

Part 1 of 16

FOR MID- AND HIGH-VOLUME LABORATORIES

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Name of instrument	Alinity ci-series	HELIOS HTC	ACE Excel
Type of instrument	combination chemistry/immunoassay	immunoassay	chemistry
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	batch/benchtop	batch, random access, continuous random access, discrete/benchtop
List price/First year sold in U.S.	—/2018	\$175,000/2017	\$34,500/2012
Targeted hospital bed size/Targeted test volume	all/—	200–1,000/daily; > 25; monthly: > 500; annual: > 5,000	—/daily: ~15–50 comprehensive metabolic panels and lipids
Company manufactures instrument	yes	yes	yes (also sold by McKesson, Henry Schein, Medline, AvMedical)
Other models in this family of analyzers	—	HELMED, HELIA	ACE Alera
No. of units in clinical use in U.S./Outside U.S. (countries)	~2,200/~13,000 (154 countries)	> 30/> 400 (Europe, North America, South America, Asia, Africa, Australia)	—
Dimensions (H × W × D)/Instrument footprint	4.4 × 3.9 × 3.84 for standalone module; up to 4.4 × 11.81 × 3.84 for 4-module system/14.98–45.31 sq. ft. for 1- to 4-module system	22.5 × 25.6 × 29.6 in./5.25 sq. ft.	33 × 28 × 26 in./10 sq. ft.
Weight empty/Weight fully loaded	chem: 1,556 lbs.; immuno: 1,371 lbs./—	73 lbs./—	150 lbs./150 lbs.
No. of different measured assays onboard simultaneously	chem: up to 280 (up to 280 can be run and calibrated at one time); immuno: up to 188 (up to 188 can be run and calibrated at one time)	4 (4 can be run and calibrated at one time)	40 (200 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	10 (10 can be active simultaneously)	—	15 (15 can be active simultaneously)
Test throughput per hour/Assay run time	up to 5,400 for Alinity c 4-module system; up to 800 for Alinity i 4-module system/depends on configuration	—	165/—
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 specimens per hr.
• 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	—	—
Methodologies supported	chemiluminescence	fluorescence, indirect fluorescent antibody	—
Separation methodologies	magnetic particle	coated IFA slide	—
Stat time until completion of a β-hCG test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approximate No. of tests per reagent set/Reagent type	up to 1,500 (chem), up to 600 (immuno)/self-contained multiuse	120/—	30–900/closed reagent system with open reagent channels
Reagents refrigerated onboard/Reagents ready to use	yes (2°–10°C [chemistry], 2°–12°C [immunoassay])/yes	no/yes	yes (10°–14°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/no	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/no	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/yes	no/no
Walkaway capability/Walkaway duration	yes/240 min. or up to 600 specimens (150 specimens per module)	yes/190 specimens or 240 tests	yes/75 min. or 75 specimens or 248 tests
Design of sample-handling system	6-position rack	rack	ring
Uses washable cuvettes/Uses disposable cuvettes	chem: yes/immuno: yes (can store up to 1,000 cuvettes)	no/no	no/yes (can store up to 248 cuvettes)
Min.–max. sample volume that can be aspirated at one time	1.5–35 µL (chemistry), 2–200 µL (immunoassay)	—	3–200 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	80 µL/assay dependent/50 µL	—/assay dependent/tube dependent	150 µL/53 µL/50 µL
Dedicated pediatric sample cup	no	no	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (10–16.1 × 72–102 mm)	yes/yes (11–16 × 55–100 mm)	—
Pierces caps on primary tubes	no	no	yes
Protects against probe collision	yes	yes	no
Detects clots/liquid level/short sample	yes/yes/yes	no/yes/yes	no/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for hemolysis, icterus, lipemia, clots; quantitation for hemolysis, icterus, lipemia	hemolysis, icterus, lipemia, clots not available	hemolysis, icterus, lipemia, clots not available
Dilutes patient samples onboard/Susceptibility to carryover	yes/≤ 0.1 parts per million	yes/no carryover	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	yes	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	—	yes	no
Analyzer requires dedicated water supply	yes (27 L/hr. consumption during operation for chemistry, <10 L/hr. for immunoassay)	no	no
Autocalibration/Multipoint calibration supported	yes (calibrants are stored onboard)/yes	no (calibrants are not stored onboard)/—	yes (calibrants are not stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	1 day/new lot or 7–45 days/new lot or 13 days/new lot or 30 days/new lot or 30 days	—	3 hrs./—/—/30 days/—
Automatic programmable start/Automatic programmable shutdown	—/no	no/no	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	no/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	—	yes
Waste management	automated collection onboard instrument or direct to drain	—	automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, UPC, Code 39, Code 128, Matrix 2/5, Code 11, EAN/JAN, more)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	yes	yes	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	—	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	no
UPS backup power supply	yes	yes	no
Data-management capability/LIS or EHR systems interfaced	onboard/—	optional add-on (AESKU.LAB)/Sunquest, Orchard	onboard/CGM LabDaq, Orchard, CGM SchuyLab, LabTrak, more
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download and host query)	no/yes (host query)	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	—/based on contract	no/—	yes/24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	240 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 0 (chem and immuno); weekly: 30 min. (chem), 16 min. (immuno); monthly: 2 min. (chem), 0 (immuno)	daily: 5 min.; weekly: 20 min.	daily: 15 min.; weekly: 20–30 min.; monthly: 30–40 min.
Maintenance records kept onboard for user/vendor	some records (includes audit trail of who replaced parts)/no	no/no	yes (includes audit trail of who replaced parts)/no
Maintenance training demonstration module onboard	yes	no	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/12 hrs. (at customer site)	yes (1 training slot)/—	yes (1 training slot)/4.5 days (at customer and vendor sites [depends on sales agreement])
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer or vendor site)/yes	yes/—	no/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (varies by contract)/varies by contract	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> 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"> provides all-in-one IFA ANA, 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"> 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 new vitamin D test provides results in 10 minutes

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			
Name of instrument	ASI Evolution RPR Syphilis Analyzer	ChemWell 2	AU 5800
Type of instrument	immunoassay	immunoassay	chemistry
Operational type/Model type	batch/benchtop	batch/benchtop	continuous random access/floor standing
List price/First year sold in U.S.	\$50,995/2018	\$40,000/2020	—/2011
Targeted hospital bed size/Targeted test volume	—/daily: 100; monthly: 3,100; annual: 37,200	50/—	—/annual: ≥ 1.5 million
Company manufactures instrument	yes (also sold by Fisher Scientific, Cardinal, McKesson, VWR)	yes (also sold by Monobind, GMI, IDE, others)	yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific)
Other models in this family of analyzers	—	ChemWell Fusion 4800	DxC 700 AU, AU480
No. of units in clinical use in U.S./Outside U.S. (countries)	141/10	—/80 (Colombia, Qatar, Ghana, Panama, Peru, UAE, Jamaica, Israel, Bolivia, Austria, more)	—
Dimensions (H × W × D)/Instrument footprint	19 × 36 × 22 in./6 sq. ft.	23 × 42 × 25 in./7 sq. ft.	50 × 168 × 62 in./72 sq. ft.
Weight empty/Weight fully loaded	78 lbs./—	133 lbs./160 lbs.	2,300–6,375 lbs. (model dependent)/—
No. of different measured assays onboard simultaneously	1 (1 can be run and calibrated at one time)	up to 10 (4 can be run and calibrated at one time)	54–216 (54–216 can be run and calibrated at one time) (model dependent)
No. of user-definable (open chemistry) channels	0	—	18 (76 can be active simultaneously)
Test throughput per hour/Assay run time	190/9–11 min. (avg. 10 min.)	2 (assay dependent)/—	2,000–9,800/8 min. 30 sec.
Chemistry:			
No. of direct ion-selective electrode channels	—	—	3
Detection methods	—	—	photometry, potentiometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	4.5 min./model dependent
• Basic metabolic panel	—	—	12.5 min./model dependent
• Complete metabolic panel	—	—	14.5 min./model dependent
Typical time delay from ordering stat test until aspiration of sample	—	—	1 min.
Immunoassay:			
Fully automated microplate immunoassay system	yes (192 tests per unit; 48 wells per microplate)	yes (96 wells per microplate)	—
Methodologies supported	agglutination, flocculation	chemiluminescence, enzyme immunoassay	—
Separation methodologies	none necessary	centrifugation, coated microwell	—
Stat time until completion of a β-hCG test	—	assay dependent	—
• Typical time delay from test order to aspiration of sample	—	assay dependent	—
Stat time until completion of a cTn test	—	assay dependent	—
• Typical time delay from test order to aspiration of sample	—	assay dependent	—
Approximate No. of tests per reagent set/Reagent type	480/self-contained multiuse	96/open reagent system	200–6,000 (varies by assay)/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	no/yes	no (37°C)/yes	yes (4°–12°C)/yes
Reagent lot tracking/Reagent inventory	yes/no	yes/no	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/62 min. or 192 specimens or 192 tests	yes/120 min. or 96 specimens or 5 tests	yes/400 specimens
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/—	yes (can store up to 192 cuvettes)/no	yes/no
Min.–max. sample volume that can be aspirated at one time	2–500 µL	5–300 µL	1–25 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	110 µL/300 µL/150 µL	200 µL/5 µL/< 5 µL	120 µL/41 µL or 1 µL with 4 mm above gel barrier/50 µL
Dedicated pediatric sample cup	no	no	yes (dead volume: 50 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/no	yes/no	yes/yes (primary, secondary tubes: 11.5–16 × 55–102 mm; nested micro cups)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	yes	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	no/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available	detection for clots	detection and quantitation for hemolysis, icterus, lipemia, clots
Dilutes patient samples onboard/Susceptibility to carryover	yes/no	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/0.001 parts per million
Automatic rerun capability	no	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results	no	no	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	no	no	yes
Analyzer requires dedicated water supply	no (0.03 L/hr. consumption during operation)	no	yes (62–248 L/hr. consumption during operation) (model dependent)
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/no	no (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—	—/—/—/—/assay dependent	1 day/14 days/14–20 days/30 days/—
Automatic programmable start/Automatic programmable shutdown	no/no	no (< 5 min. warm-up time)/—	yes (90 sec. warm-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	yes/no	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	no	yes	yes
Waste management	manually by user	manually by user or direct to drain	direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (UPC, Code 39, Code 128)/yes	yes (Code 39, Code 128)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no	no	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	no	no	yes
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/—	onboard/Cerner, Antrim, CCA, Chemware, Dawning Technologies, SCC, Dynamic Healthcare, Antek, more
LIS interface provided/Bidirectional interface capability	no/no	no/yes (host query)	yes (included in instrument price)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/48 hrs.	no/72 hrs.	yes/within 24 hrs.
Mean time between failures	365 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	1.2 down service calls per year (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 10 min.; weekly: 10 min.; monthly: 10 min.	daily: 15 min.; weekly: 30 min.; monthly: 30 min.	daily: 8 min.; weekly: 15 min.; monthly: 45 min.
Maintenance records kept onboard for user/vendor	no/no	some records (self tests, calibrations, logs)/some records (logs)	yes/no
Maintenance training demonstration module onboard	no	no	yes
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/0.5 days (at customer site)	yes (4 training slots)/2 days (at customer site)	yes (2 training slots)/3 days (combination of vendor and customer sites; includes vendor training and in-lab operator training)
Advanced operator training/Extra charge for follow-up or advanced training	no/yes	yes (at customer site)/yes (contract dependent)	yes (at vendor site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year limited, service contract required)/varies by tier of service	yes (1 year)/contract dependent	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> low-cost, automated syphilis test 510(k) cleared for diagnostic, blood donor, and cadaveric screening can provide dilutions up to 1:2048 92 percent hands-on time savings compared with manual RPR testing 	<ul style="list-style-type: none"> fully customizable flexible software/firmware; remote access for troubleshooting fully customizable sample and reagent racks affordable analyzer; open ELISA/chemiluminescence system with more than 50 tests currently programmed 	<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
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

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FOR MID- AND HIGH-VOLUME LABORATORIES

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Name of instrument	DxC 700 AU chemistry	Dxl 9000 Access Immunoassay Analyzer immunoassay	Unicel Dxl 600 immunoassay
Type of instrument			
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.	—/2016	—/2023	—/2006
Targeted hospital bed size/Targeted test volume	—/annual: 500,000–1.5 million	—	—
Company manufactures instrument	yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific)	yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific)	yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific)
Other models in this family of analyzers	AU480, AU 5800	Access 2, Unicel Dxl 600, Unicel Dxl 800	Access 2, Unicel Dxl 800
No. of units in clinical use in U.S./Outside U.S. (countries)	—	—	—
Dimensions (H × W × D)/Instrument footprint	51 × 78 × 41 in./40.1 sq. ft.	63 × 79 × 41 in./22.5 sq. ft.	67 × 61.5 × 37.5 in./16 sq. ft.
Weight empty/Weight fully loaded	1,046 lbs./—	1,785 lbs./—	1,065 lbs./—
No. of different measured assays onboard simultaneously	63 (63 can be run and calibrated at one time)	50 (50 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 (120 can be active simultaneously)	0	0
Test throughput per hour/Assay run time	1,200 (800 photometric, 400 ISE tests in throughput)/8 min. 30 sec.	up to 450/8–50 min.	up to 200/13–55 min.
Chemistry:			
No. of direct ion-selective electrode channels	3	—	—
Detection methods	photometry, potentiometry	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	4.5 min./400 specimens per hr.	—	—
• Basic metabolic panel	12.5 min./133 specimens per hr.	—	—
• Complete metabolic panel	14.5 min./72 specimens per hr.	—	—
Typical time delay from ordering stat test until aspiration of sample	1 min.	—	—
Immunoassay:			
Fully automated microplate immunoassay system	—	no	no
Methodologies supported	—	chemiluminescence	chemiluminescence
Separation methodologies	—	magnetic particle	magnetic particle
Stat time until completion of a β-hCG test	—	10 min.	15 min.
• Typical time delay from test order to aspiration of sample	—	16 sec.	18 sec.
Stat time until completion of a cTn test	—	12 min.	17 min.
• Typical time delay from test order to aspiration of sample	—	16 sec.	18 sec.
Approximate No. of tests per reagent set/Reagent type	200–2,000 (varies by assay)/self-contained multiuse	50, 100, or 200 per kit/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°–10°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 (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/no
Walkaway capability/Walkaway duration	yes/2 hrs. avg. or 150 specimens or 7,200 tests	yes/240 min. or 140 specimens	yes/180 min. or 60 specimens
Design of sample-handling system	rack	rack or direct track sampling when connected to automation	rack
Uses washable cuvettes/Uses disposable cuvettes	yes/no	no/yes	no/yes (can store > 1,000 cuvettes)
Min.–max. sample volume that can be aspirated at one time	1–25 µL	2–200 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/40 µL or 4 mm above gel barrier	10 µL/150 µL/80 µL	10 µL/150 µL/140 µL
Dedicated pediatric sample cup	yes (dead volume: 50 µL)	yes (dead volume: 150 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/no	yes/—
Pierces caps on primary tubes	no	no	no
Protects against probe collision	yes	no	no
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection and quantitation for hemolysis, icterus, lipemia, clots	hemolysis, icterus, lipemia, clots not available	detection for clots; hemolysis, icterus, lipemia not available
Dilutes patient samples onboard/Susceptibility to carryover	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)/—	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	no	no
Analyzer requires dedicated water supply	yes (28 L/hr. consumption during operation)	no	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)	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/—	—/—/—/—/28 days	—/—/—/—/28 days
Automatic programmable start/Automatic programmable shutdown	yes (90 sec. warm-up time)/yes	no/no	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	no/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)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no
Lab can control analyzer from remote computer	yes	yes	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (instrument can order parts without operator intervention)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	no	yes
Data-management capability/LIS or EHR systems interfaced	onboard/Cerner, Antrim, CCA, Chemware, Dawning Technologies, SCC, Dynamic Healthcare, Antek, more	onboard/—	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	1.1 down service calls per year (displays error codes for troubleshooting)	— (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: 6 min.; weekly: 10 min.; monthly: 45 min.	weekly: < 15 min.; monthly: 7 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 (includes audit trail of who replaced parts)/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 (at vendor site)	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	no/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"> • ZeroDaily Maintenance eliminates daily maintenance; less than 15 minutes of cleaning per week • PrecisionVision Technology uses multiple cameras with defined algorithms to detect processing errors in real time • SimpleSolve provides instrument-guided troubleshooting 24/7 with step-by-step instructions 	<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 4 of 16	Binding Site, part of Thermo Fisher Scientific Haley Braffett haley.braffett@thermofisher.com San Diego, CA 858-291-4556 www.thermofisher.com/bindingsite	Bio-Rad Laboratories Clinical Diagnostics Group Maria Crisostomo maria_crisostomo@bio-rad.com Hercules, CA 800-224-6723 www.bio-rad.com	Bio-Rad Laboratories Clinical Diagnostics Group Maria Crisostomo maria_crisostomo@bio-rad.com Hercules, CA 800-224-6723 www.bio-rad.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	Optilite	BioPlex 2200 System	EVOLIS
Type of instrument	chemistry	immunoassay	immunoassay
Operational type/Model type	continuous random access/benchtop	continuous random access/floor standing	batch, random access/benchtop
List price/First year sold in U.S.	\$111,521/2015	—/2006	—/2001
Targeted hospital bed size/Targeted test volume	> 100/daily; > 50; monthly: ~1,000; annual: ~12,000	—/daily: ~800 samples	> 50/up to 360 samples per shift
Company manufactures instrument	no (manufactured by Thermo Fisher)	yes	no (manufactured by Stratec)
Other models in this family of analyzers	—	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	282/596 (Spain, Germany, France, UK, Italy, Denmark, more)	—/— (Australia, Canada, China, Europe, Hong Kong, Israel, Japan, Korea, New Zealand, Russia, Saudi Arabia)	—
Dimensions (H × W × D)/Instrument footprint	24.4 × 37 × 27.6 in./7.09 sq. ft.	53 × 72 × 34 in./12.9 sq. ft.	37 × 44 × 30 in./10 sq. ft.
Weight empty/Weight fully loaded	242 lbs./~260 lbs.	1,032 lbs./—	209 lbs./—
No. of different measured assays onboard simultaneously	34 (34 can be run and calibrated at one time)	51 (51 can be run and calibrated at one time)	4–8 (4–8 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	10	—	—
Test throughput per hour/Assay run time	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	yes (96 wells per microplate)
Methodologies supported	—	multiplex flow (cytometric)	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	100 (assay panel dependent), 200 (HIV, vitamin D, Lyme total), 150 (ToRC IgM)/self-contained multiuse	192/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (8°–10°C below ambient)/yes	yes (2°–8°C)/yes	no/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/no
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/90 min. or 54 specimens or 180 tests	yes/480 min. or 800 specimens or 9,600 tests	yes/180 specimens or 4 tests
Design of sample-handling system	rack	rack	—
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 360 cuvettes)	no/—	no/yes
Min.–max. sample volume that can be aspirated at one time	2–200 µL	3–150 µL	10–100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	120 µL/assay dependent/150 µL	3 µL/350 µL (tube size dependent)/250 µL	10 µL/10 µL/100 µL
Dedicated pediatric sample cup	yes (dead volume: 150 µL)	no	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (13 × 75 mm, 12 × 75 mm)	yes/no	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 hemolysis, clots; 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)/<1 part per million	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	yes	no	no
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	yes	no	no
Analyzer requires dedicated water supply	no (2 L/hr. consumption during operation)	no (0.5 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: per lab protocol and every new lot)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 30 days [assay dependent])	no (calibrants are not stored onboard)/yes (recommended avg. frequency: each run)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—	—/—/—/30 days (assay dependent)	—/—/—/each run
Automatic programmable start/Automatic programmable shutdown	no/no	yes/—	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	no	yes	yes
Waste management	automated collection onboard instrument	manually by user or automated collection onboard instrument or direct to drain	manually by user or 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)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no	no	no
Instrument can diagnose its own malfunctions	no (operator intervention required to order parts)	yes (operator intervention required to order parts)	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/Epic, Sunquest, Orchard, Cerner, SCC Soft Computer	onboard/Antrim, CCA, Cerner, Sunquest, CGM Schuyllab, Data Innovations, SCC Soft Computer, Meditech, Orchard, more	onboard/—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	no/yes (broadcast download and host query)	no/yes (broadcast download)
Modem servicing provided/Service engineer on-site response time	no/next business day	yes/< 24 hrs.	yes/24 hrs.
Mean time between failures	240 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 10 min.; weekly: 15 min.; monthly: 30 min.	daily: 5 min.; weekly: 30 min.; monthly: ~60 min.	daily: 5 min.; monthly: < 60 min.
Maintenance records kept onboard for user/vendor	some records (log)/no	yes/yes (both include audit trail of who replaced parts)	yes/yes (includes audit trail of who replaced parts)
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/2 days (primarily at customer site)	yes (2 training slots)/5 days (at vendor site)	yes (2 training slots)/5 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer site)/\$2,500	no/yes	no/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/\$12,950	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<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 for monitoring test performance; 51 assays: 26 autoimmune, 24 infectious disease, vitamin D compatible track line connectivity option CylancePROTECT Antivirus program provides digital protection against malware 	<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
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

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FOR MID- AND HIGH-VOLUME LABORATORIES

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Name of instrument	PhD Ix	PR4100 Microplate Reader	VIDAS 3
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	batch/benchtop	batch/benchtop	batch, random access, continuous random access/benchtop
List price/First year sold in U.S.	—/2012	—/2012	—/2015
Targeted hospital bed size/Targeted test volume	—/daily: 50–200 samples	—	—
Company manufactures instrument	yes	yes	yes
Other models in this family of analyzers	—	—	VIDAS, MINI VIDAS
No. of units in clinical use in U.S./Outside U.S. (countries)	—	—	> 500/—
Dimensions (H × W × D)/Instrument footprint	30 × 36 × 27 in./7 sq. ft.	5.3 × 13.7 × 7.4 in./—	24 × 29.5 × 25.5 in./5.2 sq. ft.
Weight empty/Weight fully loaded	112 lbs./—	5.7 lbs./—	154 lbs./—
No. of different measured assays onboard simultaneously	—	—	12 (several different lots of assays can be stored at one time)
No. of user-definable (open chemistry) channels	—	—	—
Test throughput per hour/Assay run time	—	—	up to 36/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	—	—	—
Immunoassay:			
Fully automated microplate immunoassay system	yes (96 tests per unit containing up to 8 different assays; 96 wells per microplate)	no	no
Methodologies supported	fluorescence, enzyme immunoassay	enzyme immunoassay	enzyme-linked fluorescent assay (ELFA) technology
Separation methodologies	none necessary	none necessary	—
Stat time until completion of a β-hCG test	—	—	25 min. (measures intact molecule)
• Typical time delay from test order to aspiration of sample	—	—	—
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approximate No. of tests per reagent set/Reagent type	192/open reagent system	—	30–60 per kit/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	no/yes	no/—	no/yes
Reagent lot tracking/Reagent inventory	yes/no	no/no	yes/—
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/no	liquid chemistry (open reagent system)/—	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	—	yes/yes
Walkaway capability/Walkaway duration	yes/192 specimens or 8 EIA or 4 IFA assays	no/—	yes/27 specimens or 12 tests
Design of sample-handling system	benchtop, reagent rack	batch, benchtop	rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/no	no/—
Min.–max. sample volume that can be aspirated at one time	1–100 µL	—	100–300 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	1 µL/1 µL/150 µL	—	100 µL/100 µL/125 µL for aliquot tubes
Dedicated pediatric sample cup	no	no	yes
Primary tube sampling	yes	no	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (12–13 × 100 mm, 75 × 100 mm)	no (microplate reader)/no (microplate reader)	yes/—
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	no	—
Detects clots/liquid level/short sample	no/yes/yes	yes/yes/no	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	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)/—	no/—	yes (can be programmed to perform dilutions prior to analysis)/no carryover
Automatic rerun capability	no	no	no
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	no
Analyzer requires dedicated water supply	no	no	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: each run)	no (calibrants are not stored onboard)/no	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 14, 28, or 56 days)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/—/—/—/each run	—	—/—/—/—/every 14, 28, or 56 days
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	yes (5 min. warm-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	no/yes	no/no	yes/yes
Supports multiple QC lot numbers per analyte	no	no	yes
Waste management	manually by user or automated collection onboard instrument	manually by user	manually by user or automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination	yes (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)/yes
Lab can control analyzer from remote computer	no	no	yes
Instrument can diagnose its own malfunctions	no (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	no	no	yes
UPS backup power supply	yes	no	yes
Data-management capability/LIS or EHR systems interfaced	onboard/—	no/—	onboard/Cerner, SCC Soft Computer, Meditech, Epic, more
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download and host query)	no/no	yes (additional cost)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/24 hrs.	no/—	no/< 24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	—	> 1 year (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: < 5 min.; weekly: 15 min.; monthly: < 30 min.	—	weekly: 10–15 min.
Maintenance records kept onboard for user/vendor	no/no	no/no	yes/no
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/2 days (at customer site)	yes (2 training slots)/1 day (at customer site)	yes/— (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	no/yes	no/yes	—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes/—	yes (1 year)/—
Distinguishing features (supplied by company)	<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 	<ul style="list-style-type: none"> specialty menu of critical care (acute kidney injury, sepsis, thrombosis), infectious disease (MMRV, Lyme, <i>C. difficile</i>, <i>H. pylori</i>, toxoplasmosis, CMV), and hormone (hCG) assays easy-to-use benchtop immunoassay system with ready-to-use assay format mean time between failure > 370 days

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

Part 6 of 16	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	Diazyme Laboratories Ericka Borges marketing@diayzme.com Poway, CA 858-455-4768 www.diazyme.com
Name of instrument	LIAISON XL	Pictus 700 (P700)	DZ-Lite 3000 Plus
Type of instrument	immunoassay	chemistry	immunoassay
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	batch, random access, continuous random access, discrete/floor standing	batch, random access/floor standing
List price/First year sold in U.S.	—/2010	\$60,190/2013	\$60,000/2017
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	—/daily: 1,000; monthly: 30,000; annual: 350,000
Company manufactures instrument	no	—	no (manufactured by SNIBE Diagnostics)
Other models in this family of analyzers	LIAISON XS	Pictus 500 (P500)	—
No. of units in clinical use in U.S./Outside U.S. (countries)	> 800/> 6,500	< 100/> 750 (Europe, Latin America, Africa, Middle East, Asia)	55/1 (Philippines, Netherlands)
Dimensions (H × W × D)/Instrument footprint	59 × 59 × 36 in./14.6 sq. ft.	39.4 × 38.1 × 26.4 in./7.1 sq. ft.	59.8 in. × 56.7 in. × 30 ft./—(3.5 ft. recommended clearance)
Weight empty/Weight fully loaded	—/661 lbs.	418 lbs./478 lbs.	502 lbs./—
No. of different measured assays onboard simultaneously	25 (25 can be run and calibrated at one time)	72 (up to 72 can be run and calibrated at one time)	25 (25 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	—	0
Test throughput per hour/Assay run time	up to 171/16–65 min. (avg. 35 min.)	720/30–1,200 sec. (avg. 300 sec.)	180 (180 tests in throughput, assay dependent)/15–45 min. (avg. 30 min.)
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	chemiluminescence	—	chemiluminescence
Separation methodologies	magnetic particle	—	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	50, 100, 200 (assay dependent)/self-contained multiuse	50–200 per set, 400–1,800 per pack/self-contained multiuse, open reagent system	100/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (12°C)/yes	yes (8° ±2°C)/yes	yes (10°)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/no	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/360 min. or 120 specimens or 1,000 tests	yes/180 min. or 95 specimens or 1,800 tests	yes/144 specimens or 1,500 tests
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 1,000 cuvettes)	yes/yes (can store up to 160 cuvettes)	no/yes (can store up to 700 cuvettes)
Min.–max. sample volume that can be aspirated at one time	50–1,000 µL	2–100 µL	5–300 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—/5 µL/150 µL	180 µL/22 µL/100 µL	200 µL/120 µL/100 µL
Dedicated pediatric sample cup	yes (dead volume: 50 µL)	yes (dead volume: 20 µL)	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes	yes/no	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
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)/30 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	no	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	no	yes	no
Analyzer requires dedicated water supply	no	no (< 3 L/hr. consumption during operation)	no
Autocalibration/Multipoint calibration supported	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)	no (calibrants can be stored onboard)/yes (recommended avg. frequency: 7 days)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—	8 hr./—/7 days/14 days/14 days	—/—/—/7 days
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	automated collection onboard instrument or direct to drain	manually by user or direct to drain	manually by user or direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, EAN 8/13, Code 93, UPCA/UPCE)/yes
Lab can control analyzer from remote computer	no	yes	yes
Instrument can diagnose its own malfunctions	no (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (instrument can order parts without operator intervention)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	yes	no
Data-management capability/LIS or EHR systems interfaced	onboard/Cerner, Epic, Sunquest, Vistar, SCC Soft Computer, Orchard, Meditech, Comtron, ApolloLIMS, LabWare, more	onboard/AP Visions, Medicus, CGM Schuylab, Labtrack, CGM LabDaq, Medytox	onboard/—
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download and host query)	yes (additional cost)/yes (broadcast download and host query)	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	yes/24 hrs.	no/48 hrs.	no/24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	1 year (displays error codes for troubleshooting)	1 year (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 10 min.; weekly: 20 min.; monthly: 30 min.	daily: 30 min.; weekly: 1 hr.; monthly: 2 hr.	daily: 20 min.; weekly: 20 min.; monthly: 90 min.
Maintenance records kept onboard for user/vendor	yes/no	no/no	no/no
Maintenance training demonstration module onboard	no	no	yes
Training included with purchase/Avg. time for basic user training	yes (3 training slots)/— (at customer site)	yes (2 training slots)/3 days (at customer site)	yes (as many training slots as needed)/2 hours (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	yes (at customer site)/no
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/\$5,500	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> unique menu advanced chemiluminescent technology for clinical and research applications

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

Part 7 of 16

FOR MID- AND HIGH-VOLUME LABORATORIES

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Name of instrument	Agility Automated ELISA System immunoassay	Envoy 500/Envoy 500+ Chemistry Analyzer chemistry	EUROLabWorkstation ELISA immunoassay
Type of instrument			
Operational type/Model type	batch/benchtop	batch, random access, continuous random access, discrete/benchtop	batch/benchtop
List price/First year sold in U.S.	—/2012	\$85,000/2004 (Envoy 500), 2014 (Envoy 500+)	—/2017
Targeted hospital bed size/Targeted test volume	—	—/daily: 20–80 patients; monthly: 4,200–17,000; annual: 50,000–200,000	—/> 3,000
Company manufactures instrument	yes	no (also sold by McKesson, RedByrd, Henry Schein)	yes (also sold by EUROIMMUN US)
Other models in this family of analyzers	DSX	—	—
(No. of units in clinical use in U.S./Outside U.S. (countries))	—/425 (worldwide)	250/—	—
Dimensions (H × W × D)/Instrument footprint	49 × 50 × 36 in./12.5 sq. ft.	27 × 40 × 23 in./10 sq. ft.	~34 × 129 × 32 in./—
Weight empty/Weight fully loaded	469 lbs./—	209 lbs./219 lbs.	~760 lbs./~990 lbs.
No. of different measured assays onboard simultaneously	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)	180 (180 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	— (up to 16 can be active simultaneously)	500 (40 can be active simultaneously)	—
Test throughput per hour/Assay run time	assay dependent (up to 1,536 tests per run)/assay dependent	490/—	> 200 (assay dependent)/—
Chemistry:			
No. of direct ion-selective electrode channels	—	4	—
Detection methods	—	photometry	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	3 min., 45 sec./37 specimens per hr.	—
• Basic metabolic panel	—	10 min./588 specimens per hr.	—
• Complete metabolic panel	—	15 min./266 specimens per hr.	—
Typical time delay from ordering stat test until aspiration of sample	—	< 1 min.	—
Immunoassay:			
Fully automated microplate immunoassay system	yes (up to 12 tests per unit; 96 wells per microplate)	—	yes (180 tests per unit; 96 wells per microplate)
Methodologies supported	enzyme immunoassay	—	enzyme immunoassay
Separation methodologies	coated microwell	—	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	—/open system with self-contained multiuse SmartKit	varies/open reagent system	96/open reagent system
Reagents refrigerated onboard/Reagents ready to use	no (23° ±4°C)/yes	yes (10°–15°C)/yes	no/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/yes	no/no	no/no
Walkaway capability/Walkaway duration	yes/up to 1,152 specimens or up to 1,152 tests	yes/240 min. or 52 specimens or > 1,000 tests/assays	yes/up to 480 min. or 800 specimens or 1,440 tests
Design of sample-handling system	rack	ring	rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	yes/no (can store up to 34 cuvettes)	no/yes (can store up to 1,440 cuvettes)
Min.–max. sample volume that can be aspirated at one time	10–300 µL	1–100 µL	5–1,100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	10 µL/—/—	300 µL/1 µL/100 µL	100 µL/5 µL/75 µL
Dedicated pediatric sample cup	no	no	yes (dead volume: 75 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (17 × 100 mm)	yes/yes	yes/yes (10–16 × 100 mm)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	no/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available	detection for clots; hemolysis, icterus, lipemia not available	detection for clots
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)/1.3 parts per million
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	no	no	no
Analyzer requires dedicated water supply	no	no (1 L/hr. consumption during operation)	no
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent)	no (calibrants are not stored onboard)/yes	no/yes (recommended avg. frequency: each run)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—/assay dependent/assay dependent/—/assay dependent	4 hrs./—/—/7–31 days/—	—/—/—/—/each run
Automatic programmable start/Automatic programmable shutdown	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	—
Waste management	automated collection onboard instrument	automated collection onboard instrument or direct to drain	automated collection onboard instrument or direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (UPC, Codabar, Code 39, Code 128, Code 93)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Data Matrix)/—
Lab can control analyzer from remote computer	no	no	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/Orchard, Cerner	onboard/CGM LabDaq, CGM SchuyLab, McKesson Horizon Lab, Medicus Solutions, more	onboard/—
LIS interface provided/Bidirectional interface capability	no/yes (host query)	no/yes (host query)	yes (additional cost)/yes (host query)
Modem servicing provided/Service engineer on-site response time	no/24 hrs.	no/24 business hrs.	yes/—
Mean time between failures	200 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 10 min.; weekly: 5 min.	weekly: 15 min.; monthly: 15 min.	—
Maintenance records kept onboard for user/vendor	no/no	yes/no	yes/yes
Maintenance training demonstration module onboard	no	no	yes
Training included with purchase/Avg. time for basic user training	no/3 days (at customer site)	yes (2 training slots)/3 days (at customer site)	yes (1 training slot)/1 day (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer site)/yes	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)/—	yes (1 year)/\$8,995 (M–F, 8 AM–7 PM)	yes (1 year)/—
Distinguishing features (supplied by company)	<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 	<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

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

Part 8 of 16	EUROIMMUN Medizinische Labordiagnostika Product Management Auto. automation-pm@euroimmun.de Luebeck, Germany +49 451 2032-0 www.euroimmun.com	FUJIFILM Healthcare Americas Corp. Amador Alejandro amador.alejo@fujifilm.com Lexington, MA 877-714-1924 www.ivd.fujimed.com	Fujirebio US Amanze Orusakwe amanze.orusakwe@fujirebio-us.com Malvern, PA 844-544-3787 www.fujirebio.com
Name of instrument	EUROLabWorkstation IFA	µTASWako i30	LUMIPULSE G1200
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	batch/benchtop	random access/benchtop	continuous random access/floor standing
List price/First year sold in U.S.	—/2019	—/2011	\$118,000/2016
Targeted hospital bed size/Targeted test volume	—/up to 3,000	—	> 50/daily; 80; monthly: 16,000; annual: 200,000
Company manufactures instrument	yes (also sold by EUROIMMUN US)	no (manufactured by FUJIFILM Wako Pure Chemical Corp.)	no (manufactured by Otsuka)
Other models in this family of analyzers	—	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—	25/400 (Canada, Germany, Japan, China, South Korea, Vietnam, Thailand, Malaysia, Philippines)	18/> 1,000 (Japan, Germany, France, Italy, Belgium, more)
Dimensions (H × W × D)/Instrument footprint	~34 × 115 × 32 in./—	21.5 × 20.5 × 23.4 in./3.34 sq. ft.	57.6 × 47.2 × 31.5 in./14.2 sq. ft.
Weight empty/Weight fully loaded	~760 lbs./~990 lbs.	157 lbs./—	727 lbs./794 lbs.
No. of different measured assays onboard simultaneously	75 (75 can be run and calibrated at one time)	6 (6 can be run and calibrated at one time)	36 (36 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)/—	25/—	120 (120 tests in throughput)/avg. 25 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	no
Methodologies supported	fluorescence	fluorescence	chemiluminescence
Separation methodologies	BIOCHIPS on indirect immunofluorescence slides	microcapillary gel electrophoresis	magnetic particle
Stat time until completion of a β-hCG test	—	—	30 min.
• Typical time delay from test order to aspiration of sample	—	—	none
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approximate No. of tests per reagent set/Reagent type	up to 1,200/self-contained multiuse	100/self-contained multiuse	42/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	no/yes	yes (2°–10°C)/yes	yes (2°–8°C)/no
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)/no	liquid 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/up to 360 min. or ~700 specimens or 750 tests	yes/190 min. or 50 specimens or 80 tests	yes/100 specimens
Design of sample-handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/no	no/no
Min.–max. sample volume that can be aspirated at one time	5–1,100 µL	3 µL minimum	10–140 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	100 µL/5 µL/75 µL	—/75 µL/72 µL	150 µL/110 µL/100 µL
Dedicated pediatric sample cup	yes (dead volume: 75 µL)	no	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (10–16 × 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	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots	hemolysis, icterus, lipemia, clots 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)/1.3 parts per million	no/0.1 parts per million	yes (can be programmed to perform dilutions prior to analysis)/1 part per million
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	no	no	no
Analyzer requires dedicated water supply	no	no	no (2.1 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	no/—	yes (calibrants are not stored onboard)/—	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 30 days)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/—/—/—/assay dependent	—	—/—/—/—/30 days
Automatic programmable start/Automatic programmable shutdown	—	no/no	yes (5 min. warm-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	no/yes	yes/yes
Supports multiple QC lot numbers per analyte	—	yes	yes
Waste management	automated collection onboard instrument or direct to drain	automated collection onboard instrument	manually by user or direct to drain
Sample barcode-reading capability/Autodiscrimination	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	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Standard 2 of 5)/no
Lab can control analyzer from remote computer	yes	yes	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	no
UPS backup power supply	yes	no	yes
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/—	onboard/SCC Soft Computer, more
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (host query)	no/yes (host query)	yes (included in instrument price)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/—	no/based on contract	no/24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	400 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	—	daily: 0; weekly: 0; monthly: 15 min.	daily: 15 min.; weekly: 30 min.; monthly: 45 min.
Maintenance records kept onboard for user/vendor	yes/yes	no/—	no/no
Maintenance training demonstration module onboard	yes	no	yes (2 training slots per module)
Training included with purchase/Avg. time for basic user training	yes (1 training slot)/1 day (at customer site)	yes/~2 days (at customer site)	yes/6 hrs. (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer or vendor site)/—	—	yes (at customer site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/\$14,375
Distinguishing features (supplied by company)	<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 	<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

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

Part 10 of 16	HORIBA Medical Brooke Bradley medical-marketing.us@horiba.com Canton, MI 734-487-8300 www.horiba.com	Mindray North America Anna Chen a.chen@mindray.com Redmond, WA 416-826-1883 www.mindray.com	QuidelOrtho Laura Osborne laura.osborne@quidelortho.com Raritan, NJ 800-828-6316 www.quidelortho.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	Yumizen C560	BS480	Vitros 3600 Immunodiagnostic System
Type of instrument	chemistry	chemistry	immunoassay
Operational type/Model type	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.	\$110,000/2023	\$80,000/2014	—/2008
Targeted hospital bed size/Targeted test volume	< 275/daily; 3,000; monthly: 60,000; annual: 720,000	<280/daily; 3,000; monthly: 60,000; annual: 720,000	150–4,500/daily; > 200; monthly: > 5,000; annual: > 60,000
Company manufactures instrument	yes (also sold by distribution partners)	yes (also sold by Thermo Fisher, HORIBA)	no (manufactured by Nypro Engineering and Technology group service; also sold by Cardinal, McKesson, more)
Other models in this family of analyzers	Yumizen C230, Yumizen C240	BA800	Vitros ECI/ECIQ Immunodiagnostic System
No. of units in clinical use in U.S./Outside U.S. (countries)	—	—/— (worldwide)	> 150/> 690 (North, Central, and South Americas, more)
Dimensions (H × W × D)/Instrument footprint	45 × 46 × 28 in./35 sq. ft.	46 × 28 × 45 in./35 sq. ft.	65 × 84 × 35 in./19.4 sq. ft.
Weight empty/Weight fully loaded	661 lbs./—	661 lbs./—	1,740 lbs./—
No. of different measured assays onboard simultaneously	81 (up to 81 can be run and calibrated at one time)	81 (50 can be run and calibrated at one time)	31 (31 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	up to 50 (50 can be active simultaneously)	200	0
Test throughput per hour/Assay run time	560/1–10 min. (avg. 8 min.)	400 photometric, up to 240 ISE/1–10 min. (avg. 8 min.)	189/16–73 min. (avg. 30 min.)
Chemistry:			
No. of direct ion-selective electrode channels	3	3	—
Detection methods	photometry, potentiometry	photometry, potentiometry, kinetic, end point, fixed time	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	~4.2 min./~56 specimens per hr.	1 min./60 specimens per hr.	—
• Basic metabolic panel	~7.7 min./~53 specimens per hr.	8 min./52 specimens per hr.	—
• Complete metabolic panel	~10.5 min./~50 specimens per hr.	11 min./50 specimens per hr.	—
Typical time delay from ordering stat test until aspiration of sample	~135 sec.	~2 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	160–500 (reagent dependent)/open reagent system	160–500/open reagent system	50–100/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (2°–10°C)/variable; reagent specific	yes (2°–10°C)/yes	yes (10°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/yes	— (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/143 min. or 87 specimens or 14 test panels	yes/dependent on reagent	yes/120 min. or 90 specimens or 3,100 tests
Design of sample-handling system	ring	ring, carousel	circular routine sampling center
Uses washable cuvettes/Uses disposable cuvettes	yes/no (can store up to 90 cuvettes)	yes (can store up to 90 cuvettes)/no	no/no
Min.–max. sample volume that can be aspirated at one time	1.5–45 µL	1.5–45 µL	2–200 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	120 µL/75 µL (test dependent)/70 µL	120 µL/75 µL/70 µL or 8 mm above gel barrier	—/10 µL/35 µL
Dedicated pediatric sample cup	yes (dead volume: 70 µL)	yes (dead volume: 70 µL)	yes (dead volume: 35 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/—	yes/no	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 and quantitation for hemolysis, icterus, lipemia; detection for clots	detection for hemolysis, icterus, lipemia	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)/500 parts per million	yes (can be programmed to perform dilutions prior to analysis)/< 500 parts per million	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	yes	no
Analyzer requires dedicated water supply	yes (average of 20 L/hr. consumption during operation)	yes (20 L/hr. consumption during operation)	no (no water consumption during operation)
Autocalibration/Multipoint calibration supported	yes (calibrants can be stored onboard)/yes (assay dependent)	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: assay dependent)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	8 hrs./as needed/as needed/14 days/—	8 hrs./—/—/—/—	—/—/—/—/28 days
Automatic programmable start/Automatic programmable shutdown	yes/yes	yes (10 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	automated collection onboard instrument or direct to drain	automated collection onboard instrument or direct to drain	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/—	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/—	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/yes
Lab can control analyzer from remote computer	no	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	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 (optional)	no	yes
Data-management capability/LIS or EHR systems interfaced	onboard/CGM Labdaq, Orchard, Sunquest, Apollo, Paracelsus	onboard/yes (Paracelsus, Sunquest, Orchard, more)	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/1 business day	no/contract dependent	yes/4 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	2,500 hrs. (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: < 5 min.; weekly: 1 hr.; monthly: 25 min.	daily: < 5 min.; weekly: ~ 1 hr.; monthly: 25 min.	daily: < 10 min.; weekly: 30 min.; monthly: 20 min.
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/some records (log)	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/3 days (online and at customer site)	yes (at least 1 training slot)/1 day (combination of vendor and customer sites; geography dependent)	yes (2 training slots)/5 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	no/—	yes (combination of vendor and customer sites; geography dependent)/yes (for service training)	yes (at customer site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (2 years)/contract dependent	yes (1 year)/depends on plan selected
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> reagents: high-quality POINTE reagents, multiple lots calibrated/QC at once, reagents can be loaded while running automated functions: startup, shutdown, calibration rerun, LIH, reflex, probe (liquid level, collision, clot, bubble, more) resource efficiency: low reagent and sample use 	<ul style="list-style-type: none"> reliable, dependable, excellent support easy operation, software intuitive, auto start-up, auto shutdown, autocalibration, auto reflex, and auto HIL 	<ul style="list-style-type: none"> Intelligence technology reports on diagnostic checks throughout the testing process to minimize errors for consistent performance designed to use single-patient consumables without the need for water, eliminating risk of carryover MicroSensor technology automates detection of HIL interferences
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 11 of 16 FOR MID- AND HIGH-VOLUME LABORATORIES	QuidelOrtho Laura Osborne laura.osborne@quidelortho.com Raritan, NJ 800-828-6316 www.quidelortho.com	QuidelOrtho Laura Osborne laura.osborne@quidelortho.com Raritan, NJ 800-828-6316 www.quidelortho.com	Randox Laboratories Graeme McNeill graeme.mcneill@randox.com Kearneysville, WV 304-728-2890 www.randox.com
Name of instrument Type of instrument	Vitros 4600 Chemistry System chemistry	Vitros XT 7600 Integrated System combination chemistry/immunoassay	RX imola chemistry
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	batch, random access, continuous random access, discrete/floor standing	discrete/benchtop
List price/First year sold in U.S.	—/2011	—/2018	—/2006
Targeted hospital bed size/Targeted test volume	150–4,500/daily: 600–3,000; monthly: 17,000–85,000; annual: 200,000–1.5 million	150–4,500/daily: 600–3,000; monthly: 17,000–85,000; annual: 200,000–4 million	75/daily: > 750; monthly: > 22,500; annual: > 270,000
Company manufactures instrument	no (manufactured by Nypro Engineering and Technology group service; also sold by Cardinal, McKesson, more)	no (manufactured by Nypro Engineering and Technology group service; also sold by Cardinal, McKesson, more)	yes
Other models in this family of analyzers	Vitros 350 Chemistry System, Vitros XT 3400 Chemistry System	Vitros 5600 Integrated System	RX misano, RX monaco, RX daytona +, RX modena
No. of units in clinical use in U.S./Outside U.S. (countries)	> 160/> 980 (North, Central, and South Americas, more)	> 460/> 400 (North, Central, and South Americas, more)	34/> 1,000 (> 120 countries)
Dimensions (H × W × D)/Instrument footprint	53 × 92 × 33 in./21.4 sq. ft.	68 × 110 × 34.9 in./26.7 sq. ft.	27 × 38 × 23 in./44.28 sq. ft.
Weight empty/Weight fully loaded	1,400 lbs./—	2,360 lbs./—	331 lbs./340 lbs.
No. of different measured assays onboard simultaneously	82 (82 can be run and calibrated at one time)	150 (150 can be run and calibrated at one time)	60 (60 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	20 (20 can be active simultaneously)	20 (20 can be active simultaneously)	15 (0 can be active simultaneously)
Test throughput per hour/Assay run time	845/2.5–20 min. (avg. 5 min.)	1,320/2.5–73 min. (avg. 7 min.)	560, including ISE (50 tests in throughput)/5–10 min. (avg. 6 min.)
Chemistry:			
No. of direct ion-selective electrode channels	3	3	3
Detection methods	photometry, potentiometry, colorimetric, turbidimetric	photometry, potentiometry, turbidimetric, direct enhanced chemiluminescence	potentiometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	5 min./126 tests per hr.	5 min./126 tests per hr.	13 min. 15 sec./80 specimens per hr.
• Basic metabolic panel	6 min./84 tests per hr.	6 min./95 tests per hr.	13 min. 43 sec./80 specimens per hr.
• Complete metabolic panel	7.5 min./50 tests per hr.	7.5 min./74 tests per hr.	13 min. 15 sec./67 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	1 min.	1 min.	30 sec.
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	60/self-contained single use, open reagent system	50–100/varies for chemistry and immunoassay	200/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	yes (10°C)/yes	yes (10°C)/yes	yes (8°–15°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	dry chemistry, liquid chemistry (open reagent system)/yes	dry chemistry, liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/120 min. or 160 specimens or 8,940 tests	yes/—	yes/70 min. or 40 specimens or 10 tests
Design of sample-handling system	continuous load and unload, circular routine sample center	continuous load and unload, circular routine sample center	ring
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 348 cuvettes)	no/yes (can store up to 348 cuvettes)	yes (can store up to 90 cuvettes)/no
Min.–max. sample volume that can be aspirated at one time	2–200 µL	2–200 µL	1.5–35 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	0 µL/2 µL/35 µL	0 µL/2 µL/35 µL	150 µL/1.5–35 µL/150 µL
Dedicated pediatric sample cup	yes (dead volume: 35 µL)	yes (dead volume: 35 µL)	yes (dead volume: 100 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (micro sample cups, 10.25 × 45 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, 13 × 100 mm, 16 × 75 mm, 16 × 100 mm)	yes/yes (micro sample cups, 10.25 × 45 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, 13 × 100 mm, 16 × 75 mm, 16 × 100 mm)	—
Pierces caps on primary tubes	no	no	no
Protects against probe collision	yes	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/no
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection and quantitation for hemolysis, icterus, lipemia; detection for clots	detection and quantitation for hemolysis, icterus, lipemia; detection for clots	detection and quantitation for hemolysis, icterus, lipemia; clots not available
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/0	yes (can be programmed to perform dilutions prior to analysis)/0	yes (can be programmed to perform dilutions prior to analysis)/no carryover
Automatic rerun capability	yes	yes	yes
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	yes	yes	yes
Analyzer requires dedicated water supply	no (no water consumption during operation)	no (no water consumption during operation)	yes (18 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 6 mos. or lot change for most chemistry assays)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 6 mos. or lot change for most chemistry assays)	no (calibrants can be stored onboard)/yes (recommended avg. frequency: 14 days)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	6 mos./6 mos./6 mos./6 mos./—	6 mos./6 mos./6 mos./6 mos./28 days	1 day/7 days/7 days/14 days/28 days
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	yes (9 min. warm-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	—/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	manually by user	manually by user	direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/—	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no	no	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	yes	no
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/—	onboard/—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	yes (additional cost)/yes (broadcast download and host query)	yes (included in instrument price)/yes (host query)
Modem servicing provided/Service engineer on-site response time	yes/4 hrs.	yes/4 hrs.	no/within 24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	2 per 3 years (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 5 min.; weekly: 30 min.; monthly: 20 min.	daily: < 10 min.; weekly: 30 min.; monthly: 20 min.	daily: 5 min.; weekly: 15 min.; monthly: 1 hr.
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/no	yes (includes audit trail of who replaced parts)/no	no/no
Maintenance training demonstration module onboard	yes	yes	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/5 days (at customer site)	yes (2 training slots)/5 days (at customer site)	yes (1 training slot)/3 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer site)/yes	yes (at customer site)/yes	yes (at customer site)/yes
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/depends on plan selected	yes/depends on plan selected	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • Intellicheck technology reports on diagnostic checks throughout the testing process to minimize errors for consistent performance • designed to use single-patient consumables without the need for water, eliminating risk of carryover • MicroSensor technology automates detection of HIL interferences 	<ul style="list-style-type: none"> • XT MicroSlide performs two tests on one slide, which doubles testing output, increases productivity, and fulfills more requests from difficult draws • designed to use single-patient consumables without the need for water, eliminating risk of carryover • MicroSensor technology automates detection of HIL interferences 	<ul style="list-style-type: none"> • large and extensively dedicated test menu • stat sample capabilities • benchtop analyzer

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

Part 12 of 16 FOR MID- AND HIGH-VOLUME LABORATORIES	Roche Diagnostics John Kleinschmidt john.kleinschmidt@roche.com Indianapolis, IN 800-428-5074 diagnostics.roche.com/us/en/home.html	Roche Diagnostics John Kleinschmidt john.kleinschmidt@roche.com Indianapolis, IN 800-428-5074 diagnostics.roche.com/us/en/home.html	Roche Diagnostics John Kleinschmidt john.kleinschmidt@roche.com Indianapolis, IN 800-428-5074 go.roche.com/cobasproUS
Name of instrument Type of instrument	cobas 6000 analyzer series combination chemistry/immunoassay	cobas 8000 modular analyzer series combination chemistry/immunoassay	cobas pro integrated solutions combination chemistry/immunoassay
Operational type/Model type 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)	random access, continuous random access/floor standing —/2006 > 100/daily; 1,000–4,000; annual: 500,000–2,500,000 no (manufactured by Hitachi High-Technologies) chemistry: cobas c 501; immunoassay: cobas e 601 > 1,600/> 14,000 (56 countries)	random access, continuous random access/floor standing —/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)	random access, continuous random access/floor standing —/2019 > 200/daily: 2,000–4,000; annual: 750,000–4.5 million no (manufactured by Hitachi High-Technologies) cobas pure integrated solutions > 650/> 3,000 (> 40 countries)
Dimensions (H × W × D)/Instrument footprint Weight empty/Weight fully loaded No. of different measured assays onboard simultaneously	51 × 74–196 × 41 in./34.62 sq. ft. for 2-module configuration 830–1,990 lbs./830–1,990 lbs. up to 151 (up to 148 can be run and calibrated at one time)	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/54 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) 10 (10 can be active simultaneously) up to 4,400 (varies by module)/chem: 4.5–10 min. (avg. 10 min.); immuno: 9–27 min. (avg. 18 min.)
No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	20 (all can be active simultaneously) 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.)	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 4,400 (varies by module)/chem: 4.5–10 min. (avg. 10 min.); immuno: 9–27 min. (avg. 18 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	3 indirect photometry, potentiometry 4.5 min./133 specimens per hr. 7 min./up to 240 specimens per hr. 10 min./up to 110 specimens per hr. < 1 min.	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.
Immunoassay:			
Fully automated microplate immunoassay system Methodologies supported Separation methodologies Stat time until completion of a β-hCG test • Typical time delay from test order to aspiration of sample Stat time until completion of a cTn test • Typical time delay from test order to aspiration of sample	no electrochemiluminescence magnetic particle 9 min. 42 sec. 9 min. 42 sec.	no electrochemiluminescence magnetic particle ~10 min. < 1 min. 9 min. 24 sec.	no electrochemiluminescence magnetic particle ~10 min. < 1 min. ~10 min. < 1 min.
Approximate No. of tests per reagent set/Reagent type Reagents refrigerated onboard/Reagents ready to use Reagent lot tracking/Reagent inventory Reagent form/Reagents barcoded Separate reagent pack for each specimen/for each test run Walkaway capability/Walkaway duration	up to 800 per pack (chemistry), up to 200 per pack (immunoassay)/self-contained multiuse yes (5°–12°C [chemistry], 20°±3°C [immunoassay])/yes yes/yes liquid chemistry (open reagent system)/yes no/no yes/75 min. or 150 samples or 1,500 tests	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
Design of sample-handling system Uses washable cuvettes/Uses disposable cuvettes Min.–max. sample volume that can be aspirated at one time Min. reaction volume/Min. specimen volume/Min. dead volume 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 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	5-position rack immuno: yes (can store up to 1,008 cuvettes)/no 1–35 µL 100–250 µL (chem), 120–200 µL (immuno)/1.5 µL (chem), 4–10 µL (immuno)/500 or 1,000 µL (tube dependent) yes (dead volume: 50 µL) yes yes/yes no yes yes/yes/yes detection for hemolysis, icterus, lipemia, clots yes (can be programmed to perform dilutions prior to analysis)/< 1 part per million (chemistry), no carryover (immunoassay) yes yes yes	5-position rack yes (No. of cuvettes stored varies by module)/no 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) 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 yes yes	5-position rack yes (can store up to 221 cuvettes for chem, 1,575 for immuno)/yes 1–60 µL 75 µL/1.5 µL (chem), 4 µL (immuno)/50 µL 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) yes yes yes
Analyzer requires dedicated water supply Autocalibration/Multipoint calibration supported Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays Automatic programmable start/Automatic programmable shutdown Onboard real-time QC/Onboard software capability to review QC Supports multiple QC lot numbers per analyte Waste management	yes (10 L/hr. consumption during operation for chemistry, 12 L/hr. for immunoassay) yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 24 hrs. [ISE], once per lot [chemistry], up to 56 days per lot [immunoassay]) 24 hrs./once per lot/42 days per lot/once per lot/up to 56 days per lot yes/yes yes/yes yes direct to drain	yes (10–36 L/hr. consumption during operation for chemistry, 12–30 L/hr. for immunoassay) yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 24 hrs. [ISE], once per lot [chemistry], up to 84 days per lot [immunoassay]) 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 yes direct to drain	yes (32 L/hr. consumption during operation for chemistry, 30 L/hr. for immunoassay) yes (calibrants are not stored onboard)/yes (recommended avg. frequency: once per lot [chem], up to 84 days per lot [immuno]) 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 yes direct to drain
Sample barcode-reading capability/Autodiscrimination Lab can control analyzer from remote computer Instrument can diagnose its own malfunctions System malfunctions can be diagnosed via remote monitoring UPS backup power supply Data-management capability/LIS or EHR systems interfaced LIS interface provided/Bidirectional interface capability Modem servicing provided/Service engineer on-site response time	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes yes yes (operator intervention required to order parts) yes yes onboard/— yes (incl. in instrument price)/yes (broadcast download and host query) yes/< 8 hrs.	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.	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/—
Mean time between failures 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 Advanced operator training/Extra charge for follow-up or advanced training Warranty provided/Cost of annual service contract (24 h/7 d)	avg. 259 days per module (displays error codes for troubleshooting) daily: 4 min.; weekly: 20 min.; monthly: 35 min. yes/yes (both include audit trail of who replaced parts) yes yes (2 training slots)/varies at customer site, 5 days at vendor site yes (at vendor site)/yes	avg. 152 days per module (displays error codes for troubleshooting) 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 yes (at vendor site)/yes (cost varies by contract)	c 503 module: 220 days; e 801 module: avg. 220 days (displays error codes for troubleshooting) daily: ~5 min.; weekly: 0 min.; monthly: ~59 min. yes/yes (both include audit trail of who replaced parts) yes yes (~ 2 training slots per module)/~5 days (at customer and vendor sites) yes (at vendor site)/yes (cost varies by contract)
Distinguishing features (supplied by company) <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>	• broad test menu: > 180 assays on one integrated platform • flexible, scalable design: available in seven unique configurations	• high reagent onboard and calibration stability; no reagent prep; on-the-fly loading • broad test menu: > 180 assays on one integrated platform	• minimal operator intervention with automated maintenance, automated calibration, and continuous loading of reagents • long onboard reagent (up to 6 months) and calibration stabilities • increase revenue through expanded testing services with broad menu on consolidated platform and fast incubation times

Part 13 of 16 FOR MID- AND HIGH-VOLUME LABORATORIES	Siemens Healthineers Leslie Rau leslie.rau@siemens-healthineers.com Tarrytown, NY 800-888-7436 www.siemens-healthineers.com/en-us	Siemens Healthineers Tony Gaglio tony.gaglio@siemens-healthineers.com Tarrytown, NY 800-888-7436 www.siemens-healthineers.com/en-us	Siemens Healthineers Rachel Forsaith rachel.forsaith@siemens-healthineers.com Tarrytown, NY 800-888-7436 www.siemens-healthineers.com/en-us
Name of instrument Type of instrument	Atellica Solution Analyzer combination chemistry/immunoassay	Atellica CI Analyzer combination chemistry/immunoassay	IMMULITE 2000 XPi Immunoassay System immunoassay
Operational type/Model type	batch, random access, continuous 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.	—/2017	—/2023	—/2009
Targeted hospital bed size/Targeted test volume	—/annual: > 1 million	—/annual: 250,000–1 million	> 200/daily: > 250
Company manufactures instrument	yes (also sold by McKesson, Henry Schein, Medline)	yes (also sold by McKesson, Henry Schein, Medline, Fisher)	yes (also sold by McKesson, Henry Schein, Medline)
Other models in this family of analyzers	Atellica CH 930, IM 1300, IM 1600	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—	—	≥ 550/≥ 2,400 (> 75 countries)
Dimensions (H × W × D)/Instrument footprint	chem: 53.7 × 58.6 × 45.5 in.; immuno: 59.1 × 56.9 × 45.0 in./64.6 sq. ft.	63.0 × 80.1 × 36.8 in./20.4 sq. ft.	47 × 60 × 30 in./—
Weight empty/Weight fully loaded	chem: 1,036 lbs.; immuno: 1,265 lbs./—	1,675 lbs./—	800 lbs./—
No. of different measured assays onboard simultaneously	chem: up to 70; immuno: up to 42	chem: up to 45 (45 can be run and calibrated at one time); immuno: up to 20 (20 can be run and calibrated at one time)	24
No. of user-definable (open chemistry) channels	—	25 (25 can be active simultaneously)	none
Test throughput per hour/Assay run time	chem: up to 1,800; immuno: up to 440 (up to 2,240 tests in throughput)/10–54 min.	chem: up to 1,000 (600 photometric, 400 electrolyte tests in throughput); immuno: up to 120 (assay dependent)/24 sec.–54 min. (avg. 14 min.)	up to 200 (200 tests in throughput)/—
Chemistry:			
No. of direct ion-selective electrode channels	3	3	—
Detection methods	photometry, potentiometry, turbidimetric, EMIT	photometry, potentiometry, turbidimetric, EMIT	—
Stat time until completion/specimen throughput for:	—	—	—
• Ion-selective electrode	18–27 sec./—	24 min./—	—
• Basic metabolic panel	10 min./—	10 min./—	—
• Complete metabolic panel	10 min./—	10 min./—	—
Typical time delay from ordering stat test until aspiration of sample	60 sec. maximum	60 sec. maximum	—
Immunoassay:			
Fully automated microplate immunoassay system	no	no	no
Methodologies supported	chemiluminescence, acridinium ester chemiluminescence	chemiluminescence, acridinium ester chemiluminescence	enzyme-amplified chemiluminescence
Separation methodologies	magnetic particle	magnetic particle	bead
Stat time until completion of a β-hCG test	10 min.	10 min.	35 min.
• Typical time delay from test order to aspiration of sample	60 sec. maximum	60 sec. maximum	18 sec.
Stat time until completion of a cTn test	10 min.	10 min.	35 min.
• Typical time delay from test order to aspiration of sample	60 sec. maximum	60 sec. maximum	18 sec.
Approximate No. of tests per reagent set/Reagent type	50–8,000 (assay dependent)/self-contained multiuse, open reagent system	95–2,100 (assay dependent)/self-contained multiuse, open reagent system	200/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (4°–8°C)/yes	yes (4°–10°C)/yes	yes (2°–8°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/300 min. or 9,000 tests (chem), 450 min. or 1,200 tests (immuno)	yes/120 min. or 2,000 tests (chem), 240 tests (immuno)	yes/up to 300 min.
Design of sample-handling system	multiple rack drawer	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	yes/yes (can store up to 221 cuvettes for chem, up to 1,200 for immuno)	yes/yes (can store up to 194 cuvettes for chem, up to 856 for immuno)	no/yes (can store up to 1,300 cuvettes)
Min.–max. sample volume that can be aspirated at one time	2–50 µL (chem), 10–200 µL (immuno)	2–100 µL (assay dependent)	5–600 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	assay dependent/assay dependent/container dependent	10–100 µL/2 µL/—	—/5 µL/50 µL
Dedicated pediatric sample cup	no	no	yes (dead volume: 50 µL)
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes	yes/yes (8 × 31.37 mm)	yes/yes (12–16 × 75–100 mm; 10 × 50 mm micro sample tubes)
Pierces caps on primary tubes	—	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 hemolysis, icterus, lipemia, clots	detection for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/no	yes (can be programmed to perform dilutions prior to analysis)/< 3 parts per million
Automatic rerun capability	yes	yes	yes
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	yes	—	no
Analyzer requires dedicated water supply	yes (33 L/hr. consumption during operation for chemistry, 6 L/hr. for immunoassay)	yes (25 L/hr. consumption during operation for chem, immuno combined)	no
Autocalibration/Multipoint calibration supported	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 28–183 days [chem], 14–91 days [immuno])	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 28–183 days [chem], 14–91 days [immuno])	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 1–4 weeks [assay dependent])
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	every 4 hrs./28–63 days/40–180 days/up to 180 days/14–91 days	every 4 hrs./every 28–63 days/40–180 days/up to 180 days/14–91 days	—/2 weeks/—/—/1–4 weeks (assay dependent)
Automatic programmable start/Automatic programmable shutdown	yes/yes	yes/no	— (4 min. warm-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	manually by user or direct to drain	manually by user, automated collection onboard instrument, direct to drain	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	yes	yes	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	no
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	optional add-on (Siemens Atellica Data Manager)/yes	optional add-on (Siemens Atellica Data Manager)/yes	optional add-on (Siemens CentralLink Data Manager)/yes
LIS interface provided/Bidirectional interface capability	yes (incl. in price)/yes (broadcast download and host query)	yes (incl. in price)/yes (broadcast download and host query)	yes/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/5 hrs. avg.	yes/—	yes/2–8 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: < 5 min.; weekly: 10–15 min.; monthly: 10–15 min.	daily: < 5 min.; weekly: < 5 min.; monthly: < 15 min.	daily: 5–10 min.; weekly: 20 min.; monthly: 20–30 min.
Maintenance records kept onboard for user/vendor	yes/yes (both include audit trail of who replaced parts)	yes/yes (both include audit trail of who replaced parts)	no/no
Maintenance training demonstration module onboard	yes	yes	yes
Training included with purchase/Avg. time for basic user training	yes (3 training slots)/6.5 days (at customer and vendor sites)	yes (3 training slots)/1–3 days (at customer site)	yes (2 training slots)/3 days (at customer and vendor sites)
Advanced operator training/Extra charge for follow-up or advanced training	—	yes (at vendor site)/no	yes (at vendor site)/contract dependent
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"> patented Atellica Magline bidirectional sample transport uses individual sample carriers for rapid throughput automated high-capacity calibration and chemistry QC processing materials stored onboard with auto deployment microvolume sample technology for CC; IA controlled temperature requires no recalibration if laboratory ambient temp. changes 	<ul style="list-style-type: none"> integrated chem/immuno technologies share no major common components true random-access sampling via independent CH/IA probes standardized user interface across Atellica portfolio 	<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

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

Part 14 of 16	Thermo Fisher Scientific/BRAHMS kryptor.analyzer@thermofisher.com Hennigsdorf, Germany +49(0)33028830 www.thermoscientific.com/kryptor	Thermo Fisher Scientific Jessica Murphy jessica.murphy@thermofisher.com Portage, MI 800-346-4363 www.thermofisher.com/phadia	Tosoh Bioscience info.diag.am@tosoh.com Grove City, OH 800-248-6764 www.diagnostics.us.tosohbioscience.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	B-R-A-H-M-S KRYPTOR GOLD	Phadia 250 Laboratory System	AIA-900
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	batch, random access, continuous random access/benchtop	continuous random access, discrete/floor standing	continuous random access/floor standing
List price/First year sold in U.S.	—	—/2004	—/2011
Targeted hospital bed size/Targeted test volume	—/daily: 600; monthly: 12,000; annual: 156,000	—/annual: > 20,000–95,000	—/monthly: 500–1,500
Company manufactures instrument	yes (also sold by distribution partners)	no (manufactured by Hitachi)	yes
Other models in this family of analyzers	B-R-A-H-M-S KRYPTOR compact PLUS	Phadia 1000, Phadia 2500, Phadia 5000 Laboratory Systems	AIA-360, AIA-2000
No. of units in clinical use in U.S./Outside U.S. (countries)	—/— (worldwide)	> 260/> 2,135	~350/> 1,200 (worldwide)
Dimensions (H × W × D)/Instrument footprint	28.74 (47.64 with tower light or open hood) × 36.61 × 28.34 in./55.11 in.	73 × 50 × 30 in. plus 26-in. wide computer stand/54 sq. ft.	49 × 35 × 26 in. (loader), 49 × 51 × 26 in. (9-tray sorter), 49 × 60 × 26 in. (19-tray sorter)/—
Weight empty/Weight fully loaded	260 lbs./—	485 lbs./—	404 lbs. (loader), 562 lbs. (9-tray sorter), 602 lbs. (19-tray sorter)/—
No. of different measured assays onboard simultaneously	16 (16 can be run and calibrated at one time)	6 (6 can be run and calibrated at one time)	45
No. of user-definable (open chemistry) channels	—	0	0
Test throughput per hour/Assay run time	115 (up to 115 tests in throughput)/9–59 min.	60 tests/100 min.	90/—
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	—
Methodologies supported	fluorescence, enzyme immunoassay	fluoroenzyme immunoassay	fluorescence
Separation methodologies	none necessary	fiber matrix filter, coated microwell	—
Stat time until completion of a β-hCG test	14 min.	—	20 min.
• Typical time delay from test order to aspiration of sample	2 min.	—	—
Stat time until completion of a cTn test	—	—	20 min.
• Typical time delay from test order to aspiration of sample	—	—	—
Approximate No. of tests per reagent set/Reagent type	50–100/self-contained multiuse	varies/self-contained multiuse	100/unit dose test cup
Reagents refrigerated onboard/Reagents ready to use	yes (2°–8°C)/yes	yes (2°–8°C for conjugates, ImmunoCAP, EiiA wells; others at room temperature)/variable; reagent specific	no/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/no
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes	dry chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	yes/—
Walkaway capability/Walkaway duration	yes/430 min. or 18 specimens or 419 tests	yes/100 min.	yes/~ 2 hours or 45 specimens or 45 tests
Design of sample-handling system	sample cassette placed in sample carousel	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/no	no/no
Min.–max. sample volume that can be aspirated at one time	8–70 µL	20–40 µL	2–100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	150 µL/sample tube and assay dependent/150 µL sample tube dependent	40 µL (ImmunoCAP), 20 µL (EiiA)/—/150 µL	10 µL/110 µL/100 µL
Dedicated pediatric sample cup	yes (dead volume: 75 µL)	no	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes (11–17 × 60–120 mm)	yes/—	yes/—
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	yes	—
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available	—
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/≤ 2 parts per million (no contamination)	yes/—	no/no carryover
Automatic rerun capability	yes	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	yes	no	no
Analyzer requires dedicated water supply	no	no (1 L/hr. consumption during operation)	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/no	yes (calibrants are stored onboard)/yes (recommended avg. frequency: 28 days)	no (calibrants are stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/—/—/—/5–15 days	—/—/—/—/28 days	—/—/—/—/most assays are 90 days
Automatic programmable start/Automatic programmable shutdown	no/no	yes/yes	no (5 min. warm-up time)/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	no/no
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	manually by user or automated collection onboard instrument	automated collection onboard instrument or direct to drain	automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Code 93, EAN-8, Industrial 2 of 5, COOP 2 of 5)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, JAN)/yes
Lab can control analyzer from remote computer	no	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	no
System malfunctions can be diagnosed via remote monitoring	yes	yes	—
UPS backup power supply	yes	yes	yes
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/Antek, Cerner, Data Innovations, Epic, GE TriplerG, McKesson, Mediatech, NetLIMS, more	optional add-on (Tosoh 501RP+)/—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	—/yes (broadcast download and host query)	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	yes/Mon.–Fri.: 26 hrs. at total breakdown, 72 hrs. at workaround	no/24 business hrs.	—
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	354 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 3 min.; weekly: 3 min.; monthly: 5 min.	daily: 5 min.; weekly: 10 min.; monthly: 3 hrs.	daily: 10 min.; weekly: 15 min.; monthly: 15 min.
Maintenance records kept onboard for user/vendor	yes/yes (both include audit trail of who replaced parts)	some records (date of instrument maintenance)/no	no/no
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes (1 training slot)/1.5–2 days (at customer site)	yes (2 training slots)/4 days (vendor site preferred, at customer site on request)	yes/2.5 days (at vendor site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/yes	yes (at vendor site)/—	no/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/contract dependent	yes (1 year)/—	yes (1 year from installation date)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> fully automated random-access immunoanalyzer with unique Nobel Prize-winning TRACE technology automated timely onboard dilution in less than 5 minutes with integrated self-determining dilution factor no biotin interferences of the assays 	<ul style="list-style-type: none"> collection of high-quality, clinically relevant autoimmune disease tests with the 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 info.diag.am@tosoh.com Grove City, OH 800-248-6764 www.diagnostics.us.tosohbioscience.com	Werfen Edward Bass AID.marketing.na@werfen.com San Diego, CA 858-586-9900 www.werfen.com	Werfen Liliana Penaranda AID.marketing.na@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)	yes	yes
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	—/1,000
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)	20 (20 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	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 720/30 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	no
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/no	no/yes
Walkaway capability/Walkaway duration	yes/~3 hours or 200 specimens or 960 tests	yes/6.5 hrs.	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	4–250 µL
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	yes
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	—
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/—	no/—	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	yes	yes	yes
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	yes
Sample volume can be concentrated to rerun out-of-linear-range low results	no	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)	yes (calibrants can be stored onboard)/yes	no (calibrants are not stored onboard)/yes
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)/yes
Lab can control analyzer from remote computer	no	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	no (operator intervention required to order parts)	no (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	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)	no/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 consumable walkaway time; generates up to 720 results per hour 	<ul style="list-style-type: none"> • improves laboratory workflow and productivity; eliminates batching and reagent waste with stable onboard reagents • provides simultaneous random-access processing of all isotopes and assays from one sample on a single run • delivers results, including stat orders, in as little as 30 minutes; minimal hands-on time for user maintenance
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

