Advanced operator training/Extra charge for follow-up or advanced training	no/—	no/—	yes (at vendor site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes/—	yes (1 year)/depends on plan selected
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>4-µL sample size requirement per test</li> <li>up to 13 hours true walkaway time when system is directly connected to deionized water lines and waste lines</li> <li>high onboard test capacity of 10,500 tests; no interference from biotin or solid-phase-related cross-reactive carbohydrate determinant (CCD) interference</li> </ul>	<ul style="list-style-type: none"> <li>huge sample delivery capacity: 440 positions total, including 140 positions on sample tray and 300 positions on racks</li> <li>minimum reaction volume of 100 µL; offers reagent savings to the customer</li> <li>sample delivery module allows loading 300 samples at a time, provides long operator walkaway time</li> </ul>	<ul style="list-style-type: none"> <li>Intellitect technology process checks reduce misreported results and provide real-time quality status and traceability</li> <li>single-use disposable tips for sample and reagent metering eliminate 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 11 of 16 FOR MID- AND HIGH-VOLUME LABORATORIES	<b>QuidelOrtho</b> Laura Osborne laura.osborne@quidelortho.com Raritan, NJ 800-828-6316 www.quidelortho.com	<b>QuidelOrtho</b> Laura Osborne laura.osborne@quidelortho.com Raritan, NJ 800-828-6316 www.quidelortho.com	<b>Randox Laboratories</b> Graeme McNeill graeme.mcneill@randox.com Kearneysville, WV 304-728-2890 www.randox.com
Name of instrument	Vitros 4600 Chemistry System chemistry	Vitros XT 7600 Integrated System combination chemistry/immunoassay	RX imola chemistry
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	batch, random access, continuous random access, discrete/floor standing	discrete/benchtop
List price/First year sold in U.S.	—/2011	—/2018	—/2006
Targeted hospital bed size/Targeted test volume	150–4,500/daily: 600–3,000; monthly: 17,000–85,000; annual: 200,000–1.5 million	150–4,500/daily: 600–3,000; monthly: 17,000–85,000; annual: 200,000–4 million	75/daily: > 750; monthly: > 22,500; annual: > 270,000
Company manufactures instrument	no (manufactured by Nypro Engineering and Technology group service; also sold by Cardinal, McKesson, more)	no (manufactured by Nypro Engineering and Technology group service; also sold by Cardinal, McKesson, more)	yes
Other models in this family of analyzers	Vitros 350 Chemistry System, Vitros XT 3400 Chemistry System	Vitros 5600 Integrated System	RX misano, RX monaco, RX daytona +, RX modena
No. of units in clinical use in U.S./Outside U.S. (countries)	> 160/> 980 (North, Central, and South Americas, more)	> 460/> 400 (North, Central, and South Americas, more)	34/> 1,000 (> 120 countries)
Dimensions (H × W × D)/Instrument footprint	53 × 92 × 33 in./21.4 sq. ft.	68 × 110 × 34.9 in./26.7 sq. ft.	27 × 38 × 23 in./44.28 sq. ft.
Weight empty/Weight fully loaded	1,400 lbs./—	2,360 lbs./—	331 lbs./340 lbs.
No. of different measured assays onboard simultaneously	82 (82 can be run and calibrated at one time)	150 (150 can be run and calibrated at one time)	60 (60 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	20 (20 can be active simultaneously)	20 (20 can be active simultaneously)	15 (0 can be active simultaneously)
Test throughput per hour/Assay run time	845/2.5–20 min. (avg. 5 min.)	1,320/2.5–73 min. (avg. 7 min.)	560, including ISE (50 tests in throughput)/5–10 min. (avg. 6 min.)
<b>Chemistry:</b>			
No. of direct ion-selective electrode channels	3	3	3
Detection methods	photometry, potentiometry, colorimetric, turbidimetric	photometry, potentiometry, turbidimetric, direct enhanced chemiluminescence	potentiometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	5 min./126 tests per hr.	5 min./126 tests per hr.	13 min. 15 sec./80 specimens per hr.
• Basic metabolic panel	6 min./84 tests per hr.	6 min./95 tests per hr.	13 min. 43 sec./80 specimens per hr.
• Complete metabolic panel	7.5 min./50 tests per hr.	7.5 min./74 tests per hr.	13 min. 15 sec./67 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	1 min.	1 min.	30 sec.
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	—	no	—
Methodologies supported	—	chemiluminescence, enzyme immunoassay, direct enhanced chemiluminescence	—
Separation methodologies	—	coated microwell	—
Stat time until completion of a β-hCG test	—	24 min.	—
• Typical time delay from test order to aspiration of sample	—	1 min.	—
Stat time until completion of a cTn test	—	18 min.	—
• Typical time delay from test order to aspiration of sample	—	1 min.	—
Approximate No. of tests per reagent set/Reagent type	60/self-contained single use, open reagent system	50–100/varies for chemistry and immunoassay	200/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	yes (10°C)/yes	yes (10°C)/yes	yes (8°–15°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	dry chemistry, liquid chemistry (open reagent system)/yes	dry chemistry, 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/120 min. or 160 specimens or 8,940 tests	yes/—	yes/70 min. or 40 specimens or 10 tests
Design of sample-handling system	continuous load and unload, circular routine sample center	continuous load and unload, circular routine sample center	ring
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 348 cuvettes)	no/yes (can store up to 348 cuvettes)	yes (can store up to 90 cuvettes)/no
Min.–max. sample volume that can be aspirated at one time	2–200 µL	2–200 µL	1.5–35 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	0 µL/2 µL/35 µL	0 µL/2 µL/35 µL	150 µL/1.5–35 µL/150 µL
Dedicated pediatric sample cup	yes (dead volume: 35 µL)	yes (dead volume: 35 µL)	yes (dead volume: 100 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (micro sample cups, 10.25 × 45 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, 13 × 100 mm, 16 × 75 mm, 16 × 100 mm)	yes/yes (micro sample cups, 10.25 × 45 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, 13 × 100 mm, 16 × 75 mm, 16 × 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/no
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection and quantitation for hemolysis, icterus, lipemia; detection for clots	detection and quantitation for hemolysis, icterus, lipemia; detection for clots	detection and quantitation for hemolysis, icterus, lipemia; clots not available
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/0	yes (can be programmed to perform dilutions prior to analysis)/0	yes (can be programmed to perform dilutions prior to analysis)/no carryover
Automatic rerun capability	yes	yes	yes
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	yes	yes	yes
Analyzer requires dedicated water supply	no (no water consumption during operation)	no (no water consumption during operation)	yes (18 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 6 mos. or lot change for most chemistry assays)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 6 mos. or lot change for most chemistry assays)	no (calibrants can be stored onboard)/yes (recommended avg. frequency: 14 days)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	6 mos./6 mos./6 mos./6 mos./—	6 mos./6 mos./6 mos./6 mos./28 days	1 day/7 days/7 days/14 days/28 days
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	yes (9 min. warm-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	—/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	manually by user	manually by user	direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/—	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no	no	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	yes	no
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/—	onboard/—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	yes (additional cost)/yes (broadcast download and host query)	yes (included in instrument price)/yes (host query)
Modem servicing provided/Service engineer on-site response time	yes/4 hrs.	yes/4 hrs.	no/within 24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	2 per 3 years (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 5 min.; weekly: 30 min.; monthly: 20 min.	daily: < 10 min.; weekly: 30 min.; monthly: 20 min.	daily: 5 min.; weekly: 15 min.; monthly: 1 hr.
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/no	yes (includes audit trail of who replaced parts)/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)/5 days (at customer and vendor sites)	yes (2 training slots)/5 days (at customer and vendor sites)	yes (1 training slot)/3 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 customer site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/depends on plan selected	yes/depends on plan selected	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>• Intellichem technology process checks reduce misreported results and provide real-time quality status and traceability</li> <li>• single-use disposable tips for sample and reagent metering eliminate sample and reagent carryover</li> <li>• MicroSensor technology detects HIL and turbidity without using reagents or additional sample and time</li> </ul>	<ul style="list-style-type: none"> <li>• capable of processing two unique chem tests on one XT Microslide</li> <li>• single-use disposable tips eliminate carryover</li> <li>• MicroSensor technology detects HIL and turbidity without using reagents or additional sample and time</li> </ul>	<ul style="list-style-type: none"> <li>• large and extensively dedicated test menu</li> <li>• stat sample capabilities</li> <li>• benchtop analyzer</li> </ul>
<p><i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i></p>			

Part 12 of 16	Roche Diagnostics John Kleinschmidt john.kleinschmidt@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	Roche Diagnostics John Kleinschmidt john.kleinschmidt@roche.com Indianapolis, IN 800-428-5074 diagnostics.roche.com/us/en/home.html
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	cobas 6000 analyzer series	cobas 8000 modular analyzer series	cobas pro integrated solution
Type of instrument	combination chemistry/immunoassay	combination chemistry/immunoassay	combination chemistry/immunoassay
Operational type/Model type	random access, continuous random access/floor standing	random access, continuous random access/floor standing	random access, continuous random access/floor standing
List price/First year sold in U.S.	—/2006	—/2010	—/2020
Targeted hospital bed size/Targeted test volume	> 100/daily; 1,000–4,000; annual: 500,000–2,500,000	> 250/daily; > 4,000; annual: ≥ 2,500,000	> 200/daily; 2,000–4,000; annual: 750,000–4 million
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	chemistry: cobas c 501; immunoassay: cobas e 601	chem.: cobas c 701, c 702, c 502; immuno.: cobas e 801, e 602	chem: cobas c 503; immuno: cobas e 801
No. of units in clinical use in U.S./Outside U.S. (countries)	> 1,600/> 14,000 (56 countries)	> 400/> 5,000 (49 countries)	> 300/> 5,800 (> 40 countries)
Dimensions (H × W × D)/Instrument footprint	51 × 74–196 × 41 in./34.62 sq. ft. for 2-module configuration	40–53 × 99–294 × 45 in./66.35 sq. ft. for 3-module config.	56 × 172.2 × 47 in. for integrated 2-module system/56 sq. ft.
Weight empty/Weight fully loaded	830–1,990 lbs./830–1,990 lbs.	1,150–5,485 lbs./1,150–5,485 lbs.	for integrated 2-module system: 4,388 lbs./4,388 lbs.
No. of different measured assays onboard simultaneously	up to 151 (up to 148 can be run and calibrated at one time)	up to 283 (> 300 can be run and calibrated at one time)	chem: 63 (63 can be run and calibrated at one time); immuno: 48 (48 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	20 (all can be active simultaneously)	10 for c 70x, c 502 (all can be active simultaneously)	10 (10 can be active simultaneously)
Test throughput per hour/Assay run time	up to 2,170 (2,170 tests in throughput)/ISE: 12 sec.; chemistry: 3–10 min. in 1-min. steps; immunoassay: 9–27 min. (avg. 18 min.)	up to 9,800 (varies by module)/ISE: 12 sec.; chemistry: 3–10 min. in 1-min. steps; immunoassay: 9–27 min. (avg. 18 min.)	up to 2,200 (varies by module)/chem: 4.5–10 min. (avg. 10 min.); immuno: 9–27 min. (avg. 18 min.)
<b>Chemistry:</b>			
No. of direct ion-selective electrode channels	3 indirect	3 indirect	3 indirect
Detection methods	photometry, potentiometry	photometry, potentiometry	photometry, potentiometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	4.5 min./133 specimens per hr.	4.5 min./600 specimens per hr.	4.5 min. for ISE, 10 min. with CO <sub>2</sub> /300 specimens per hr.
• Basic metabolic panel	7 min./up to 240 specimens per hr.	7 min./up to 400 specimens per hr.	10 min./200 specimens per hr.
• Complete metabolic panel	10 min./up to 110 specimens per hr.	10 min./up to 181 specimens per hr.	10 min./100 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	< 1 min.	< 1 min.	< 1 min.
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	no	no	no
Methodologies supported	electrochemiluminescence	electrochemiluminescence	electrochemiluminescence
Separation methodologies	magnetic particle	magnetic particle	magnetic particle
Stat time until completion of a β-hCG test	9 min.	~10 min.	~10 min.
• Typical time delay from test order to aspiration of sample	42 sec.	< 1 min.	< 1 min.
Stat time until completion of a cTn test	9 min.	9 min.	~10 min.
• Typical time delay from test order to aspiration of sample	42 sec.	24 sec.	< 1 min.
Approximate No. of tests per reagent set/Reagent type	up to 800 per pack (chemistry), up to 200 per pack (immunoassay)/self-contained multiuse	up to 3,000 per pack (chemistry), up to 300 per pack (immunoassay)/self-contained multiuse	up to 3,300 (chemistry), up to 300 (immunoassay)/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (5°–12°C [chemistry], 20°±3°C [immunoassay])/yes	yes (5°–15°C [chem], 6°–10°C [immuno])/reagent specific	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 (open 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/75 min. or 150 samples or 1,500 tests	yes/45 min. or 300 samples or 3,000 tests	yes/30–45 min. or 300 samples or ~3,000 tests
Design of sample-handling system	5-position rack	5-position rack	5-position rack
Uses washable cuvettes/Uses disposable cuvettes	immuno: yes (can store up to 1,008 cuvettes)/no	yes (No. of cuvettes stored varies by module)/no	yes (can store up to 221 cuvettes for chem, 1,575 for immuno)/yes
Min.–max. sample volume that can be aspirated at one time	1–35 µL	1–35 µL (chemistry), 1–60 µL (immunoassay)	1–60 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	100–250 µL (chem), 120–200 µL (immuno)/1.5 µL (chem), 4–10 µL (immuno)/500 or 1,000 µL (tube dependent)	100–250 µL (chem), 120–200 µL (immuno)/1 µL (chem), 4–10 µL (immuno)/50–1,000 µL (container dependent)	75 µL/1.5 µL (chem), 4 µL (immuno)/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	yes/yes	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 hemolysis, icterus, lipemia, clots	quantitation for hemolysis, icterus, lipemia; detection for clots	quantitation for hemolysis, icterus, lipemia; detection for 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)/< 1 part per million (chemistry), no carryover (immunoassay)	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 (10 L/hr. consumption during operation for chemistry, 12 L/hr. for immunoassay)	yes (10–36 L/hr. consumption during operation for chemistry, 12–30 L/hr. for immunoassay)	yes (32 L/hr. consumption during operation for chemistry, 30 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], up to 56 days per lot [immunoassay])	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 24 hrs. [ISE], once per lot [chemistry], up to 84 days per lot [immunoassay])	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./once per lot/42 days per lot/once per lot/up to 56 days per lot	24 hrs./once per lot/42 days per lot/once per lot/up to 84 days per lot	once per lot/once per lot/once per lot/once per lot/up to 84 days per lot
Automatic programmable start/Automatic programmable shutdown	yes/yes	yes (6.5 min. start-up time)/yes	yes (6.5 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	direct to drain	direct to drain	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)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
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	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/SCC, Meditech, Cerner, Epic, Sunquest, more	onboard, optional add-on (Bio-Rad MAS)/SCC, Cerner, Epic, more
LIS interface provided/Bidirectional interface capability	yes (incl. in instrument price)/yes (broadcast download and host query)	yes (incl. in instrument price)/yes (broadcast download and host query)	yes (incl. in price)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/< 8 hrs.	yes/< 8 hrs.	yes/—
Mean time between failures	avg. 259 days per module (displays error codes for troubleshooting)	avg. 152 days per module (displays error codes for troubleshooting)	c 503 module: 220 days; e 801 module: avg. 220 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 4 min.; weekly: 20 min.; monthly: 35 min.	daily: 4–5 min.; weekly: 20 min.; monthly: 25 min.	daily: 3–4 min.; bi-weekly: 23 min.; monthly: 20 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)	yes/yes (both include 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 (2 training slots)/varies at customer site, 5 days at vendor site	yes (4 training slots)/varies at customer site, 5 days at vendor site	yes (~ 2 training slots per module)/4–5 days (at customer and vendor sites)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/yes	yes (at vendor site)/yes (cost varies by contract)	yes (at vendor site)/yes (cost varies by contract)
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/configuration dependent	yes (1 year)/configuration dependent	yes (1 year)/varies by contract
Distinguishing features (supplied by company)	• broad test menu: > 180 assays on one integrated platform • flexible, scalable design: available in seven unique configurations	• high reagent onboard and calibration stability; no reagent prep; on-the-fly loading • broad test menu: > 180 assays on one integrated platform	• minimal operator intervention with automated maintenance, automated calibration, and continuous loading of reagents • long onboard reagent (up to 6 months) and calibration stabilities • increase revenue through expanded testing services with broad menu on consolidated platform and fast incubation times
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 13 of 16	Siemens Healthineers John Boone john.boone@siemens-healthineers.com Hoffman Estates, IL siemens-healthineers.com/en-us	Siemens Healthineers Leslie Hartman leslie.hartman@siemens-healthineers.com Tarrytown, NY siemens-healthineers.com/en-us	Siemens Healthineers Stijn Bammens stijn.bammens@siemens-healthineers.com Hoffman Estates, IL siemens-healthineers.com/en-us
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	Atellica Solution	Dimension EXL 200 Integrated Chemistry System	Immolute 2000 XPi Immunoassay System
Type of instrument	combination chemistry/immunoassay	combination chemistry/immunoassay	immunoassay
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	random access/floor standing	batch, random access, continuous random access, discrete/floor standing
List price/First year sold in U.S.	—/2017	\$252,000/2008	—/2009
Targeted hospital bed size/Targeted test volume	high volume/annual: > 750,000	—/annual: < 1 million	> 200/daily: > 250
Company manufactures instrument	yes (also sold by McKesson, Henry Schein, Medline)	yes (also sold by Henry Schein, McKesson, Medline)	yes (also sold by McKesson, Henry Schein, Medline)
Other models in this family of analyzers	Atellica CH 930, IM 1300, IM 1600	Dimension EXL with LM	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—	> 1,500/—	≥ 550/≥ 2,400 (> 75 countries)
Dimensions (H × W × D)/Instrument footprint	chem: 53.7 × 58.6 × 45.5 in.; immuno: 59.1 × 56.9 × 45.0 in./64.6 sq. ft.	48.7 × 56.1 × 41.1 in./16 sq. ft.	47 × 60 × 30 in./—
Weight empty/Weight fully loaded	chem: 1,036 lbs.; immuno: 1,265 lbs./—	788 lbs./788 lbs.	800 lbs./—
No. of different measured assays onboard simultaneously	variable based on configuration	47 (47 can be run and calibrated at one time)	24
No. of user-definable (open chemistry) channels	chem: 25 (25 can be active simultaneously); immuno: 0	15 (110 can be active simultaneously)	none
Test throughput per hour/Assay run time	chem: up to 1,800; immuno: up to 440/18–54 sec. (assay dependent)	627 (up to 440 photometric, 187 integrated multisensor technology, 167 immuno tests in throughput)/< 1–32 min. (avg. 8 min.)	up to 200 (200 tests in throughput)/—
<b>Chemistry:</b>			
No. of direct ion-selective electrode channels	0	3	—
Detection methods	photometry, potentiometry, turbidimetric, EMIT	photometry, potentiometry, luminescent oxygen channeling assay, heterogeneous immunoassay, particle enhanced turbidimetric inhibition immunoassay, antibody-conjugated magnetic immunoassay turbidimetric, enzyme-multiplied immunoassay technique	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	2 min./—	< 1 min. for sodium, potassium chloride, 2.2 min for carbon dioxide/—	—
• Basic metabolic panel	10 min./—	4 min./—	—
• Complete metabolic panel	10 min./—	9 min./—	—
Typical time delay from ordering stat test until aspiration of sample	60 sec. maximum	< 24 sec.	—
<b>Immunoassay:</b>			
Fully automated microplate immunoassay system	no	no	no
Methodologies supported	chemiluminescence, acridinium ester chemiluminescence	chemiluminescence	enzyme-amplified chemiluminescence
Separation methodologies	magnetic particle	none necessary	bead
Stat time until completion of a β-hCG test	10 min.	14 min.	35 min.
• Typical time delay from test order to aspiration of sample	60 sec. maximum	—	18 sec.
Stat time until completion of a cTn test	10 min.	—	35 min.
• Typical time delay from test order to aspiration of sample	60 sec. maximum	—	18 sec.
Approximate No. of tests per reagent set/Reagent type	50–2,100 (assay dependent)/self-contained multiuse, open reagent system	15–360/self-contained multiuse	200/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (4°–8°C)/yes	yes (2°–8°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 (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/300 min. or 9,000 tests (chem), up to 450 min. or 1,200 tests (immuno)	yes/60 min. or > 12,000 tests	yes/up to 300 min.
Design of sample-handling system	multiple rack drawer	sample wheel	rack
Uses washable cuvettes/Uses disposable cuvettes	chem: yes (can store up to 221 cuvettes)/immuno: yes (can store up to 1,200 cuvettes)	no/yes (can store up to 12,000 cuvettes)	no/yes (can store up to 1,300 cuvettes)
Min.–max. sample volume that can be aspirated at one time	2–50 µL (chem), 10–200 µL (immuno)	2–60 µL	5–600 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	assay dependent/assay dependent/container dependent	2 µL/2 µL/30 µL	—/5 µL/50 µL
Dedicated pediatric sample cup	no	yes (dead volume: 30 µL)	yes (dead volume: 50 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (8 × 31.75 mm)	yes/—	yes/yes (12–16 × 75–100 mm; 10 × 50 mm micro sample tubes)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	yes	no	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 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	yes (can be programmed to perform dilutions prior to analysis)/no carryover (immuno), <0.1 parts per million (chem)	yes (can be programmed to perform dilutions prior to analysis)/< 1 part per million	yes (can be programmed to perform dilutions prior to analysis)/< 3 parts per million
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	no	no
Analyzer requires dedicated water supply	yes (33 L/hr. consumption during operation for chemistry, 6 L/hr. for immunoassay)	yes (5 L/hr. consumption during operation)	no
Autocalibration/Multipoint calibration supported	yes (calibrants are stored onboard)/yes (recommended avg. frequency: 28–183 days [chem], 14–91 days [immuno])	yes (calibrants are stored onboard)/yes (recommended avg. frequency: 60–90 days)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 1–4 weeks [assay dependent])
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	every 4 hrs./28–63 days/40–180 days/up to 180 days/14–91 days	30–90 days/30–60 days/30–90 days/30–90 days/30–90 days	—/2 weeks/—/—/1–4 weeks (assay dependent)
Automatic programmable start/Automatic programmable shutdown	yes/no	no/no	— (4 min. warm-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 or direct to drain	direct to drain	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, 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	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	no
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	optional add-on (Siemens Atellica Data Manager)/—	onboard/—	optional add-on (Siemens Centralink Data Manager)/yes
LIS interface provided/Bidirectional interface capability	yes (incl. in price)/yes (broadcast download and host query)	yes (additional cost)/yes (broadcast download and host query)	yes/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/5 hrs. avg.	yes/2–8 hrs.	yes/2–8 hrs.
Mean time between failures	— (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: 10–15 min.; monthly: 10–15 min.	daily: 5 min.; weekly: 10 min.; monthly: < 25 min.	daily: 5–10 min.; weekly: 20 min.; monthly: 20–30 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	yes
Training included with purchase/Avg. time for basic user training	yes (3 training slots)/6.5 days (at customer and vendor sites)	yes (2 training slots)/3 days (at vendor site)	yes (2 training slots)/3 days (at customer and vendor sites)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer and vendor sites)/no	yes (at vendor site)/contract dependent	yes (at vendor site)/contract dependent
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/contract dependent	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>patented Atellica Magline bidirectional sample transport uses individual sample carriers for rapid throughput</li> <li>automated onboard calibration, QC</li> <li>microvolume sample technology for CC; IA controlled temperature requires no recalibration if laboratory ambient temp. changes</li> </ul>	<ul style="list-style-type: none"> <li>true integration of chemistry and immunoassay in one analyzer with a compact footprint</li> <li>10-min. high-sensitivity troponin</li> <li>low maintenance: 5 min. daily, &lt; 25 min. monthly</li> </ul>	<ul style="list-style-type: none"> <li>extensive routine and specialty immunoassay menu; includes menu of more than 300 allergens</li> <li>specific allergens and panels; provides opportunity to reduce sendouts and boost revenue</li> <li>reagent onboard stability of 90 days</li> </ul>
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 14 of 16	<b>Thermo Fisher Scientific/BRAHMS</b> info.brahms@thermofisher.com <b>Hennigsdorf, Germany</b> <b>+49(0)33028830</b> www.thermoscientific.com/kryptor	<b>Thermo Fisher Scientific</b> <b>John Karr</b> john.karr@thermofisher.com <b>Portage, MI</b> <b>800-346-4364</b> www.thermofisher.com/phadia	<b>Tosoh Bioscience</b> <b>Karen Wrona</b> karen.wrona@tosoh.com <b>South San Francisco, CA</b> <b>800-248-6764</b> www.diagnostics.us.tosohbioscience.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	B-R-A-H-M-S KRYPTOR GOLD	Phadia 250 Laboratory System	AIA-900
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	batch, random access, continuous random access/benchtop	continuous random access, discrete/floor standing	continuous random access/floor standing
List price/First year sold in U.S.	—	—/2004	—/2011
Targeted hospital bed size/Targeted test volume	—/daily: 600; monthly: 12,000; annual: 156,000	—/annual: > 20,000–95,000	—/monthly: 500–1,500
Company manufactures instrument	yes (also sold by distribution partners)	no (manufactured by Hitachi)	yes
Other models in this family of analyzers	B-R-A-H-M-S KRYPTOR compact PLUS	Phadia 1000, Phadia 2500, Phadia 5000 Laboratory Systems	AIA-360, AIA-2000
No. of units in clinical use in U.S./Outside U.S. (countries)	—/— (worldwide)	> 260/> 2,135	~350/> 1,200 (worldwide)
Dimensions (H × W × D)/Instrument footprint	28.74 (47.64 with tower light or open hood) × 36.61 × 28.34 in./55.11 in.	73 × 50 × 30 in. plus 26-in. wide computer stand/54 sq. ft.	49 × 35 × 26 in. (loader), 49 × 51 × 26 in. (9-tray sorter), 49 × 60 × 26 in. (19-tray sorter)/—
Weight empty/Weight fully loaded	260 lbs./—	485 lbs./—	404 lbs. (loader), 562 lbs. (9-tray sorter), 602 lbs. (19-tray sorter)/—
No. of different measured assays onboard simultaneously	16 (16 can be run and calibrated at one time)	6 (6 can be run and calibrated at one time)	45
No. of user-definable (open chemistry) channels	—	0	0
Test throughput per hour/Assay run time	115 (up to 115 tests in throughput)/9–59 min.	60 tests/100 min.	90/—
<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	no	no	—
Methodologies supported	fluorescence, enzyme immunoassay	fluoroenzyme immunoassay	fluorescence
Separation methodologies	none necessary	fiber matrix filter, coated microwell	—
Stat time until completion of a β-hCG test	14 min.	—	20 min.
• Typical time delay from test order to aspiration of sample	2 min.	—	—
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	50–100/self-contained multiuse	varies/self-contained multiuse	100/unit dose test cup
Reagents refrigerated onboard/Reagents ready to use	yes (2°–8°C)/yes	yes (2°–8°C for conjugates, ImmunoCAP, EIA wells; others at room temperature)/variable; reagent specific	no/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/no
Reagent form/Reagents barcoded	liquid chemistry (closed 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	yes/—
Walkaway capability/Walkaway duration	yes/430 min. or 18 specimens or 419 tests	yes/100 min.	yes/~ 2 hours or 45 specimens or 45 tests
Design of sample-handling system	sample cassette placed in sample carousel	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/no	no/no
Min.–max. sample volume that can be aspirated at one time	8–70 µL	20–40 µL	2–100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	150 µL/sample tube and assay dependent/150 µL sample tube dependent	40 µL (ImmunoCAP), 20 µL (EIA)/—/150 µL	10 µL/110 µL/100 µL
Dedicated pediatric sample cup	yes (dead volume: 75 µL)	no	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (11–17 × 60–120 mm)	yes/—	yes/—
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	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 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)/≤ 2 parts per million (no contamination)	yes/—	no/no carryover
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	no (1 L/hr. consumption during operation)	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/no	yes (calibrants are stored onboard)/yes (recommended avg. frequency: 28 days)	no (calibrants are stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/—/—/—/5–15 days	—/—/—/—/28 days	—/—/—/—/most assays are 90 days
Automatic programmable start/Automatic programmable shutdown	no/no	yes/yes	no (5 min. warm-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	yes
Waste management	manually by user or automated collection onboard instrument	automated collection onboard instrument or direct to drain	automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Code 93, EAN-8, Industrial 2 of 5, COOP 2 of 5)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, JAN)/yes
Lab can control analyzer from remote computer	no	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/—	onboard/Antek, Cerner, Data Innovations, Epic, GE TriplerG, McKesson, Meditech, NetLIMS, more	optional add-on (Tosoh 501RP+)/—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	—/yes (broadcast download and host query)	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	yes/Mon.–Fri.: 26 hrs. at total breakdown, 72 hrs. at workaroud	no/24 business hrs.	—
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	354 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 3 min.; weekly: 3 min.; monthly: 5 min.	daily: 5 min.; weekly: 10 min.; monthly: 3 hrs.	daily: 10 min.; weekly: 15 min.; monthly: 15 min.
Maintenance records kept onboard for user/vendor	yes/yes (both include audit trail of who replaced parts)	some records (date of instrument maintenance)/no	no/no
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes (1 training slot)/1.5–2 days (at customer site)	yes (2 training slots)/4 days (vendor site preferred, at customer site on request)	yes/2.5 days (at vendor site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/yes	yes (at vendor site)/—	no/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/contract dependent	yes (1 year)/—	yes (1 year from installation date)/—
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>ability to run allergy and autoimmune tests in the same run</li> <li>broad specific IgE whole allergen and allergen component menu</li> <li>master isotype calibration curves</li> </ul>	<ul style="list-style-type: none"> <li>unit dose test cup; dry reagent, no premixing or reagent preparation</li> <li>no interference from biotin; broad menu with fast results</li> <li>90-day calibration stability for most assays</li> </ul>
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 15 of 16	Tosoh Bioscience Karen Wrona karen.wrona@tosoh.com South San Francisco, CA 800-248-6764 www.diagnostics.us.tosohbioscience.com	Werfen Edward Bass ebass@werfen.com San Diego, CA 858-586-9900 www.werfen.com	Werfen Liliana Penaranda lpenaranda@werfen.com San Diego, CA 858-586-9900 www.werfen.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	AIA-2000	Aptiva	BIO-FLASH
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	continuous random access/floor standing	random access, continuous random access/benchtop	continuous random access/benchtop
List price/First year sold in U.S.	—/2008	—/2021	—/2012
Targeted hospital bed size/Targeted test volume	> 65/monthly; > 1,500	200/daily; 150; monthly; 3,000; annual: 36,000	—
Company manufactures instrument	yes (also sold by McKesson, Henry Schein, Thermo Fisher, Medline)	no	—
Other models in this family of analyzers	AIA-360, AIA-900	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	~80/> 1,000 (worldwide)	—/50	—
Dimensions (H x W x D)/Instrument footprint	AIA-2000 ST: 50 x 59 x 35 in./AIA-2000 LA: 50 x 59 x 47 in./14.6 sq. ft.	30 x 60 x 24 in./10 sq. ft.	21 x 34 x 24 in./—
Weight empty/Weight fully loaded	882 lbs./—	275 lbs./285 lbs.	170 lbs./—
No. of different measured assays onboard simultaneously	48 (48 can be run and calibrated at one time)	60 (60 can be run and calibrated at one time)	20 (20 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	0	—
Test throughput per hour/Assay run time	200 (18 min. to first result, 18 sec. for subsequent results)/18–58 min. (avg. 38 min.)	up to 720 (60 tests in throughput)/30 min.	60 (60 tests in throughput)/30 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	no	no	yes (50–100 tests per unit)
Methodologies supported	fluorescence, enzyme immunoassay	fluorescence	chemiluminescence
Separation methodologies	magnetic particle, bead	magnetic particle	magnetic particle, bead
Stat time until completion of a $\beta$ -hCG test	18 min.	—	—
• Typical time delay from test order to aspiration of sample	18 sec.	—	—
Stat time until completion of a cTn test	18 min.	—	—
• Typical time delay from test order to aspiration of sample	18 sec.	—	—
Approximate No. of tests per reagent set/Reagent type	100–200 (varies by assay)/self-contained single use	100–250/self-contained multiuse	50–100/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	no/yes	yes (5°C)/yes	yes/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	dry chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/yes	no/yes
Walkaway capability/Walkaway duration	yes/~3 hours or 200 specimens or 960 tests	yes/390 min. or 360 specimens or 3,960 tests	yes/30 specimens or 140 tests
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/yes (can store up to 728 cuvettes)	no/yes (can store up to 280 cuvettes)
Min.–max. sample volume that can be aspirated at one time	2–100 $\mu$ L	10–100 $\mu$ L	5 $\mu$ L minimum
Min. reaction volume/Min. specimen volume/Min. dead volume	10 $\mu$ L/10 $\mu$ L/100 $\mu$ L	10 $\mu$ L/10 $\mu$ L/50 $\mu$ L	20 $\mu$ L/5 $\mu$ L/200 $\mu$ L
Dedicated pediatric sample cup	no	no	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/no	yes/yes	yes/no
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; 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)/—	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	yes	yes	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	no	yes	no
Analyzer requires dedicated water supply	no	no	no
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 90 days)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 6 months)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: once per year)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/—/—/—/90 days	—/—/—/—/each lot or 6 months	—/—/—/—/once per year
Automatic programmable start/Automatic programmable shutdown	no/no	yes (10 min. warm-up time)/yes	yes (5 min. warm-up time)/yes
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	no
Waste management	automated collection onboard instrument or direct to drain	automated collection onboard instrument or direct to drain	automated collection onboard instrument or direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, JAN)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/—
Lab can control analyzer from remote computer	no	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	no (instrument can order parts without operator intervention)	no (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	no	yes	no
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/Orchard, Data Innovations, Sunquest, Cerner, MedLab, SCC Soft Computer, SchuyLab, IDEAS, more	onboard/Cerner, Sunquest, Meditech	onboard/—
LIS interface provided/Bidirectional interface capability	no/yes (host query)	yes/yes (broadcast download and host query)	—/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/within 24 hours	yes/12 hrs.	no/24 hrs.
Mean time between failures	106 days (displays error codes for troubleshooting)	180 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 5 min.; weekly: 5 min.; monthly: 10 min.	daily: 10 min.; weekly: 15 min.; monthly: 20 min.	daily: performed automatically; weekly: 5 min.; monthly: 15 min.
Maintenance records kept onboard for user/vendor	yes/yes (both include audit trail of who replaced parts)	yes/yes (includes audit trail of who replaced parts)	some records/some records
Maintenance training demonstration module onboard	no	yes	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/4 days (at vendor site)	yes (2 training slots)/3 days (at customer site)	yes/3 hrs. (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	no/—	yes (at customer site)/no	yes (at customer or vendor site)/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year from installation date)/—	yes (1 year)/—	yes/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> <li>• dry reagent with no biotin interference, unit dose test cup, 90-day calibration stability for most assays</li> <li>• 3 separate incubators to minimize processing time; dual clot detection, automated dilutions, and pretreatment</li> <li>• available in 2 models—standard (ST) and line automation (LA)—appropriate for stat and routine use</li> </ul>	<ul style="list-style-type: none"> <li>• multianalyte system allows simultaneous analysis of up to 12 analytes</li> <li>• introduces novel analytes to improve utility of autoimmune diagnosis</li> <li>• 6.5-hour walkaway time with 10-minute daily maintenance</li> </ul>	<ul style="list-style-type: none"> <li>• improves laboratory workflow and productivity; eliminates batching and reagent waste with stable onboard reagents</li> <li>• delivers results, including stat orders, in 30 min. and allows serum and fecal samples to be run simultaneously</li> <li>• generates up to 450 results in a single shift and makes even the most specialized assays efficient to perform</li> </ul>

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

