

Part 1 of 16

FOR MID- AND HIGH-VOLUME LABORATORIES

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Name of instrument	Alinity ci-series	ACE Excel	ASI Evolution RPR Syphilis Analyzer
Type of instrument	combination chemistry/immunoassay	chemistry	immunoassay
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	batch, random access, continuous random access, discrete/benchtop	batch/benchtop
List price/First year sold in U.S.	—/2018	\$34,500/2012	\$50,995/2018
Targeted hospital bed size/Targeted test volume	all/—	—/daily: ~15–50 comprehensive metabolic panels and lipids	—/daily: 100; monthly: 3,100; annual: 37,200
Company manufactures instrument	yes	yes (also sold by McKesson, Henry Schein, Medline, AvMedical)	yes (also sold by Fisher Scientific, Cardinal, McKesson, VWR)
Other models in this family of analyzers	—	ACE Alera	—
No. of units in clinical use in U.S./Outside U.S. (countries)	~ 1,300/~ 8,800 (154 countries)	—	19/—
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	33 × 28 × 26 in./10 sq. ft.	19 × 36 × 22 in./6 sq. ft.
Weight empty/Weight fully loaded	chem: 1,556 lbs.; immuno: 1,371 lbs./—	150 lbs./150 lbs.	78 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)	40 (200 can be run and calibrated at one time)	1 (0 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)	0
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/—	190 (1 test in throughput)/—
Chemistry:			
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	—
• Basic metabolic panel	—	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	< 30 sec.	10 sec.	—
Immunoassay:			
Fully automated microplate immunoassay system	no	—	yes (48 wells per microplate)
Methodologies supported	chemiluminescence	—	agglutination
Separation methodologies	magnetic particle	—	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	up to 1,500 (chem), up to 600 (immuno)/self-contained multiuse	30–900/closed reagent system with open reagent channels	varies/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (2°–10°C [chemistry], 2°–12°C [immunoassay])/yes	yes (10°–14°C)/yes	no/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/no
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (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 up to 600 specimens (150 specimens per module)	yes/75 min. or 75 specimens or 248 tests	yes/62 min. or 192 specimens or 192 tests
Design of sample-handling system	6-position rack	ring	rack
Uses washable cuvettes/Uses disposable cuvettes	chem: yes/immuno: yes (can store up to 1,000 cuvettes)	no/yes (can store up to 248 cuvettes)	no/—
Min.–max. sample volume that can be aspirated at one time	1.5–35 µL (chemistry), 2–200 µL (immunoassay)	3–200 µL	2–500 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	80 µL/assay dependent/50 µL	150 µL/53 µL/50 µL	110 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 (10–16.1 × 72–102 mm)	—	yes/no
Pierces caps on primary tubes	no	yes	no
Protects against probe collision	yes	no	yes
Detects clots/liquid level/short sample	yes/yes/yes	no/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for hemolysis, icterus, lipemia, clots; quantitation for hemolysis, icterus, lipemia	hemolysis, icterus, lipemia, clots not available	detection for clots; hemolysis, icterus, lipemia not available
Dilutes patient samples onboard/Susceptibility to carryover	yes/≤ 0.1 parts per million	yes (can be programmed to perform dilutions prior to analysis)/—	no/—
Automatic rerun capability	yes	yes	no
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	no
Sample volume can be concentrated to rerun out-of-linear-range low results	—	no	no
Analyzer requires dedicated water supply	yes (27 L/hr. consumption during operation for chemistry, <10 L/hr. for immunoassay)	no	no (0.03 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	yes (calibrants are stored onboard)/yes	yes (calibrants are not stored onboard)/yes	no (calibrants are not stored onboard)/no
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	yes/yes	no/no
Supports multiple QC lot numbers per analyte	yes	yes	no
Waste management	automated collection onboard instrument or direct to drain	automated collection onboard instrument	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (UPC, Code 39, Code 128)/no
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	no	yes
UPS backup power supply	yes	no	no
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/CGM LabDaa, Orchard, CGM SchuyLab, LabTrak, more	onboard/—
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download and host query)	no/yes (host query)	no/no
Modem servicing provided/Service engineer on-site response time	—/based on contract	yes/24 hrs.	no/48 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	240 days (displays error codes for troubleshooting)	365 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: 15 min.; weekly: 20–30 min.; monthly: 30–40 min.	daily: 10 min.; weekly: 10 min.; monthly: 10 min.
Maintenance records kept onboard for user/vendor	some records (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	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)/4.5 days (at customer and vendor sites [depends on sales agreement])	yes (2 training slots)/0.5 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer or vendor site)/yes	no/—	no/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (varies by contract)/varies by contract	yes (1 year)/—	yes (1 year limited, service contract required)/varies by tier of service
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> compact, flexible, and scalable up to four modules and 14 configurations harmonized family of systems across key lab disciplines leading to easier cross-training for lab staff broad menu of high-quality assays aligned to CLSI guidelines 	<ul style="list-style-type: none"> self-contained analyzer; closed-tube sampling; stat interrupt capability; onboard sample, reagent refrigeration; ready-to-use reagents; onboard reagent inventory management integrated ISE module; no external water source or waste drainage Internet connectivity allows for external technical support, remote access, and laboratory integration 	<ul style="list-style-type: none"> 190 RPR syphilis tests per hour low-cost, automated syphilis test can provide titers up to 1:2048

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

Part 2 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	Beckman Coulter Onyi Nacionales onacionales@beckman.com Brea, CA 800-526-3821 www.beckmancoulter.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	AU 5800	DxC 700 AU	Unicel DxI 600
Type of instrument	chemistry	chemistry	immunoassay
Operational type/Model type	continuous random access/floor standing	continuous random access/floor standing	continuous random access/floor standing
List price/First year sold in U.S.	—/2011	—/2016	—/2006
Targeted hospital bed size/Targeted test volume	—/annual: ≥ 1.5 million	—/annual: 500,000–1.5 million	—
Company manufactures instrument	yes (also sold by McKesson, Henry Schein, Medline)	yes (also sold by McKesson, Henry Schein, Medline)	yes (also sold by McKesson, Henry Schein, Medline)
Other models in this family of analyzers	DxC 700 AU, AU480	AU480, AU 5800	Access 2, Unicel DxI 800
No. of units in clinical use in U.S./Outside U.S. (countries)	—	—	—
Dimensions (H × W × D)/Instrument footprint	50 × 168 × 62 in./72 sq. ft.	51 × 78 × 41 in./40.1 sq. ft.	67 × 61.5 × 37.5 in./16 sq. ft.
Weight empty/Weight fully loaded	2,300–6,375 lbs. (model dependent)/—	1,046 lbs./—	1,065 lbs./—
No. of different measured assays onboard simultaneously	54–216 (54–216 can be run and calibrated at one time) (model dependent)	63 (63 can be run and calibrated at one time)	50 (50 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	18 (76 can be active simultaneously)	18 (120 can be active simultaneously)	0
Test throughput per hour/Assay run time	2,000–9,800/8 min. 30 sec.	1,200 (800 photometric, 400 ISE tests in throughput)/8 min. 30 sec.	up to 200/13–55 min.
Chemistry:			
No. of direct ion-selective electrode channels	3	3	—
Detection methods	photometry, potentiometry	photometry, potentiometry	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	4.5 min./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.	—
Immunoassay:			
Fully automated microplate immunoassay system	—	—	no
Methodologies supported	—	—	chemiluminescence
Separation methodologies	—	—	magnetic particle
Stat time until completion of a β-hCG test	—	—	15 min.
• Typical time delay from test order to aspiration of sample	—	—	18 sec.
Stat time until completion of a cTn test	—	—	17 min.
• Typical time delay from test order to aspiration of sample	—	—	18 sec.
Approximate No. of tests per reagent set/Reagent type	200–6,000 (varies by assay)/self-contained multiuse	200–2,000 (varies by assay)/self-contained multiuse	50 per pack or 100 per kit/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (4°–12°C)/yes	yes (4°–12°C)/yes	yes (4°–10°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (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/400 specimens	yes/2 hrs. avg. or 150 specimens or 7,200 tests	yes/180 min. or 60 specimens
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	yes/no	yes/no	no/yes (can store > 1,000 cuvettes)
Min.–max. sample volume that can be aspirated at one time	1–25 µL	1–25 µL	5–200 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	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	10 µL/150 µL/140 µL
Dedicated pediatric sample cup	yes (dead volume: 50 µL)	yes (dead volume: 50 µL)	yes (dead volume: 100 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (primary, secondary tubes: 11.5–16 × 55–102 mm; nested micro cups)	yes/yes (primary, secondary tubes: 11.5–16 × 55–102 mm; nested micro cups)	yes/—
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 and quantitation for hemolysis, icterus, lipemia, clots	detection and quantitation for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/0.001 parts per million	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)/—
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	no
Analyzer requires dedicated water supply	yes (62–248 L/hr. consumption during operation) (model dependent)	yes (28 L/hr. consumption during operation)	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	1 day/14 days/14–20 days/30 days/—	1 day/14 days/14–20 days/30 days/—	—/—/—/28 days
Automatic programmable start/Automatic programmable shutdown	yes (90 sec. warm-up time)/yes	yes (90 sec. warm-up time)/yes	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	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)/no
Lab can control analyzer from remote computer	yes	yes	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/Cerner, Antrim, CCA, Chemware, Dawning Technologies, SCC, Dynamic Healthcare, Antek, more	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	yes (included in instrument price)/yes (broadcast download and host query)	yes (included in instrument price)/yes (broadcast download and host query)	yes (included in instrument price)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/within 24 hrs.	yes/within 24 hrs.	yes/within 24 hrs.
Mean time between failures	1.2 down service calls per year (displays error codes for troubleshooting)	1.1 down service calls per year (displays error codes for troubleshooting)	3.1 down service calls per year (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 8 min.; weekly: 15 min.; monthly: 45 min.	daily: 6 min.; weekly: 10 min.; monthly: 45 min.	daily: < 10 min.; weekly: 15 min. at 5,000 tests; monthly: 35 min. at 10,000 tests
Maintenance records kept onboard for user/vendor	yes/no	yes/no	yes/no
Maintenance training demonstration module onboard	yes	yes	yes
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/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)	yes (2 training slots)/3 days (at vendor site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/yes	yes (at vendor site)/yes	yes (at vendor site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> standardization across the AU family of chemistry analyzers lower total cost of ownership due to fewer consumables and concentrated reagents most common parts can be changed in three steps in less than 60 seconds and without tools 	<ul style="list-style-type: none"> standardization across the AU family of chemistry analyzers lower total cost of ownership due to fewer consumables and concentrated reagents most common parts can be changed in three steps in less than 60 seconds and without tools 	<ul style="list-style-type: none"> onboard aliquoting quickly frees samples for other analyses scalable results across all immunoassay systems liquid, ready-to-use reagents
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 3 of 16 FOR MID- AND HIGH-VOLUME LABORATORIES	Beckman Coulter Onyi Nacionales onacionales@beckman.com Brea, CA 800-526-3821 www.beckmancoulter.com	Binding Site Darrell Majewski darrell.majewski@bindingsite.com San Diego, CA 858-291-4556 www.us.bindingsite.com	Bio-Rad Laboratories Clinical Diagnostics Group Maria Crisostomo maria_crisostomo@bio-rad.com Hercules, CA 800-224-6723 www.bio-rad.com
Name of instrument	Unicel DxI 800	Optilite	BioPlex 2200 System
Type of instrument	immunoassay	chemistry	immunoassay
Operational type/Model type	continuous random access/floor standing	continuous random access/benchtot	continuous random access/floor standing
List price/First year sold in U.S.	—/2003	\$111,521/2015	—/2006
Targeted hospital bed size/Targeted test volume	—	> 100/daily: > 50; monthly: ~1,000; annual: ~12,000	—/daily: ~800 samples
Company manufactures instrument	yes (also sold by McKesson, Henry Schein, Medline)	no (manufactured by Thermo Fisher)	yes
Other models in this family of analyzers	Access 2, Unicel DxI 600	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—	282/596 (Spain, Germany, France, UK, Italy, Denmark, more)	—/— (Australia, Canada, Czech Republic, France, Germany, Hong Kong, Israel, Italy, Japan, New Zealand, Norway, more)
Dimensions (H × W × D)/Instrument footprint	67 × 67.5 × 37.5 in./17.5 sq. ft.	24.4 × 37 × 27.6 in./7.09 sq. ft.	53 × 72 × 34 in./12.9 sq. ft.
Weight empty/Weight fully loaded	1,390 lbs./—	242 lbs./~260 lbs.	1,032 lbs./—
No. of different measured assays onboard simultaneously	50 (50 can be run and calibrated at one time)	34 (34 can be run and calibrated at one time)	51 (51 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	10	—
Test throughput per hour/Assay run time	up to 400/13–55 min.	108 (108 tests in throughput)/8–23 min. (avg. 13 min.)	up to 2,200 (up to 22 tests in throughput)/avg. 45 min. (assay dependent)
Chemistry:			
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	—	—	—
Immunoassay:			
Fully automated microplate immunoassay system	no	—	no
Methodologies supported	chemiluminescence	—	multiplex flow (cytometric)
Separation methodologies	magnetic particle	—	magnetic particle
Stat time until completion of a β-hCG test	15 min.	—	—
• Typical time delay from test order to aspiration of sample	18 sec.	—	—
Stat time until completion of a cTn test	17 min.	—	—
• Typical time delay from test order to aspiration of sample	18 sec.	—	—
Approximate No. of tests per reagent set/Reagent type	50 per pack or 100 per kit/self-contained multiuse	100/self-contained multiuse	100 (assay panel dependent), 200 (HIV, vitamin D, Lyme total), 150 (ToRC IgM)/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (4°–10°C)/yes	yes (8°–10°C below ambient)/yes	yes (2°–8°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	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/180 min. or 120 specimens	yes/90 min. or 54 specimens or 180 tests	yes/480 min. or 800 specimens or 9,600 tests
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 1,000 cuvettes)	no/yes (can store up to 360 cuvettes)	no/—
Min.–max. sample volume that can be aspirated at one time	5–200 µL	2–200 µL	3–150 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	10 µL/150 µL/140 µL	120 µL/assay dependent/150 µL	3 µL/350 µL (tube size dependent)/250 µL
Dedicated pediatric sample cup	yes (dead volume: 100 µL)	yes (dead volume: 150 µL)	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/—	yes/yes (13 × 75 mm, 12 × 75 mm)	yes/no
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available	detection for hemolysis, clots; 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)/—	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/<1 part per million
Automatic rerun capability	yes	yes	no
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	no	yes	no
Analyzer requires dedicated water supply	no	no (2 L/hr. consumption during operation)	no (0.5 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: per lab protocol and every new lot)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 30 days [assay dependent])
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—/—/—/—/28 days	—	—/—/—/—/30 days (assay dependent)
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	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	no	yes
Waste management	direct to drain	automated collection onboard instrument	manually by user or 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)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	yes	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	no (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	no	yes
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/Cerner, Antrim, CCA, Chemware, Dawning Technologies, SCC, Dynamic Healthcare, Antek, more	onboard/Epic, Sunquest, Orchard, Cerner, SCC Soft Computer	onboard/Antrim, CCA, Cerner, Sunquest, CGM Schuyllab, Data Innovations, SCC Soft Computer, Meditech, Orchard, more
LIS interface provided/Bidirectional interface capability	yes (included in instrument price)/yes (broadcast download and host query)	yes (additional cost)/yes (broadcast download and host query)	no/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/within 24 hrs.	no/next business day	yes/< 24 hrs.
Mean time between failures	5.1 down service calls per year (displays error codes for troubleshooting)	240 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	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.	daily: 5 min.; weekly: 30 min.; monthly: ~60 min.
Maintenance records kept onboard for user/vendor	yes/no	some records (log)/no	yes/yes (both include audit trail of who replaced parts)
Maintenance training demonstration module onboard	yes	no	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/3 days (at vendor site)	yes (2 training slots)/2 days (primarily at customer site)	yes (2 training slots)/5 days (at vendor site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/yes	yes (at customer site)/\$2,500	no/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/\$12,950	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • one of the highest throughputs from a single analyzer • liquid, ready-to-use reagents • onboard aliquoting quickly frees samples for other analyses 	<ul style="list-style-type: none"> • reduced carryover due to disposable cuvettes • dilution cascade to final result • intuitive software that includes three different antigen excess protection methods, optimized by assay 	<ul style="list-style-type: none"> • full random-access automation with innovative multiplex chemistry; internal QC beads run simultaneously with each sample • compatible track line connectivity option • CylancePROTECT Antivirus program provides digital protection against malware
<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

FOR MID- AND HIGH-VOLUME LABORATORIES

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Name of instrument	EVOLIS	PhD Ix	PR4100 Microplate Reader
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	batch, random access/benchtop	batch/benchtop	batch/benchtop
List price/First year sold in U.S.	—/2001	—/2012	—/2012
Targeted hospital bed size/Targeted test volume	> 50/up to 360 samples per shift	—/daily: 50–200 samples	—
Company manufactures instrument	no (manufactured by Stratec)	yes	yes
Other models in this family of analyzers	—	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—	—	—
Dimensions (H × W × D)/Instrument footprint	37 × 44 × 30 in./10 sq. ft.	30 × 36 × 27 in./7 sq. ft.	5.3 × 13.7 × 7.4 in./—
Weight empty/Weight fully loaded	209 lbs./—	112 lbs./—	5.7 lbs./—
No. of different measured assays onboard simultaneously	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	—	—	—
Chemistry:			
No. of direct ion-selective electrode channels	—	—	—
Detection methods	—	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	—
• Basic metabolic panel	—	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	—	—	—
Immunoassay:			
Fully automated microplate immunoassay system	yes (96 wells per microplate)	yes (96 tests per unit containing up to 8 different assays; 96 wells per microplate)	no
Methodologies supported	enzyme immunoassay	fluorescence, enzyme immunoassay	enzyme immunoassay
Separation methodologies	coated microwell	none necessary	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	192/self-contained multiuse	192/open reagent system	—
Reagents refrigerated onboard/Reagents ready to use	no/yes	no/yes	no/—
Reagent lot tracking/Reagent inventory	yes/no	yes/no	no/no
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/no	liquid chemistry (open reagent system)/—
Separate reagent pack for each specimen/for each test run	no/no	no/no	—
Walkaway capability/Walkaway duration	yes/180 specimens or 4 tests	yes/192 specimens or 8 EIA or 4 IFA assays	no/—
Design of sample-handling system	—	benchtop, reagent rack	batch, benchtop
Uses washable cuvettes/Uses disposable cuvettes	no/yes	no/no	no/no
Min.–max. sample volume that can be aspirated at one time	10–100 µL	1–100 µL	—
Min. reaction volume/Min. specimen volume/Min. dead volume	10 µL/10 µL/100 µL	1 µL/1 µL/150 µL	—
Dedicated pediatric sample cup	no	no	no
Primary tube sampling	yes	yes	no
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/no	yes/yes (12–13 × 100 mm, 75 × 100 mm)	no (microplate reader)/no (microplate reader)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	no	no
Detects clots/liquid level/short sample	yes/yes/yes	no/yes/yes	yes/yes/no
Detection or quantitation for hemolysis, icterus, lipemia, clots	hemolysis, icterus, lipemia, clots 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)/—	yes (can be programmed to perform dilutions prior to analysis)/—	no/—
Automatic rerun capability	no	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 (0.5 L/hr. consumption during operation)	no	no
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: each run)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: each run)	no (calibrants are not stored onboard)/no
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—/—/—/—/each run	—/—/—/—/each run	—
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	no/yes	no/no
Supports multiple QC lot numbers per analyte	yes	no	no
Waste management	manually by user or automated collection onboard instrument	manually by user or automated collection onboard instrument	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (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	no	no
Instrument can diagnose its own malfunctions	no (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	no	no	no
UPS backup power supply	yes	yes	no
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/—	no/—
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download)	no/yes (broadcast download and host query)	no/no
Modem servicing provided/Service engineer on-site response time	yes/24 hrs.	no/24 hrs.	no/—
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	—
Average scheduled maintenance time by lab personnel	daily: 5 min.; monthly: < 60 min.	daily: < 5 min.; < weekly: 15 min.; monthly: < 30 min.	—
Maintenance records kept onboard for user/vendor	yes/yes (includes audit trail of who replaced parts)	no/no	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 customer site)	yes (2 training slots)/2 days (at customer site)	yes (2 training slots)/1 day (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/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> fully automated system that performs EIA assays with positive sample identification network workstations for higher throughput semi-open system with bidirectional LIS and comprehensive range of assays 	<ul style="list-style-type: none"> open platform with assay programming wizard and capability to run IFA and EIA methods on a single instrument accurate delivery of volumes as low as 1 µL unique IFA hyperwash, resulting in lower background fluorescence 	<ul style="list-style-type: none"> comprehensive data-analysis software for full traceability LIS connectivity compact size—space saver

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

Part 5 of 16	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	Diatron Frank Matuszak frank.matuszak@diatron.com Medley, FL 833-228-7931 www.diatron.com
Name of instrument	VIDAS 3	LIAISON XL	Pictus 700 (P700)
Type of instrument	immunoassay	immunoassay	chemistry
Operational type/Model type	batch, random access, continuous random access/ benchtop	batch, random access, continuous random access, discrete/ floor standing	batch, random access, continuous random access, discrete/floor standing
List price/First year sold in U.S.	—/2015	—/2010	\$60,190/2013
Targeted hospital bed size/Targeted test volume	—	> 300/≥ 50,000	50–250/daily: 1,000–4,000; monthly: 30,000–120,000; annual: 365,000–1,460,000
Company manufactures instrument	yes	no	—
Other models in this family of analyzers	VIDAS, MINI VIDAS	LIAISON XS	Pictus 500 (P500)
No. of units in clinical use in U.S./Outside U.S. (countries)	> 500/—	> 600/> 4,100	< 100/> 750 (Europe, Latin America, Africa, Middle East, Asia)
Dimensions (H × W × D)/Instrument footprint	24 × 29.5 × 25.5 in./5.2 sq. ft.	59 × 59 × 36 in./14.6 sq. ft.	39.4 × 38.1 × 26.4 in./7.1 sq. ft.
Weight empty/Weight fully loaded	154 lbs./—	—/661 lbs.	418 lbs./478 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)	72 (up to 72 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.)	720/30–1,200 sec. (avg. 300 sec.)
Chemistry:			
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.
Immunoassay:			
Fully automated microplate immunoassay system	no	no	—
Methodologies supported	enzyme-linked fluorescent assay (ELFA) technology	chemiluminescence	—
Separation methodologies	—	magnetic particle	—
Stat time until completion of a B-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	50–200 per set, 400–1,800 per pack/self-contained multiuse, open reagent system
Reagents refrigerated onboard/Reagents ready to use	no/yes	yes (12°C)/yes	yes (8° ±2°C)/yes
Reagent lot tracking/Reagent inventory	yes/—	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/no
Separate reagent pack for each specimen/for each test run	yes/yes	no/no	no/no
Walkaway capability/Walkaway duration	yes/27 specimens or 12 tests	yes/360 min. or 120 specimens or 1,000 tests	yes/180 min. or 95 specimens or 1,800 tests
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/—	no/yes (can store up to 1,000 cuvettes)	yes/yes (can store up to 160 cuvettes)
Min.–max. sample volume that can be aspirated at one time	100–300 µL	50–1,000 µL	2–100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	100 µL/100 µL/125 µL for aliquot tubes	—/5 µL/150 µL	180 µL/22 µL/100 µL
Dedicated pediatric sample cup	yes	yes (dead volume: 50 µL)	yes (dead volume: 20 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/—	yes/yes	yes/no
Pierces caps on primary tubes	no	no	no
Protects against probe collision	—	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	—	detection for clots; hemolysis, icterus, lipemia not available	detection for 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	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/30 parts per million
Automatic rerun capability	no	yes	yes
Sample volume can be diluted to rerun out-of-linear-range high results	yes	no	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	no	no	yes
Analyzer requires dedicated water supply	no	no	no (< 3 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	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])	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 7 days)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—/—/—/—/every 14–28 days	—	8 hr./—/7 days/14 days/14 days
Automatic programmable start/Automatic programmable shutdown	yes (5 min. warm-up time)/yes	no/no	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	manually by user or automated collection onboard instrument	automated collection onboard instrument or direct to drain	manually by user or direct to drain
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)/no	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no
Lab can control analyzer from remote computer	yes	no	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	no (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/Cerner, SCC Soft Computer, Meditech, Epic, more	onboard/Cerner, Epic, Sunquest, Vistar, SCC Soft Computer, Orchard, Meditech, Comtron, ApolloLIMS, LabWare, more	onboard/AP Visions, Medicus, CGM Schuyllab, Labtrack, CGM LabDaq, Medytox
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/< 24 hrs.	yes/24 hrs.	no/48 hrs.
Mean time between failures	> 1 year (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	1 year (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.	daily: 30 min.; weekly: 1 hr.; monthly: 2 hr.
Maintenance records kept onboard for user/vendor	yes/no	yes/no	no/no
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes/— (at customer site)	yes (3 training slots)/— (at customer site)	yes (2 training slots)/3 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	—	yes (at vendor site)/—	yes (at customer or vendor site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/\$5,500
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> reliable, easy-to-use benchtop immunoassay system with a mean time between failure of more than a year routine and emergency (stat) testing in a ready-to-use assay format adaptable to batch or single test runs specialty menu of critical care and infectious diseases assays 	<ul style="list-style-type: none"> secure traceability of all processes, status of reagents, and consumables disposable pipette tips prevent sample carryover no daily maintenance—instrument monitors maintenance needs 	<ul style="list-style-type: none"> uninterrupted workflow Windows-based, intuitive, user-friendly software high-quality components for long stability and result reliability

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

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FOR MID- AND HIGH-VOLUME LABORATORIES

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ELITechGroup
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Name of instrument	DZ-Lite 3000 Plus	Agility Automated ELISA System	Envoy 500/Envoy 500+ Chemistry Analyzer
Type of instrument	immunoassay	immunoassay	chemistry
Operational type/Model type	batch, random access/floor standing	batch/benchtop	batch, random access, continuous random access, discrete/benchtop
List price/First year sold in U.S.	\$60,000/2017	—/2012	\$85,000/2004 (Envoy 500), 2014 (Envoy 500+)
Targeted hospital bed size/Targeted test volume	—/daily: 1,000; monthly: 30,000; annual: 350,000	—	—/daily: 20–80 patients; monthly: 4,200–17,000; annual: 50,000–200,000
Company manufactures instrument	no (manufactured by SNIBE Diagnostics)	yes	no (also sold by McKesson, RedByrd, Henry Schein)
Other models in this family of analyzers	—	DSX	—
No. of units in clinical use in U.S./Outside U.S. (countries)	55/1 (Philippines, Netherlands)	—/425 (worldwide)	250/—
Dimensions (H × W × D)/Instrument footprint	59.8 in. × 56.7 in. × 30 ft./—(3.5 ft. recommended clearance)	49 × 50 × 36 in./8.7 sq. ft.	27 × 40 × 23 in./10 sq. ft.
Weight empty/Weight fully loaded	502 lbs./—	469 lbs./—	209 lbs./219 lbs.
No. of different measured assays onboard simultaneously	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)	40 (40 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	— (up to 16 can be active simultaneously)	500 (40 can be active simultaneously)
Test throughput per hour/Assay run time	180 (180 tests in throughput, assay dependent)/15–45 min. (avg. 30 min.)	assay dependent (up to 1,536 tests per run)/assay dependent	490/—
Chemistry:			
No. of direct ion-selective electrode channels	—	—	4
Detection methods	—	—	potentiometry
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.
Immunoassay:			
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	100/self-contained multiuse	—/open system with self-contained multiuse SmartKit	varies/open reagent system
Reagents refrigerated onboard/Reagents ready to use	yes (10°)/yes	no (23° ±4°C)/yes	yes (10°–15°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 (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/144 specimens or 1,500 tests	yes/up to 1,152 specimens or up to 1,152 tests	yes/240 min. or 52 specimens or > 1,000 tests/assays
Design of sample-handling system	rack	rack	ring
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 700 cuvettes)	no/no	yes/no (can store up to 34 cuvettes)
Min.–max. sample volume that can be aspirated at one time	5–300 µL	10–300 µL	1–100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	200 µL/120 µL/100 µL	10 µL/—/—	300 µL/1 µL/100 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/yes (17 × 100 mm)	yes/yes
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
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)/—	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	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	no	no	no
Analyzer requires dedicated water supply	no	no	no (1 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	no (calibrants can be stored onboard)/yes (recommended avg. frequency: 7 days)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)	no (calibrants are not stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/—/—/—/7 days	—/assay dependent/assay dependent/—/assay dependent	4 hrs./—/—/7–31 days/—
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	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	yes	yes
Waste management	manually by user or direct to drain	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, EAN 8/13, Code 93, UPCA/UPCE)/yes	yes (UPC, Codabar, Code 39, Code 128, Code 93)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no
Lab can control analyzer from remote computer	yes	no	no
Instrument can diagnose its own malfunctions	yes (instrument can order parts without operator intervention)	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/Orchard, Cerner	onboard/CGM LabDaq, CGM SchuyLab, McKesson Horizon Lab, Medicus Solutions, more
LIS interface provided/Bidirectional interface capability	no/yes (host query)	no/yes (host query)	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	no/24 hrs.	no/24 hrs.	no/24 business hrs.
Mean time between failures	1 year (displays error codes for troubleshooting)	200 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 20 min.; weekly: 20 min.; monthly: 90 min.	daily: 10 min.; weekly: 5 min.	weekly: 15 min.; monthly: 15 min.
Maintenance records kept onboard for user/vendor	no/no	no/no	yes/no
Maintenance training demonstration module onboard	yes	no	no
Training included with purchase/Avg. time for basic user training	yes (as many training slots as needed)/2 hours (at customer site)	no/3 days (at customer site)	yes (2 training slots)/3 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer site)/no	yes (at customer site)/yes	yes (at customer site)/no
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/\$8,995 (M–F, 8 AM–7 PM)
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • unique menu • advanced chemiluminescent technology • for clinical and research applications 	<ul style="list-style-type: none"> • increases productivity—full walkaway processing from beginning of testing with up to 16 SmartKit carriers stored • practical automation—assesses testing requirements, develops efficient work list, continuous sample loading • value—frees up labor time, allows for multitasking by eliminating most of ELISA labor 	<ul style="list-style-type: none"> • fast benchtop chemistry system • reusable glass cuvettes eliminate cost of disposable cuvettes • 4-parameter (Na+, K+, Cl-, CO2) dry electrodes reduce costs and maintenance time, increase reliability of results

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

Part 7 of 16	EUROIMMUN Medizinische Labordiagnostika Product Management Auto. automation-pm@euroimmun.de Luebeck, Germany +49 451 2032-0 www.euroimmun.com	EUROIMMUN Medizinische Labordiagnostika Product Management Auto. automation-pm@euroimmun.de Luebeck, Germany +49 451 2032-0 www.euroimmun.com	FUJIFILM Healthcare Americas Corp. Amador Alejo wakodx-customerservice@fujifilm.com Lexington, MA 877-714-1924 www.ivd.fujimed.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	EUROLabWorkstation ELISA	EUROLabWorkstation IFA	µTASWako i30
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	batch/benchtop	batch/benchtop	random access/benchtop
List price/First year sold in U.S.	—/2017	—/2019	—/2011
Targeted hospital bed size/Targeted test volume	—/> 3,000	—/up to 3,000	—
Company manufactures instrument	yes (also sold by EUROIMMUN US)	yes (also sold by EUROIMMUN US)	no (manufactured by FUJIFILM Wako Pure Chemical Corp.)
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)
Dimensions (H × W × D)/Instrument footprint	~34 × 129 × 32 in./—	~34 × 115 × 32 in./—	21.5 × 20.5 × 23.4 in./3.34 sq. ft.
Weight empty/Weight fully loaded	~760 lbs./~990 lbs.	~760 lbs./~990 lbs.	157 lbs./—
No. of different measured assays onboard simultaneously	180 (180 can be run and calibrated at one time)	75 (75 can be run and calibrated at one time)	6 (6 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	—	0
Test throughput per hour/Assay run time	> 200 (assay dependent)/—	> 200 (assay dependent)/—	25/—
Chemistry:			
No. of direct ion-selective electrode channels	—	—	—
Detection methods	—	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	—
• Basic metabolic panel	—	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	—	—	—
Immunoassay:			
Fully automated microplate immunoassay system	yes (180 tests per unit; 96 wells per microplate)	no	no
Methodologies supported	enzyme immunoassay	fluorescence	fluorescence
Separation methodologies	coated microwell	BIOCHIPS on indirect immunofluorescence slides	microcapillary gel electrophoresis
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	96/open reagent system	up to 1,200/self-contained multiuse	100/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	no/yes	no/yes	yes (2°–10°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/no
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/up to 480 min. or 800 specimens or 1,440 tests	yes/up to 360 min. or ~ 700 specimens or 750 tests	yes/190 min. or 50 specimens or 80 tests
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 1,440 cuvettes)	no/no	no/no
Min.–max. sample volume that can be aspirated at one time	5–1,100 µL	5–1,100 µL	3 µL minimum
Min. reaction volume/Min. specimen volume/Min. dead volume	100 µL/5 µL/75 µL	100 µL/5 µL/75 µL	—/75 µL/72 µL
Dedicated pediatric sample cup	yes (dead volume: 75 µL)	yes (dead volume: 75 µL)	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (10–16 × 100 mm)	yes/yes (10–16 × 100 mm)	yes/yes
Pierces caps on primary tubes	no	no	no
Protects against probe collision	yes	yes	yes
Detects clots/liquid level/short sample	no/yes/yes	no/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots	detection for clots	hemolysis, icterus, lipemia, clots not available
Dilutes patient samples onboard/Susceptibility to carryover	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	no/0.1 parts per million
Automatic rerun capability	no	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	no	no	no
Analyzer requires dedicated water supply	no	no	no
Autocalibration/Multipoint calibration supported	no/yes (recommended avg. frequency: each run)	no/—	yes (calibrants are not stored onboard)/—
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—/—/—/—/each run	—/—/—/—/assay dependent	—
Automatic programmable start/Automatic programmable shutdown	—	—	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
Waste management	automated collection onboard instrument or direct to drain	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, Data Matrix)/—	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Data Matrix)/—	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ITF, EAN/JAN-13, EAN/JAN-18, STF(5BER), EAN-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)	no (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/—	onboard/—	onboard/—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (host query)	yes (additional cost)/yes (host query)	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	yes/—	yes/—	no/based on contract
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: 0; weekly: 0; monthly: 15 min.
Maintenance records kept onboard for user/vendor	yes/yes	yes/yes	no/—
Maintenance training demonstration module onboard	yes	yes	no
Training included with purchase/Avg. time for basic user training	yes (1 training slot)/1 day (at customer site)	yes (1 training slot)/1 day (at customer site)	yes/~2 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	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)/—	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> high-throughput system: more than 200 tests per hour for up to 15 ELISA plates in one run flexible and fully code-tracked loading for patient samples, reagents, and labware without predefined positioning convenient and intuitive operation of hardware and software with QC conformant tracking of actions and real walkaway time 	<ul style="list-style-type: none"> high-throughput system: more than 200 tests per hour for up to 750 reaction fields in one run flexible and fully code-tracked loading for patient samples, reagents, and labware without predefined positioning fully automated IIFT processing from primary sample to cover-slipped slide with real walkaway time 	<ul style="list-style-type: none"> microfluidics technology; small footprint—tabletop; liver cancer risk markers small sample volume fast turnaround time

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

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FOR MID- AND HIGH-VOLUME LABORATORIES

Fujirebio US
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Name of instrument	LUMIPULSE G1200	AIX1000 Agglutination Instrument	ThunderBolt
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	continuous random access/floor standing	batch/benchtop	batch/benchtop
List price/First year sold in U.S.	\$90,000/2016	—/2016	—/2011
Targeted hospital bed size/Targeted test volume	> 50/daily; 800; monthly: 16,000; annual: 200,000	—	—
Company manufactures instrument	no (manufactured by Otsuka)	yes (also sold by Cardinal Health, Thermo Fisher Scientific, VWR)	yes (also sold by distribution partners)
Other models in this family of analyzers	—	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	18/> 1,000 (Japan, Germany, France, Italy, Belgium, more)	—	—/— (Australia, Austria, Belgium, Bolivia, Brazil, Canada, Chile, Colombia, Czech Republic, England, Finland, more)
Dimensions (H × W × D)/Instrument footprint	57.6 × 47.2 × 31.5 in./14.2 sq. ft.	17.7 × 25.3 × 22.5 in./4.1 sq. ft.	17.7 × 25.2 × 22.5 in./6.5 sq. ft.
Weight empty/Weight fully loaded	727 lbs./794 lbs.	62 lbs./~110 lbs.	62 lbs./110 lbs.
No. of different measured assays onboard simultaneously	36 (24 can be run and calibrated at one time)	1 (1 can be run and calibrated at one time)	up to 24 (with limitations)
No. of user-definable (open chemistry) channels	—	—	—
Test throughput per hour/Assay run time	120 (120 tests in throughput)/avg. 30 min.	128 (128 tests in throughput)/75 min.	dependent on assay incubation times (192 tests in throughput)/20 min.—4 hr. (avg. 2 hr.)
Chemistry:			
No. of direct ion-selective electrode channels	—	—	—
Detection methods	—	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	—
• Basic metabolic panel	—	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	—	—	—
Immunoassay:			
Fully automated microplate immunoassay system	no	no	yes (192 tests per unit; 96 wells per microplate)
Methodologies supported	chemiluminescence	agglutination	chemiluminescence, enzyme immunoassay
Separation methodologies	magnetic particle	none necessary	coated microwell
Stat time until completion of a β-hCG test	25 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	42/self-contained single use	480/self-contained multiuse	96/open reagent system
Reagents refrigerated onboard/Reagents ready to use	yes (2°–12°C)/yes	no/—	no (room temperature–40°C)/variable; reagent specific
Reagent lot tracking/Reagent inventory	yes/yes	no/no	yes/no
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/no
Separate reagent pack for each specimen/for each test run	—/yes	no/no	no/yes
Walkaway capability/Walkaway duration	yes/252 min. or 100 specimens or 504 tests	yes/90 min. or 192 specimens or 1 test	yes/120 min. or 192 specimens or 2 tests
Design of sample-handling system	rack	universal slide-in racks	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	10–140 µL	1–150 µL	1–300 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	150 µL/110 µL/100 µL	105 µL/300 µL/150 µL	25 µL/151 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 (12–16 × up to 100 mm)	yes/no
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	no/yes/yes	no/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available	detection for 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/—	yes (can be programmed to perform dilutions prior to analysis)/assay specific
Automatic rerun capability	no	no	no
Sample volume can be diluted to rerun out-of-linear-range high results	yes	no	no
Sample volume can be concentrated to rerun out-of-linear-range low results	no	no	no
Analyzer requires dedicated water supply	no (2.1 L/hr. consumption during operation)	no (0.045 L/hr. consumption during operation)	no
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 30 days for most assays)	—	no (calibrants are not stored onboard)/yes (recommended avg. frequency: per batch)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/—/—/—/30 days for most assays	—	—/—/—/—/per batch
Automatic programmable start/Automatic programmable shutdown	yes (5 min. warm-up time)/yes	no (< 5 min. warm-up time)/no	no (5 min. warm-up time)/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	no	yes
Waste management	manually by user or direct to drain	manually by user	manually by user
Sample barcode-reading capability/Autodiscrimination	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	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, Code 93, more)/no
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)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	no	yes	yes
UPS backup power supply	yes	no	no
Data-management capability/LIS or EHR systems interfaced	onboard/SCC, more	onboard/—	onboard/—
LIS interface provided/Bidirectional interface capability	yes (included in instrument price)/yes (broadcast download and host query)	no/no	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	no/24 hrs.	—	no/48 hrs.
Mean time between failures	400 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 15 min.; weekly: 30 min.; monthly: 45 min.	daily: < 5 min.; weekly: < 20 min.	daily: 5 min.; weekly: 15 min.; monthly: 20 min.
Maintenance records kept onboard for user/vendor	no/no	yes/yes	yes/some records (dye tests and calibrations)
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes/6 hrs. (at customer site)	yes (minimum 1 training slot)/2 days (at customer site or online)	yes/4 hrs. (at customer or vendor site)
Advanced operator training/Extra charge for follow-up or advanced training	no/yes	yes/—	yes (at customer or vendor site)/yes (contract dependent)
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/\$12,500	yes (1 year)/—	yes (1 year from shipment date)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • unitized immunoreaction cartridge eliminates open bottle stability concerns and waste due to dead volume • 30-min. time to result for all assays • uninterrupted productivity—replenishes samples, reagents, and consumables on the fly 	<ul style="list-style-type: none"> • universal slide-in racks accommodate a variety of tube sizes for easier and faster sample loading • ability to add SMS and email alerts for notification of errors or test completion • automated processing, analysis, interpretation, and result archiving 	<ul style="list-style-type: none"> • open architecture: program any EIA or CLIA protocol; fully customizable with flexible and intuitive software • space saving: high capacity (192 samples) in a 2 × 2 ft. footprint • cost saving: low instrument price point with no routine consumables required

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

Part 9 of 16	Grifols Diego del Rio diego.delrio@grifols.com San Marcos, TX 512-749-1685 www.diagnostic.grifols.com	HORIBA Medical Susan Behnke medical-marketing.us@horiba.com Irvine, CA 888-903-5001 www.horiba.com/us/en/medical/	HYCOR Biomedical Erik van Megen marketingdept@hycorbiomedical.com Garden Grove, CA 800-382-2527 www.hycorbiomedical.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	HELIOS HTC	Yumizen C1200	NOVEOS Immunoassay Analyzer
Type of instrument	immunoassay	chemistry	immunoassay
Operational type/Model type	batch/benchtop	continuous random access/floor standing	batch/floor standing
List price/First year sold in U.S.	\$227,700/2017	\$179,800/2020	—
Targeted hospital bed size/Targeted test volume	200–1,000/daily; > 25; monthly: > 500; annual: > 5,000	< 300/daily: 9,520; monthly: 17,000; annual: 2 million	—/daily: 180; monthly: 5,417; annual: 65,000
Company manufactures instrument	no (manufactured by AESKU)	yes (manufactured by HORIBA ABX SAS; also sold by distribution partners)	yes (also sold by Sysmex, Axon Laboratories, Diagnostica Longwood, Aris Mantzoros S.A.)
Other models in this family of analyzers	HELIOS, HELMED	Yumizen C1200 AL	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—/> 350 (> 35 countries)	—	—/— (France, Germany, Netherlands, Switzerland, Greece, Spain, China)
Dimensions (H × W × D)/Instrument footprint	22.5 × 25.6 × 29.6 in./5.25 sq. ft.	44 × 48 × 33.5 in./—	51 × 61.5 × 32.5 in./15 sq. ft.
Weight empty/Weight fully loaded	73 lbs./—	992 lbs./—	881 lbs./960 lbs.
No. of different measured assays onboard simultaneously	4 (4 can be run and calibrated at one time)	45 (45 can be run and calibrated at one time)	1,200 (9 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	100 (100 can be active simultaneously)	0
Test throughput per hour/Assay run time	—	1,200 (45 plus 3 ISE tests in throughput)/3–15 min.	~100 tests per hour after first test result (~100 tests in throughput)/107 min.— approx. 8 hrs.
Chemistry:			
No. of direct ion-selective electrode channels	—	3	—
Detection methods	—	photometry, potentiometry, enzyme immunoassay, immunoturbidimetry	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	2.4 min./200 specimens per hr.	—
• Basic metabolic panel	—	12 min./60 specimens per hr.	—
• Complete metabolic panel	—	12 min./58 specimens per hr.	—
Typical time delay from ordering stat test until aspiration of sample	—	81 sec.	—
Immunoassay:			
Fully automated microplate immunoassay system	—	—	no
Methodologies supported	fluorescence, indirect fluorescent antibody	—	chemiluminescence
Separation methodologies	coated IFA slide	—	magnetic particle
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	120/—	500–2,200/self-contained multiuse, open reagent system	75/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	no/yes	yes (2°–8°C)/variable; reagent specific	yes (2°–15°C)/yes
Reagent lot tracking/Reagent inventory	yes/no	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/no	liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/yes	no/no	no/yes
Walkaway capability/Walkaway duration	yes/190 specimens or 240 tests	yes/dependent on reagent	yes/96 min. or 51 specimens or 1,200 tests
Design of sample-handling system	rack	84 sample continuous loading ring, optional autoloading rack	ring
Uses washable cuvettes/Uses disposable cuvettes	no/no	yes/no (can store up to 231 cuvettes)	yes (can store up to 20 cuvettes)/no
Min.–max. sample volume that can be aspirated at one time	—	1–25 µL	6–50 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—/assay dependent/tube dependent	80 µL/—/200 µL for primary tube sampling	50 µL/4 µL/100 µL
Dedicated pediatric sample cup	no	yes (dead volume: 50 µL)	no
Primary tube sampling	yes	yes	no
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (11–16 × 55–100 mm)	yes/yes	yes/yes
Pierces caps on primary tubes	no	no	no
Protects against probe collision	yes	yes	no
Detects clots/liquid level/short sample	no/yes/yes	yes/yes/yes	no/yes/—
Detection or quantitation for hemolysis, icterus, lipemia, clots	hemolysis, icterus, lipemia, clots not available	detection for hemolysis, icterus, lipemia, clots	hemolysis, icterus, lipemia, clots not available
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/no carryover	yes/—	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	no	yes	no
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	yes	—	no
Analyzer requires dedicated water supply	no	yes (average of 20 L/hr. consumption during operation)	no
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/—	yes (calibrants can be stored onboard [ISE])/yes (recommended avg. frequency: with each test kit) daily/for QC failure/for QC failure/per test kit/—	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—	—	—
Automatic programmable start/Automatic programmable shutdown	no/no	yes (40 min. start-up time)/yes	no (1–5 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	—	no	yes
Waste management	—	direct to drain	automated collection onboard instrument or direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Code 39, Code 128, Matrix 2/5, Code 11, EAN/JAN, more)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, EAN)/—	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no
Lab can control analyzer from remote computer	yes	no	yes
Instrument can diagnose its own malfunctions	—	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	no	no
Data-management capability/LIS or EHR systems interfaced	optional add-on (AESKU.LAB)/Sunquest, Orchard Software	onboard/CGM Labdaq	onboard/—
LIS interface provided/Bidirectional interface capability	no/yes (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/—	no/< 24 hrs.	no/contract dependent
Mean time between failures	— (displays error codes for troubleshooting)	122 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 15 min.; weekly: 20 min.	daily: 10–15 min. (walkaway); weekly: 20–30 min.; monthly: < 60 min.	daily: 5 min.; weekly: 50 min.; monthly: 20 min.
Maintenance records kept onboard for user/vendor	no/no	no/no	yes/no
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes (1 training slot)/—	yes (1 training slot)/3 days (at vendor or customer site)	yes (2 training slots)/3 days (at vendor or customer site)
Advanced operator training/Extra charge for follow-up or advanced training	—	yes (at vendor site)/yes	no/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (contract dependent)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> provides all-in-one IFA HEP-2, ANCA, and nDNA slide processing and reading on one instrument FDA cleared to identify seven HEP-2 patterns plus negative results utilizes pattern-recognition software and can estimate the endpoint titer 	<ul style="list-style-type: none"> microvolume technology for improved cost efficiency big lab automation in a small footprint; processes 1,200 tests per hour with ion-selective electrodes 100 programmable applications; optional autoloader 	<ul style="list-style-type: none"> 4-µL sample size requirement per test up to 13 hours true walkaway time when system is directly connected to deionized water lines and waste lines high onboard test capacity of 10,500 tests; no interference from biotin or solid-phase-related cross-reactive carbohydrate determinant (CCD) interference
<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	Mindray North America Anna Chen a.chen@mindray.com Redmond, WA 416-826-1663 www.mindraynorthamerica.com	Ortho Clinical Diagnostics Laura Osborne laura.osborne@orthoclinicaldiagnostics.com Raritan, NJ 800-828-6316 www.orthoclinicaldiagnostics.com	Ortho Clinical Diagnostics Laura Osborne laura.osborne@orthoclinicaldiagnostics.com Raritan, NJ 800-828-6316 www.orthoclinicaldiagnostics.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	BA-800M	VITROS 3600 Immunodiagnostic System	VITROS 4600 Chemistry System
Type of instrument	chemistry	immunoassay	chemistry
Operational type/Model type	batch, random access, discrete/floor standing	batch, random access, continuous 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	—/2011
Targeted hospital bed size/Targeted test volume	—/daily: 1,600–6,000	150–4,500/daily: > 200; monthly: > 5,000; annual: > 60,000	150–4,500/daily: 600–3,000; monthly: 17,000–85,000; annual: 200,000–1.5 million
Company manufactures instrument	yes (also sold by MedTest)	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)
Other models in this family of analyzers	BS-480	VITROS ECi/ECiQ Immunodiagnostic System	VITROS 350 Chemistry System, VITROS 5,1R Chemistry System, VITROS XT 3400 Chemistry System
No. of units in clinical use in U.S./Outside U.S. (countries)	—/> 2,000 (49 countries)	> 150/> 690 (North, Central, and South Americas, more)	> 160/> 980 (North, Central, and South Americas, more)
Dimensions (H × W × D)/Instrument footprint	47 × 91 × 40 in./25.19 sq. ft.	65 × 84 × 35 in./19.4 sq. ft.	53 × 92 × 33 in./21.4 sq. ft.
Weight empty/Weight fully loaded	1,430 lbs./1,654 lbs.	1,740 lbs./—	1,400 lbs./—
No. of different measured assays onboard simultaneously	68 (68 can be run and calibrated at one time)	31 (31 can be run and calibrated at one time)	82 (82 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	0	20 (20 can be active simultaneously)
Test throughput per hour/Assay run time	800–1,200 with ISE (68 tests in throughput)/1–15 min.	189/16–73 min. (avg. 30 min.)	845/2.5–20 min. (avg. 5 min.)
Chemistry:			
No. of direct ion-selective electrode channels	3 indirect	—	3
Detection methods	photometry, potentiometry, turbidimetry	—	photometry, potentiometry, colorimetric, turbidimetric
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	1 min./56 specimens per hr.	—	5 min./126 tests per hr.
• Basic metabolic panel	10.45 min./80 specimens per hr.	—	6 min./84 tests per hr.
• Complete metabolic panel	13.08 min./48 specimens per hr.	—	7.5 min./50 tests per hr.
Typical time delay from ordering stat test until aspiration of sample	~135 sec.	—	1 min.
Immunoassay:			
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	133–500 per reagent bottle/self-contained single use	50–100/self-contained multiuse	60/self-contained single use, open reagent system
Reagents refrigerated onboard/Reagents ready to use	yes (2°–8°C)/yes	yes (10°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	— (closed reagent system)/yes	dry chemistry, 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/~462 min. or 300 specimens or 12 test panels	yes/120 min. or 90 specimens or 3,100 tests	yes/120 min. or 160 specimens or 8,940 tests
Design of sample-handling system	rack and ring	circular routine sampling center	continuous load and unload, circular routine sample center
Uses washable cuvettes/Uses disposable cuvettes	yes (can store up to 165 cuvettes)/no	no/no	no/yes (can store up to 348 cuvettes)
Min.–max. sample volume that can be aspirated at one time	1.5–35 µL	2–200 µL	2–200 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	100 µL/1.5 µL/50 µL	—/10 µL/35 µL	0 µL/2 µL/35 µL
Dedicated pediatric sample cup	yes (dead volume: 50 µL)	yes (dead volume: 35 µL)	yes (dead volume: 35 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	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)	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/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection 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
Dilutes patient samples onboard/Susceptibility to carryover	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	yes (can be programmed to perform dilutions prior to analysis)/0
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	yes
Analyzer requires dedicated water supply	yes (35 L/hr. consumption during operation)	no (no water consumption during operation)	no (no water consumption during operation)
Autocalibration/Multipoint calibration supported	yes (calibrants can be stored onboard)/yes	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 6 mos. or lot change for most chemistry assays)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	8 hrs./—/7 days/14 days/—	—/—/—/28 days	6 mos./6 mos./6 mos./6 mos./—
Automatic programmable start/Automatic programmable shutdown	yes/yes	no/no	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	direct to drain	manually by user	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/—
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)	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/—	onboard/—
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download and host query)	yes (additional cost)/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/24 hrs.	yes/4 hrs.	yes/4 hrs.
Mean time between failures	2,400 hrs. (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: < 10 min.; weekly: < 1 hr.; monthly: < 1 hr.	daily: < 10 min.; weekly: 30 min.; monthly: 20 min.	daily: 5 min.; weekly: 30 min.; monthly: 20 min.
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/some records	yes (includes audit trail of who replaced parts)/no	yes (includes audit trail of who replaced parts)/no
Maintenance training demonstration module onboard	yes	yes	yes
Training included with purchase/Avg. time for basic user training	yes (1+ training slot)/3 days (at customer site)	yes (2 training slots)/5 days (at customer and vendor sites)	yes (2 training slots)/5 days (at customer and vendor sites)
Advanced operator training/Extra charge for follow-up or advanced training	no/—	yes (at vendor site)/yes	yes (at vendor site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes/—	yes (1 year)/depends on plan selected	yes (1 year)/depends on plan selected
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • huge sample delivery capacity: 440 positions total, including 140 positions on sample tray and 300 positions on racks • minimum reaction volume of 100 µL; offers reagent savings to the customer • sample delivery module allows loading 300 samples at a time, provides long operator walkaway time 	<ul style="list-style-type: none"> • Intellicheck technology process checks reduce misreported results and provide real-time quality status and traceability • single-use disposable tips for sample and reagent metering eliminate sample and reagent carryover • MicroSensor technology detects HIL and turbidity without using reagents or additional sample and time 	<ul style="list-style-type: none"> • Intellicheck technology process checks reduce misreported results and provide real-time quality status and traceability • single-use disposable tips for sample and reagent metering eliminate sample and reagent carryover • MicroSensor technology detects HIL and turbidity without using reagents or additional sample and time
<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	Ortho Clinical Diagnostics Laura Osborne laura.osborne@orthoclinicaldiagnostics.com Raritan, NJ 800-828-6316 www.orthoclinicaldiagnostics.com	Randox Laboratories Graeme McNeill graeme.mcneill@randox.com Kearneysville, WV 304-728-2890 www.randox.com	Roche Diagnostics Mark Sprunger mark.sprunger@roche.com Indianapolis, IN 800-428-5074 diagnostics.roche.com/us/en/home.html
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	VITROS XT 7600 Integrated System	RX imola	cobas 6000 analyzer series
Type of instrument	combination chemistry/immunoassay	chemistry	combination chemistry/immunoassay
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	discrete/benchtop	random access, continuous random access/floor standing
List price/First year sold in U.S.	—/2018	—/2006	—/2006
Targeted hospital bed size/Targeted test volume	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	> 100/daily: 1,000–4,000; annual: 500,000–2,500,000
Company manufactures instrument	no (manufactured by Nypro Engineering and Technology group service; also sold by Cardinal, McKesson, more)	yes	no (manufactured by Hitachi High-Technologies)
Other models in this family of analyzers	VITROS 5600 Integrated System	RX misano, RX monaco, RX daytona +, RX modena	chemistry: cobas c 501; immunoassay: cobas e 601
No. of units in clinical use in U.S./Outside U.S. (countries)	> 460/> 400 (North, Central, and South Americas, more)	34/> 1,000 (> 120 countries)	> 1,600/> 14,000 (56 countries)
Dimensions (H × W × D)/Instrument footprint	68 × 110 × 34.9 in./26.7 sq. ft.	27 × 38 × 23 in./44.28 sq. ft.	51 × 74–196 × 41 in./34.62 sq. ft. for 2-module configuration
Weight empty/Weight fully loaded	2,360 lbs./—	331 lbs./340 lbs.	830–1,990 lbs./830–1,990 lbs.
No. of different measured assays onboard simultaneously	150 (150 can be run and calibrated at one time)	60 (60 can be run and calibrated at one time)	up to 151 (up to 148 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	20 (20 can be active simultaneously)	15 (0 can be active simultaneously)	20 (all can be active simultaneously)
Test throughput per hour/Assay run time	1,320/2.5–73 min. (avg. 7 min.)	560, including ISE (50 tests in throughput)/5–10 min. (avg. 6 min.)	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.)
Chemistry:			
No. of direct ion-selective electrode channels	3	3	3 indirect
Detection methods	photometry, potentiometry, turbidimetric, direct enhanced chemiluminescence	potentiometry	photometry, potentiometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	5 min./126 tests per hr.	13 min. 15 sec./80 specimens per hr.	4.5 min./133 specimens per hr.
• Basic metabolic panel	6 min./95 tests per hr.	13 min. 43 sec./80 specimens per hr.	7 min./up to 240 specimens per hr.
• Complete metabolic panel	7.5 min./74 tests per hr.	7.5 min. 15 sec./67 specimens per hr.	10 min./up to 110 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	1 min.	30 sec.	< 1 min.
Immunoassay:			
Fully automated microplate immunoassay system	no	—	no
Methodologies supported	chemiluminescence, enzyme immunoassay, direct enhanced chemiluminescence	—	electrochemiluminescence
Separation methodologies	coated microwell	—	magnetic particle
Stat time until completion of a β-hCG test	24 min.	—	9 min.
• Typical time delay from test order to aspiration of sample	1 min.	—	42 sec.
Stat time until completion of a cTn test	18 min.	—	9 min.
• Typical time delay from test order to aspiration of sample	1 min.	—	42 sec.
Approximate No. of tests per reagent set/Reagent type	50–100/varies for chemistry and immunoassay	200/self-contained single use	up to 800 per pack (chemistry), up to 200 per pack (immunoassay)/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (10°C)/yes	yes (8°–15°C)/yes	yes (5°–12°C [chemistry], 20°±3°C [immunoassay])/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	dry chemistry, liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/—	yes/70 min. or 40 specimens or 10 tests	yes/75 min. or 150 samples or 1,500 tests
Design of sample-handling system	continuous load and unload, circular routine sample center	ring	5-position rack
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 348 cuvettes)	yes (can store up to 90 cuvettes)/no	immuno: yes (can store up to 1,008 cuvettes)/no
Min.–max. sample volume that can be aspirated at one time	2–200 µL	1.5–35 µL	1–35 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	0 µL/2 µL/35 µL	150 µL/1.5–35 µL/150 µL	100–250 µL (chem), 120–200 µL (immuno)/1.5 µL (chem), 4–10 µL (immuno)/500 or 1,000 µL (tube dependent)
Dedicated pediatric sample cup	yes (dead volume: 35 µL)	yes (dead volume: 100 µL)	yes (dead volume: 50 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (micro sample cups, 10.25 × 45 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, 13 × 100 mm, 16 × 75 mm, 16 × 100 mm)	—	yes/yes
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/no	yes/yes/yes
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; clots not available	detection for hemolysis, icterus, lipemia, clots
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)/no carryover	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	no (no water consumption during operation)	yes (18 L/hr. consumption during operation)	yes (10 L/hr. consumption during operation for chemistry, 12 L/hr. for immunoassay)
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 can be stored onboard)/yes (recommended avg. frequency: 14 days)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 24 hrs. [ISE], once per lot [chemistry], up to 56 days per lot [immunoassay])
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	6 mos./6 mos./6 mos./6 mos./28 days	1 day/7 days/7 days/14 days/28 days	24 hrs./once per lot/42 days per lot/once per lot/up to 56 days per lot
Automatic programmable start/Automatic programmable shutdown	no/no	yes (9 min. warm-up time)/yes	yes/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	direct to drain	direct to drain
Sample barcode-reading capability/Autodiscrimination	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	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	yes	no	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)	yes (included in instrument price)/yes (host query)	yes (incl. in instrument price)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/4 hrs.	no/within 24 hrs.	yes/< 8 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	2 per 3 years (displays error codes for troubleshooting)	avg. 259 days per module (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: < 10 min.; weekly: 30 min.; monthly: 20 min.	daily: 5 min.; weekly: 15 min.; monthly: 1 hr.	daily: 4 min.; weekly: 20 min.; monthly: 35 min.
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/no	no/no	yes/yes (both include audit trail of who replaced parts)
Maintenance training demonstration module onboard	yes	no	yes
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/5 days (at customer and vendor sites)	yes (1 training slot)/3 days (at customer site)	yes (2 training slots)/varies at customer site, 5 days at vendor site
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/yes	yes (at customer site)/yes	yes (at vendor site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes/depends on plan selected	yes (1 year)/—	yes (1 year)/configuration dependent
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> capable of processing two unique chem tests on one XT Microslide single-use disposable tips eliminate carryover MicroSensor technology detects HIL and turbidity without using reagents or additional sample and time 	<ul style="list-style-type: none"> large and extensively dedicated test menu stat sample capabilities benchtop analyzer 	<ul style="list-style-type: none"> broad test menu: > 180 assays on one integrated platform flexible, scalable design: available in seven unique configurations
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 12 of 16 FOR MID- AND HIGH-VOLUME LABORATORIES	Roche Diagnostics Mark Sprunger mark.sprunger@roche.com Indianapolis, IN 800-428-5074 diagnostics.roche.com/us/en/home.html	Roche Diagnostics Mark Sprunger mark.sprunger@roche.com Indianapolis, IN 800-428-5074 diagnostics.roche.com	Siemens Healthineers John Boone john.boone@siemens-healthineers.com Hoffman Estates, IL siemens-healthineers.us
Name of instrument Type of instrument Operational type/Model type	cobas 8000 modular analyzer series combination chemistry/immunoassay random access, continuous random access/floor standing	cobas pro integrated solution combination chemistry/immunoassay random access, continuous random access/floor standing	Atellica Solution combination chemistry/immunoassay batch, random access, continuous random access, discrete/floor standing
List price/First year sold in U.S. Targeted hospital bed size/Targeted test volume Company manufactures instrument Other models in this family of analyzers No. of units in clinical use in U.S./Outside U.S. (countries)	—/2010 > 250/daily; > 4,000; annual: ≥ 2,500,000 no (manufactured by Hitachi High-Technologies) chem.: cobas c 701, c 702, c 502; immuno.: cobas e 801, e 602 > 400/> 5,000 (49 countries)	—/2020 > 200/daily; 2,000–4,000; annual: 750,000–4 million no (manufactured by Hitachi High-Technologies) chem: cobas c 503; immuno: cobas e 801 > 300/> 5,800 (> 40 countries)	—/2017 high volume/annual: > 750,000 yes (also sold by McKesson, Henry Schein, Medline) Atellica CH 930, IM 1300, IM 1600 —
Dimensions (H × W × D)/Instrument footprint Weight empty/Weight fully loaded No. of different measured assays onboard simultaneously	40–53 × 99–294 × 45 in./66.35 sq. ft. for 3-module config. 1,150–5,485 lbs./1,150–5,485 lbs. up to 283 (> 300 can be run and calibrated at one time)	56 × 172.2 × 47 in. for integrated 2-module system/56 sq. ft. for integrated 2-module system: 4,388 lbs./4,388 lbs. chem: 63 (63 can be run and calibrated at one time); immuno: 48 (48 can be run and calibrated at one time)	chem: 53.7 × 58.6 × 45.5 in.; immuno: 59.1 × 56.9 × 45.0 in./64.6 sq. ft. chem: 1,036 lbs.; immuno: 1,265 lbs./— variable based on configuration
No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	10 for c 70x, c 502 (all can be active simultaneously) 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.)	10 (10 can be active simultaneously) up to 2,200 (varies by module)/chem: 4.5–10 min. (avg. 10 min.); immuno: 9–27 min. (avg. 18 min.)	chem: 25 (25 can be active simultaneously); immuno: 0 chem: up to 1,800; immuno: up to 440/18–54 sec. (assay dependent)
Chemistry:			
No. of direct ion-selective electrode channels Detection methods Stat time until completion/specimen throughput for: • Ion-selective electrode • Basic metabolic panel • Complete metabolic panel Typical time delay from ordering stat test until aspiration of sample	3 indirect photometry, potentiometry 4.5 min./600 specimens per hr. 7 min./up to 400 specimens per hr. 10 min./up to 181 specimens per hr. < 1 min.	3 indirect photometry, potentiometry 4.5 min. for ISE, 10 min. with CO2/300 specimens per hr. 10 min./200 specimens per hr. 10 min./100 specimens per hr. < 1 min.	0 photometry, potentiometry, turbidimetric, EMIT 2 min./— 10 min./— 10 min./— 60 sec. maximum
Immunoassay:			
Fully automated microplate immunoassay system Methodologies supported Separation methodologies Stat time until completion of a B-hCG test • Typical time delay from test order to aspiration of sample Stat time until completion of a cTn test • Typical time delay from test order to aspiration of sample	no electrochemiluminescence magnetic particle ~10 min. < 1 min. 9 min. 24 sec.	no electrochemiluminescence magnetic particle ~10 min. < 1 min. ~10 min. < 1 min.	no chemiluminescence, acridinium ester chemiluminescence magnetic particle 10 min. 60 sec. maximum 10 min. 60 sec. maximum
Approximate No. of tests per reagent set/Reagent type Reagents refrigerated onboard/Reagents ready to use Reagent lot tracking/Reagent inventory Reagent form/Reagents barcoded Separate reagent pack for each specimen/for each test run Walkaway capability/Walkaway duration	up to 3,000 per pack (chemistry), up to 300 per pack (immunoassay)/self-contained multiuse yes (5°–15°C [chem], 6°–10°C [immuno])/reagent specific yes/yes liquid chemistry (open reagent system)/yes no/no yes/45 min. or 300 samples or 3,000 tests	up to 3,300 (chemistry), up to 300 (immunoassay)/self-contained multiuse yes (5°–15°C [chemistry], 6°–10°C [immunoassay])/yes yes/yes liquid chemistry (open reagent system)/yes no/yes yes/30–45 min. or 300 samples or ~3,000 tests	50–2,100 (assay dependent)/self-contained multiuse, open reagent system yes (4°–8°C)/yes yes/yes liquid chemistry (open reagent system)/yes no/no yes/300 min. or 9,000 tests (chem), up to 450 min. or 1,200 tests (immuno)
Design of sample-handling system Uses washable cuvettes/Uses disposable cuvettes	5-position rack yes (No. of cuvettes stored varies by module)/no	5-position rack yes (can store up to 221 cuvettes for chem, 1,575 for immuno)/yes	multiple rack drawer chem: yes (can store up to 221 cuvettes)/immuno: yes (can store up to 1,200 cuvettes)
Min.–max. sample volume that can be aspirated at one time Min. reaction volume/Min. specimen volume/Min. dead volume	1–35 µL (chemistry), 1–60 µL (immunoassay) 100–250 µL (chem), 120–200 µL (immuno)/1 µL (chem), 4–10 µL (immuno)/50–1,000 µL (container dependent)	1–60 µL 75 µL/1.5 µL (chem), 4 µL (immuno)/50 µL	2–50 µL (chem), 10–200 µL (immuno) assay dependent/assay dependent/container dependent
Dedicated pediatric sample cup Primary tube sampling Accommodates most standard tube sizes/Accepts nonstandard tube sizes Pierces caps on primary tubes Protects against probe collision Detects clots/liquid level/short sample Detection or quantitation for hemolysis, icterus, lipemia, clots Dilutes patient samples onboard/Susceptibility to carryover	yes (dead volume: 50 µL) yes yes/yes no yes yes/yes/yes quantitation for hemolysis, icterus, lipemia; detection for clots yes (can be programmed to perform dilutions prior to analysis)/ <1 part per million (chemistry), no carryover (immunoassay)	yes (dead volume: 50 µL) yes yes/yes (11 × 102 mm [chem], 13 × 102 mm [immuno]) no yes yes/yes/yes quantitation for hemolysis, icterus, lipemia; detection for clots yes (can be programmed to perform dilutions prior to analysis)/ <1 part per million (chemistry), no carryover (immunoassay)	no yes yes/yes (8 × 31.75 mm) no yes yes/yes/yes detection for hemolysis, icterus, lipemia, clots yes (can be programmed to perform dilutions prior to analysis)/ no carryover (immuno), <0.1 parts per million (chem)
Automatic rerun capability Sample volume can be diluted to rerun out-of-linear-range high results Sample volume can be concentrated to rerun out-of-linear-range low results	yes yes yes	yes yes yes	yes yes yes
Analyzer requires dedicated water supply	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)	yes (33 L/hr. consumption during operation for chemistry, 6 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 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])	yes (calibrants are stored onboard)/yes (recommended avg. frequency: 28–183 days [chem], 14–91 days [immuno])
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays Automatic programmable start/Automatic programmable shutdown Onboard real-time QC/Onboard software capability to review QC Supports multiple QC lot numbers per analyte	24 hrs./once per lot/42 days per lot/once per lot/up to 84 days per lot yes (6.5 min. start-up time)/yes yes/yes	once per lot/once per lot/once per lot/once per lot/up to 84 days per lot yes (6.5 min. start-up time)/yes yes/yes	every 4 hrs./28–63 days/40–180 days/up to 180 days/14–91 days yes/no yes/yes
Waste management Sample barcode-reading capability/Autodiscrimination Lab can control analyzer from remote computer Instrument can diagnose its own malfunctions System malfunctions can be diagnosed via remote monitoring UPS backup power supply Data-management capability/LIS or EHR systems interfaced LIS interface provided/Bidirectional interface capability Modern servicing provided/Service engineer on-site response time	direct to drain yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes yes yes (operator intervention required to order parts) yes yes onboard/SCC, Meditech, Cerner, Epic, Sunquest, more yes (incl. in instrument price)/yes (broadcast download and host query) yes/< 8 hrs.	direct to drain yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes yes yes (operator intervention required to order parts) yes yes onboard, optional add-on (Bio-Rad MAS)/SCC, Cerner, Epic, more yes (incl. in price)/yes (broadcast download and host query) yes/—	manually by user or direct to drain yes (Interleaved 2 of 5, Code 39, Code 128)/yes yes yes (operator intervention required to order parts) yes yes optional add-on (Siemens Atellica Data Manager)/— yes (incl. in price)/yes (broadcast download and host query) yes/5 hrs. avg.
Mean time between failures	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)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel Maintenance records kept onboard for user/vendor Maintenance training demonstration module onboard Training included with purchase/Avg. time for basic user training	daily: 4–5 min.; weekly: 20 min.; monthly: 25 min. yes/yes (both include audit trail of who replaced parts) yes yes (4 training slots)/varies at customer site, 5 days at vendor site	daily: 3–4 min.; bi-weekly: 23 min.; monthly: 20 min. yes/yes (both include audit trail of who replaced parts) yes yes (~ 2 training slots per module)/4–5 days (at customer and vendor sites)	daily: < 5 min.; weekly: 10–15 min.; monthly: 10–15 min. yes/yes (both include audit trail of who replaced parts) yes yes (3 training slots)/6.5 days (at customer and vendor sites)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/yes (cost varies by contract)	yes (at vendor site)/yes (cost varies by contract)	yes (at customer and vendor sites)/no
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/configuration dependent	yes (1 year)/varies by contract	yes (1 year)/—
Distinguishing features (supplied by company)	• 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	• patented Atellica Magline bidirectional sample transport uses individual sample carriers for rapid throughput • automated onboard calibration, QC • microvolume sample technology for CC; IA controlled temperature requires no recalibration if lab ambient temp. changes

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

Part 13 of 16 FOR MID- AND HIGH-VOLUME LABORATORIES	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.us	Thermo Fisher Scientific/BRAHMS info.brahms@thermofisher.com Hennigsdorf, Germany +49(0)33028830 www.thermoscientific.com/kryptor
Name of instrument	Dimension EXL 200 Integrated Chemistry System	Immulite 2000 XPI Immunoassay System	B-R-A-H-M-S KRYPTOR GOLD
Type of instrument	combination chemistry/immunoassay	immunoassay	immunoassay
Operational type/Model type	random access/floor standing	batch, random access, continuous random access, discrete/floor standing	batch, random access, continuous random access/benchtop
List price/First year sold in U.S.	\$252,000/2008	—/2009	—
Targeted hospital bed size/Targeted test volume	—/annual: < 1 million	> 200/daily: > 250	—/daily: 600; monthly: 12,000; annual: 156,000
Company manufactures instrument	yes (also sold by Henry Schein, McKesson, Medline)	yes (also sold by McKesson, Henry Schein, Medline)	yes (also sold by distribution partners)
Other models in this family of analyzers	Dimension EXL with LM	—	B-R-A-H-M-S KRYPTOR compact PLUS
No. of units in clinical use in U.S./Outside U.S. (countries)	> 1,500/—	≥ 550/≥ 2,400 (> 75 countries)	—/— (worldwide)
Dimensions (H × W × D)/Instrument footprint	48.7 × 56.1 × 41.1 in./16 sq. ft.	47 × 60 × 30 in./—	28.74 (47.64 with tower light or open hood) × 36.61 × 28.34 in./55.11 in.
Weight empty/Weight fully loaded	788 lbs./788 lbs.	800 lbs./—	260 lbs./—
No. of different measured assays onboard simultaneously	47 (47 can be run and calibrated at one time)	24	16 (16 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	15 (15 can be active simultaneously)	none	—
Test throughput per hour/Assay run time	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)/—	115 (up to 115 tests in throughput)/9–59 min.
Chemistry:			
No. of direct ion-selective electrode channels	3	—	—
Detection methods	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	< 1 min. for sodium, potassium chloride, 2.2 min for carbon dioxide/—	—	—
• Basic metabolic panel	4 min./—	—	—
• Complete metabolic panel	9 min./—	—	—
Typical time delay from ordering stat test until aspiration of sample	< 24 sec.	—	—
Immunoassay:			
Fully automated microplate immunoassay system	no	no	no
Methodologies supported	chemiluminescence	enzyme-amplified chemiluminescence	fluorescence, enzyme immunoassay
Separation methodologies	none necessary	bead	none necessary
Stat time until completion of a β-hCG test	14 min.	35 min.	14 min.
• Typical time delay from test order to aspiration of sample	—	18 sec.	2 min.
Stat time until completion of a cTn test	—	35 min.	—
• Typical time delay from test order to aspiration of sample	—	18 sec.	—
Approximate No. of tests per reagent set/Reagent type	15–360/self-contained multiuse	200/self-contained multiuse	50–100/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (2°–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 (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/60 min. or > 12,000 tests	yes/up to 300 min.	yes/430 min. or 18 specimens or 419 tests
Design of sample-handling system	sample wheel	rack	sample cassette placed in sample carousel
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 12,000 cuvettes)	no/yes (can store up to 1,300 cuvettes)	no/no
Min.–max. sample volume that can be aspirated at one time	2–60 µL	5–600 µL	8–70 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	2 µL/2 µL/30 µL	—/5 µL/50 µL	150 µL/sample tube and assay dependent/150 µL sample tube dependent
Dedicated pediatric sample cup	yes (dead volume: 30 µL)	yes (dead volume: 50 µL)	yes (dead volume: 75 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/—	yes/yes (12–16 × 75–100 mm; 10 × 50 mm micro sample tubes)	yes/yes (11–17 × 60–120 mm)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	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 clots; hemolysis, icterus, lipemia not available	detection for hemolysis, icterus, lipemia, clots
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/< 1 part per million	yes (can be programmed to perform dilutions prior to analysis)/< 3 parts per million	yes (can be programmed to perform dilutions prior to analysis)/≤ 2 parts per million (no contamination)
Automatic rerun capability	yes	yes	yes
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	no	no	yes
Analyzer requires dedicated water supply	yes (5 L/hr. consumption during operation)	no	no
Autocalibration/Multipoint calibration supported	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])	yes (calibrants are not stored onboard)/no
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	30–90 days/30–60 days/30–90 days/30–90 days/30–90 days	—/2 weeks/—/—/1–4 weeks (assay dependent)	—/—/—/—/5–15 days
Automatic programmable start/Automatic programmable shutdown	no/no	— (4 min. warm-up time)/yes	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	direct to drain	manually by user	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 (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	yes	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	no	yes
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/—	optional add-on (Siemens CentraLink Data Manager)/yes	onboard/—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	yes/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/2–8 hrs.	yes/2–8 hrs.	yes/Mon.–Fri.: 26 hrs. at total breakdown, 72 hrs. at workaround
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 5 min.; weekly: 10 min.; monthly: < 25 min.	daily: 5–10 min.; weekly: 20 min.; monthly: 20–30 min.	daily: 3 min.; weekly: 3 min.; monthly: 5 min.
Maintenance records kept onboard for user/vendor	yes/yes (both include audit trail of who replaced parts)	no/no	yes/yes (both include audit trail of who replaced parts)
Maintenance training demonstration module onboard	no	yes	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/3 days (at vendor site)	yes (2 training slots)/3 days (at customer and vendor sites)	yes (1 training slot)/1.5–2 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/contract dependent	yes (at vendor site)/contract dependent	yes (at vendor site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/contract dependent	yes (1 year)/—	yes (1 year)/contract dependent
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • true integration of chemistry and immunoassay in one analyzer with a compact footprint • 10-min. high-sensitivity troponin • low maintenance: 5 min. daily, < 25 min. monthly 	<ul style="list-style-type: none"> • extensive routine and specialty immunoassay menu; includes menu of more than 300 allergens • specific allergens and panels; provides opportunity to reduce sendouts and boost revenue • reagent onboard stability of 90 days 	<ul style="list-style-type: none"> • fully automated random-access immunoanalyzer with unique Nobel Prize-winning TRACE technology • automated timely onboard dilution in less than 5 minutes with integrated self-determining dilution factor • no biotin interferences of the assays
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 14 of 16		Thermo Fisher Scientific	Thermo Fisher Scientific	Tosoh Bioscience
FOR MID- AND HIGH-VOLUME LABORATORIES		Peter Cooke cascadion.info@thermofisher.com Fremont, CA 781-467-9749 thermofisher.com/cascadion	John Karr john.karr@thermofisher.com Portage, MI 800-346-4364 thermofisher.com/phadia	Karen Wrona karen.wrona@tosoh.com South San Francisco, CA 800-248-6764 www.diagnostics.us.tosohbioscience.com
Name of instrument	Cascadion SM Clinical Analyzer	Phadia 250 Laboratory System	AIA-900	
Type of instrument	chemistry	immunoassay	immunoassay	
Operational type/Model type	random access/floor standing	continuous random access, discrete/floor standing	continuous random access/floor standing	
List price/First year sold in U.S.	—/2020	—/2004	—/2011	
Targeted hospital bed size/Targeted test volume	300+/daily: 200; monthly: 6,000; annual: 50,000	—/annual: > 20,000–95,000	—/monthly: 500–1,500	
Company manufactures instrument	yes	no (manufactured by Hitachi)	yes	
Other models in this family of analyzers	—	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)	—/— (western EU countries, Canada, Australia, Hong Kong)	> 260/> 2,135	~350/> 1,200 (worldwide)	
Dimensions (H × W × D)/Instrument footprint	55.1 × 88.6 × 37.8 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	1,698 lbs./1,786 lbs.	485 lbs./—	404 lbs. (loader), 562 lbs. (9-tray sorter), 602 lbs. (19-tray sorter)/—	
No. of different measured assays onboard simultaneously	3 (3 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	0	
Test throughput per hour/Assay run time	25 samples (3 tests in throughput)/~20 min.	60 tests/100 min.	90/—	
Chemistry:				
No. of direct ion-selective electrode channels	0	—	—	
Detection methods	liquid chromatography-mass spectrometry	—	—	
Stat time until completion/specimen throughput for:				
• Ion-selective electrode	—	—	—	
• Basic metabolic panel	—	—	—	
• Complete metabolic panel	—	—	—	
Typical time delay from ordering stat test until aspiration of sample	—	—	—	
Immunoassay:				
Fully automated microplate immunoassay system	—	no	—	
Methodologies supported	—	fluoroenzyme immunoassay	fluorescence	
Separation methodologies	—	fiber matrix filter, coated microwell	—	
Stat time until completion of a β-hCG test	—	—	20 min.	
• Typical time delay from test order to aspiration of sample	—	—	—	
Stat time until completion of a cTn test	—	—	20 min.	
• Typical time delay from test order to aspiration of sample	—	—	—	
Approximate No. of tests per reagent set/Reagent type	3–4/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/240 min. or 60 specimens or 100 tests	yes/100 min.	yes/~ 2 hours or 45 specimens or 45 tests	
Design of sample-handling system	rack	rack	rack	
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 150 cuvettes)	no/no	no/no	
Min.–max. sample volume that can be aspirated at one time	20–300 μL (assay specific)	20–40 μL	2–100 μL	
Min. reaction volume/Min. specimen volume/Min. dead volume	85 μL (assay specific)/350 μL/200 μL (excluding whole blood assays)	40 μL (ImmunoCAP), 20 μL (EIA)/—/150 μL	10 μL/110 μL/100 μL	
Dedicated pediatric sample cup	yes (dead volume: 200 μL)	no	no	
Primary tube sampling	yes	yes	yes	
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (13 × 75–100 mm)	yes/—	yes/—	
Pierces caps on primary tubes	no	no	no	
Protects against probe collision	yes	yes	—	
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes	
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available	detection for clots; hemolysis, icterus, lipemia not available	—	
Dilutes patient samples onboard/Susceptibility to carryover	no/—	yes/—	no/no carryover	
Automatic rerun capability	yes	no	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	no	no	
Analyzer requires dedicated water supply	no	no (1 L/hr. consumption during operation)	no	
Autocalibration/Multipoint calibration supported	no (calibrants are stored onboard)/yes (recommended avg. frequency: 30 days)	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	—/30 days/—/30 days/—	—/—/—/—/28 days	—/—/—/—/most assays are 90 days	
Automatic programmable start/Automatic programmable shutdown	yes (20 min. warm-up time)/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	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, Codabar, Code 39, Code 128)/no	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	no/yes (host query)	—/yes (broadcast download and host query)	no/yes (host query)	
Modem servicing provided/Service engineer on-site response time	no/24 hrs.	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: 10 min.; weekly: 20 min.; monthly: 2 hrs.	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 (includes audit trail of who replaced parts)/no	some records (date of instrument maintenance)/no	no/no	
Maintenance training demonstration module onboard	yes	no	no	
Training included with purchase/Avg. time for basic user training	yes (3 training slots)/3 days (at customer site)	yes (2 training slots)/4 days (vendor site preferred, at customer site upon request)	yes/2.5 days (at vendor site)	
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer site)/no	yes (at vendor site)/—	no/—	
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year from installation date)/—	
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> gold standard LC-MS/MS measurement technology for enhanced accuracy, precision, and specificity fully automated, easy-to-use system designed for walkaway operation with no specialized LC-MS/MS knowledge needed random access and continuous workflow eliminates sample sorting and batch loading 	<ul style="list-style-type: none"> ability to run allergy and autoimmune tests in the same run broad specific IgE whole allergen and allergen component menu master isotype calibration curves 	<ul style="list-style-type: none"> unit dose test cup; dry reagent, no premixing or reagent preparation no interference from biotin; broad menu with fast results 90-day calibration stability for most assays 	
<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 × W × D)/Instrument footprint	AIA-2000 ST: 50 × 59 × 35 in./AIA-2000 LA: 50 × 59 × 47 in./14.6 sq. ft.	30 × 60 × 24 in./10 sq. ft.	21 × 34 × 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.
Chemistry:			
No. of direct ion-selective electrode channels	—	—	—
Detection methods	—	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	—
• Basic metabolic panel	—	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	—	—	—
Immunoassay:			
Fully automated microplate immunoassay system	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 β-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 µL	10–100 µL	5 µL minimum
Min. reaction volume/Min. specimen volume/Min. dead volume	10 µL/10 µL/100 µL	10 µL/10 µL/50 µL	20 µL/5 µL/200 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/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"> • dry reagent with no biotin interference, unit dose test cup, 90-day calibration stability for most assays • 3 separate incubators to minimize processing time; dual clot detection, automated dilutions, and pretreatment • available in 2 models—standard (ST) and line automation (LA)—appropriate for stat and routine use 	<ul style="list-style-type: none"> • multianalyte system allows simultaneous analysis of up to 12 analytes • introduces novel analytes to improve utility of autoimmune diagnosis • 6.5-hour walkaway time with 10-minute daily maintenance 	<ul style="list-style-type: none"> • improves laboratory workflow and productivity; eliminates batching and reagent waste with stable onboard reagents • delivers results, including stat orders, in 30 min. and allows serum and fecal samples to be run simultaneously • generates up to 450 results in a single shift and makes even the most specialized assays efficient to perform
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

