

Part 1 of 15	Abbott US Marketing Core Diagnostics ats@abbott.com Abbott Park, IL 800-323-9100 corelaboratory.abbott	Aesku Amanda Aulicino amanda.aulicino@thermofisher.com Des Plaines, IL 844-544-5044 www.aesku.com	Alfa Wassermann Diagnostic Technologies info@alfawassermannus.com West Caldwell, NJ 800-220-4488 www.alfawassermannus.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument Type of instrument	Alinity ci-series combination chemistry/immunoassay	HELIOS HTC immunoassay	ACE Axcel 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	\$41,875/2012
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 (also sold by Thermo Fisher Scientific)	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)	~3,625/~16,600 (154 countries)	> 60/> 500 (Europe, North and South America, Asia, Africa, more)	—
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	180/—	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/yes	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 (HERA lab management system)/Clinisys	onboard/CGM LabDaq, Clinisys, 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/—	—/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)	• 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	• 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 • AI pattern-recognition software and endpoint titer estimation	• 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
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

FOR MID- AND HIGH-VOLUME LABORATORIES	Part 2 of 15	Arlington Scientific Mike Ladow mldadow@arlingtonscientific.com Springville, UT 800-654-0146 www.arlingtonscientific.com	Awareness Technology Rafael Castillo rcastillo@awaretech.com Palm City, FL 772-283-6540 www.awaretech.com	Beckman Coulter Doug Lee dylee@beckman.com Brea, CA 800-526-3821 www.beckmancoulter.com
	Name of instrument Type of instrument	ASI Evolution RPR Syphilis Analyzer immunoassay	ChemWell 2 immunoassay	AU5800 chemistry
	Operational type/Model type List price/First year sold in U.S. Targeted hospital bed size/Targeted test volume Company manufactures instrument	batch/benchtop \$50,995/2018 —/daily: 100; monthly: 3,100; annual: 37,200 yes (also sold by Fisher Scientific, Cardinal, McKesson, VWR, Medline)	batch/benchtop \$40,000/2020 50/— yes (also sold by Monobind, GMI, IDE, others)	continuous random access/floor standing —/2011 —/annual: ≥ 1.5 million yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific) DxC 700 AU, AU480
	Other models in this family of analyzers No. of units in clinical use in U.S./Outside U.S. (countries)	— 141/10	ChemWell Fusion 4800 —/80 (Colombia, Qatar, Ghana, Panama, Peru, UAE, Jamaica, Israel, Bolivia, Austria, more)	—
	Dimensions (H × W × D)/Instrument footprint Weight empty/Weight fully loaded No. of different measured assays onboard simultaneously	19 × 36 × 22 in./6 sq. ft. 78 lbs./— 1 (1 can be run and calibrated at one time)	23 × 42 × 25 in./7 sq. ft. 133 lbs./160 lbs. up to 10 (4 can be run and calibrated at one time)	50 × 168 × 62 in./72 sq. ft. 2,300–6,375 lbs. (model dependent)/— 54–216 (54–216 can be run and calibrated at one time) (model dependent)
	No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	0 190/9–11 min. (avg. 10 min.)	— 2 (assay dependent)/—	18 (76 can be active simultaneously) 2,000–9,800/8 min. 30 sec.
	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 photometry, potentiometry 4.5 min./model dependent 9 min./model dependent 9 min. 20 sec./model dependent 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	yes (192 tests per unit; 48 wells per microplate) agglutination, flocculation none necessary — — — —	yes (96 wells per microplate) chemiluminescence, enzyme immunoassay centrifugation, coated microwell assay dependent assay dependent assay dependent assay dependent	— — — — — —
	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	480/self-contained multiuse no/yes yes/no liquid chemistry (closed reagent system)/yes no/no yes/62 min. or 192 specimens or 192 tests	96/open reagent system no (37°C)/yes yes/no liquid chemistry (open reagent system)/yes no/no yes/120 min. or 96 specimens or 5 tests	200–6,000 (varies by assay)/self-contained multiuse yes (4°–12°C)/yes yes/yes liquid chemistry (open reagent system)/yes no/no yes/400 specimens
	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	rack no/— 2–500 µL 110 µL/300 µL/150 µL no yes yes/no no yes yes/yes/yes yes/no	rack yes (can store up to 192 cuvettes)/no 5–300 µL 200 µL/5 µL/< 5 µL no yes yes/no no yes no/yes/yes detection for clots yes (can be programmed to perform dilutions prior to analysis)/— no no no	rack yes/no 1–25 µL 120 µL/41 µL or 1 µL with 4 mm above gel barrier/50 µL yes (dead volume: 50 µL) yes yes/yes (primary, secondary tubes: 11.5–16 × 55–102 mm; nested micro cups) no yes yes/yes/yes detection and quantitation for hemolysis, icterus, lipemia, clots yes (can be programmed to perform dilutions prior to analysis)/0.001 parts per million yes yes yes
	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	no no no	no no no	yes (62–248 L/hr. consumption during operation) (model dependent) yes (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent) 1 day/14 days/14–20 days/30 days/—
	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) —/—/—/—/assay dependent	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent) 1 day/14 days/14–20 days/30 days/—
	Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays Automatic programmable start/Automatic programmable shutdown Onboard real-time QC/Onboard software capability to review QC Supports multiple QC lot numbers per analyte Waste management	— no/no yes/no no manually by user	no (< 5 min. warm-up time)/— yes/yes yes manually by user or direct to drain	yes (90 sec. warm-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	yes (UPC, Code 39, Code 128)/yes no yes (operator intervention required to order parts) yes no onboard/—	yes (Code 39, Code 128)/no no yes (operator intervention required to order parts) yes no onboard/—	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes yes yes (operator intervention required to order parts) yes yes onboard/Oracle Health, Antrim, CCA, Chemware, Dawning Technologies, SCC, Dynamic Healthcare, Antek, more yes (included in instrument price)/yes (broadcast download and host query) yes/within 24 hrs.
	LIS interface provided/Bidirectional interface capability	no/no	yes/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 Maintenance records kept onboard for user/vendor	daily: 10 min.; weekly: 10 min.; monthly: 10 min. no/no	daily: 15 min.; weekly: 30 min.; monthly: 30 min. some records (self tests, calibrations, logs)/some records (logs) no	daily: 8 min.; weekly: 15 min.; monthly: 45 min. yes/no
	Maintenance training demonstration module onboard Training included with purchase/Avg. time for basic user training	no yes (2 training slots)/0.5 days (at customer site)	yes (4 training slots)/2 days (at customer site)	yes yes (2 training slots)/3 days (combination of vendor and customer sites [includes vendor training and in-lab operator training]) yes (at vendor site)/yes
	Advanced operator training/Extra charge for follow-up or advanced training Warranty provided/Cost of annual service contract (24 h/7 d)	no/yes yes (1 year limited, service contract required)/varies by tier of service	yes (at customer site)/yes (contract dependent) yes (1 year)/contract dependent	yes (at vendor site)/yes yes (1 year)/—
	Distinguishing features (supplied by company)	• 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	• 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	• 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
Note: a dash in lieu of an answer means company did not answer question or question is not applicable				

Part 3 of 15	Beckman Coulter Doug Lee dylee@beckman.com Brea, CA 800-526-3821 www.beckmancoulter.com	Beckman Coulter Doug Lee dylee@beckman.com Brea, CA 800-526-3821 www.beckmancoulter.com	Beckman Coulter Doug Lee dylee@beckman.com Brea, CA 800-526-3821 www.beckmancoulter.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument Type of instrument	DxC 700 AU chemistry	Dxl 9000 Access Immunoassay Analyzer immunoassay	Unicel Dxl 600 immunoassay
Operational type/Model type List price/First year sold in U.S. Targeted hospital bed size/Targeted test volume Company manufactures instrument	continuous random access/floor standing —/2016 —/annual: 500,000–1.5 million yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific) AU480, AU5800	continuous random access/floor standing —/2023 — yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific) Access 2, Unicel Dxl 600, Unicel Dxl 800	continuous random access/floor standing —/2006 — yes (also sold by McKesson, Henry Schein, Medline, Thermo Fisher Scientific) Access 2, Unicel Dxl 800
Other models in this family of analyzers No. of units in clinical use in U.S./Outside U.S. (countries)	AU480, AU5800 —	—	—
Dimensions (H × W × D)/Instrument footprint Weight empty/Weight fully loaded No. of different measured assays onboard simultaneously No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	51 × 78 × 41 in./40.1 sq. ft. 1,046 lbs./— 63 (63 can be run and calibrated at one time) 18 (120 can be active simultaneously) 1,200 (800 photometric, 400 ISE tests in throughput)/8 min. 30 sec.	63 × 79 × 41 in./22.5 sq. ft. 1,785 lbs./— 50 (50 can be run and calibrated at one time) 0 up to 450/8–50 min.	67 × 61.5 × 37.5 in./16 sq. ft. 1,065 lbs./— 50 (50 can be run and calibrated at one time) 0 up to 200/13–55 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 photometry, potentiometry 4.5 min./400 specimens per hr. 9 min./133 specimens per hr. 9 min. 20 sec./72 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 chemiluminescence magnetic particle 10 min. 16 sec. 12 min. 16 sec.	no chemiluminescence magnetic particle 15 min. 18 sec. 17 min. 18 sec.
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	200–2,000 (varies by assay)/self-contained multiuse yes (4°–12°C)/yes yes/yes liquid chemistry (open reagent system)/yes no/no yes/2 hrs. avg. or 150 specimens or 7,200 tests	50, 100, or 200 per kit/self-contained multiuse yes (4°–10°C)/yes yes/yes liquid chemistry (closed reagent system)/yes no/yes yes/240 min. or 140 specimens	50 per pack or 100 per kit/self-contained multiuse yes (4°–10°C)/yes yes/yes liquid chemistry (closed reagent system)/yes no/no yes/180 min. or 60 specimens
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	rack yes/no 1–25 µL 120 µL/41 µL or 1 µL with 4 mm above gel barrier/40 µL or 4 mm above gel barrier yes (dead volume: 50 µL) yes yes/yes (primary, secondary tubes: 11.5–16 × 55–102 mm; nested micro cups) no yes yes/yes/yes detection and quantitation for hemolysis, icterus, lipemia, clots yes (can be programmed to perform dilutions prior to analysis)/0.001 parts per million yes yes yes	rack or direct track sampling when connected to automation no/yes 2–200 µL 5 µL/85 µL with direct sampling, 150 µL with standard sampling/80 µL yes (dead volume: 150 µL) yes yes/no no no yes/yes/yes hemolysis, icterus, lipemia, clots not available yes (can be programmed to perform dilutions prior to analysis)/— yes yes no	rack no/yes (can store > 1,000 cuvettes) 5–200 µL 10 µL/150 µL/140 µL yes (dead volume: 100 µL) yes yes/— no no yes/yes/yes detection for clots; hemolysis, icterus, lipemia not available yes (can be programmed to perform dilutions prior to analysis)/— yes yes no
Analyzer requires dedicated water supply Autocalibration/Multipoint calibration supported Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays Automatic programmable start/Automatic programmable shutdown Onboard real-time QC/Onboard software capability to review QC Supports multiple QC lot numbers per analyte Waste management	yes (28 L/hr. consumption during operation) yes (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent) 1 day/14 days/14–20 days/30 days/— yes (90 sec. warm-up time)/yes yes/yes yes direct to drain	no no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days) —/—/—/—/28 days no/no no/yes yes direct to drain	no no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days) —/—/—/—/28 days no/no no/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/Oracle Health, Antrim, CCA, Chemware, Dawning Technologies, SCC, Dynamic Healthcare, Antek, more yes (included in instrument price)/yes (broadcast download and host query) yes/within 24 hrs.	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no yes yes (instrument can order parts without operator intervention) yes no onboard/— yes (included in instrument price)/yes (broadcast download and host query) yes/within 24 hrs.	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no yes yes (operator intervention required to order parts) yes yes onboard/Oracle Health, Antrim, CCA, Chemware, Dawning Technologies, SCC, Dynamic Healthcare, Antek, more yes (included in instrument price)/yes (broadcast download and host query) yes/within 24 hrs.
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)	1.1 down service calls per year (displays error codes for troubleshooting) daily: 6 min.; weekly: 10 min.; monthly: 45 min. yes/no yes yes (2 training slots)/3 days (combination of vendor and customer sites [includes vendor training and in-lab operator training]) yes (at vendor site)/yes yes (1 year)/—	— (displays error codes for troubleshooting) weekly: < 15 min.; monthly: 7 min. yes (includes audit trail of who replaced parts)/no yes yes (2 training slots)/3 days (at vendor site) no/yes yes (1 year)/—	3.1 down service calls per year (displays error codes for troubleshooting) daily: < 10 min.; weekly: 15 min. at 5,000 tests; monthly: 35 min. at 10,000 tests yes/no yes yes (2 training slots)/3 days (at vendor site) yes (at vendor site)/yes yes (1 year)/—
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>	• 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	• 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 Onboard Guide provides instrument-guided troubleshooting with step-by-step instructions	• onboard aliquoting quickly frees samples for other analyses • scalable results across all immunoassay systems • liquid, ready-to-use reagents

Part 4 of 15	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	yes	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)	360/1,611 (Europe, Latin America, Asia-Pacific, Middle East)	—/— (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	36 (36 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	120/8–23 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	turbidimetry	—	—
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, Clinisys, Oracle Health, SCC Soft Computer	onboard/Antrim, CCA, Oracle Health, CGM Schuylab, SCC Soft Computer, Meditech, Clinisys, 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	502 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)	• reduced carryover due to disposable cuvettes • dilution cascade to final result • intuitive software that includes three different antigen excess protection methods, optimized by assay	• 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	• 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>			

Part 5 of 15	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	Diasorin Technical Support tech.support@diasorin.com Stillwater, MN 800-328-1482 or 651-439-9710 www.diasorin.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument Type of instrument	Geenius System immunoassay	PR4100 Microplate Reader immunoassay	LIAISON XL immunoassay
Operational type/Model type	batch/benchtop	batch/benchtop	batch, random access/floor standing
List price/First year sold in U.S. Targeted hospital bed size/Targeted test volume Company manufactures instrument Other models in this family of analyzers No. of units in clinical use in U.S./Outside U.S. (countries)	—/2014 all/— yes — >450/>700 (Europe, Middle East, Africa, Asia-Pacific, Canada, Latin America)	—/2012 — yes — —	—/2010 > 300/annual: > 50,000 no LIAISON XS > 950/> 6,500 (Continental Europe, Israel, Canada, Mexico, Brazil, China, India, Australia)
Dimensions (H × W × D)/Instrument footprint Weight empty/Weight fully loaded No. of different measured assays onboard simultaneously No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	5.9 × 7.6 × 5.9 in./0.31 sq. ft. 2.1 lbs./~2.1 lbs. 2 — ~3/15–30 min. (avg. 20 min.)	5.3 × 13.7 × 7.4 in./— 5.7 lbs./— — — —	59 × 59 × 36 in./14.6 sq. ft. —/661 lbs. 25 0 up to 170 (31 tests in throughput)/16–65 min. (avg. 35 min.)
Chemistry: No. of direct ion-selective electrode channels Detection methods Stat time until completion/specimen throughput for: • Ion-selective electrode • Basic metabolic panel • Complete metabolic panel Typical time delay from ordering stat test until aspiration of sample	— — — — — —	— — — — — —	— — — — — —
Immunoassay: Fully automated microplate immunoassay system Methodologies supported 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 lateral flow immunochromatography none necessary — — — —	no enzyme immunoassay none necessary — — — —	no chemiluminescence magnetic particle — — — —
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	—/self-contained single use no (2°–30°C)/yes yes/no dry chemistry (closed reagent system)/yes — no/—	— no/— no/no liquid chemistry (open reagent system)/— — no/—	100–200/self-contained multiuse yes (13°±2°C)/yes yes/no liquid chemistry (closed reagent system)/yes no/no yes/360 min.
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	— no/no — 15 µL (whole blood), 5 µL (serum, plasma)/15 µL (whole blood), 5 µL (serum, plasma)/— no — — no no no/no/no hemolysis, icterus, lipemia, clots not available no/— no no no	batch, benchtop no/no — — no no no (microplate reader)/no (microplate reader) no no yes/yes/no hemolysis, icterus, lipemia, clots not available no/— no no no	rack no/yes (can store up to 800 cuvettes) 50–1,000 µL —/15 µL/150 µL yes (dead volume: 50 µL) yes yes/yes no yes yes/yes/yes detection for hemolysis, icterus, lipemia, clots no/— 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	no —/no — yes/no yes/yes yes manually by user	no no (calibrants are not stored onboard)/no — no/no no/no no manually by user	no yes (calibrants can be stored onboard)/yes (recommended avg. frequency: assay dependent) —/—/—/—/assay dependent yes (15 min. warm-up time)/no yes/yes yes automated collection onboard instrument or 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	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Data Matrix)/— no yes (operator intervention required to order parts) no no onboard/Epic	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no no no (operator intervention required to order parts) no no no/—	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes no yes (operator intervention required to order parts) yes yes onboard/Mediatech, Oracle Health, Veradigm, Epic, CompuGroup Medical, Comtron, Aspyra, NetLims, LabHealth, McKesson, Starlims, more no/yes (broadcast download and host query) no/48 hrs.
LIS interface provided/Bidirectional interface capability Modem servicing provided/Service engineer on-site response time	no/no no/—	no/no no/—	
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)	— (displays error codes for troubleshooting) daily: < 5 min.; weekly: < 5 min.; monthly: — no/some records (5-year maintenance) no yes (1 training slot)/~2 hrs. (at customer site) no/— yes (1 year)/—	— — no/no no yes (2 training slots)/1 day (at customer site) no/yes yes/—	2.9–4.1 months (displays error codes for troubleshooting) daily: 0 min.; weekly: 10 min.; monthly: 30 min. yes/some records (post-service/maintenance requalification data) no yes (3 training slots)/2–3 days (at customer site) yes (at vendor site)/no yes (1 year)/—
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>	• fast: ~ 20 min. to results • traceability: positive identification of controls and patients • results interpretation: system software performs automated interpretation of band identification with HIV 1/2 differentiation	• comprehensive data-analysis software for full traceability • LIS connectivity • compact size—space saver	• secure traceability of all processes, status of reagents, and consumables • disposable pipette tips prevent sample carryover • no daily maintenance—instrument monitors maintenance needs

Part 6 of 15	Diatron Palmer Bailey p.bailey@strateg.com Budapest, Hungary 336-596-8753 www.diatron.com	Diatron Frank Matuszak frank.matuszak@diatron.com Medley, FL 833-228-7931 www.diatron.com	Diazyme Laboratories sales@diazyme.com Poway, CA 858-455-4768 www.diazyme.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument Type of instrument	KleeYa [†] immunoassay	Pictus 700 (P700) [†] chemistry	DZ-Lite c270 chemistry
Operational type/Model type	random access, continuous random access/floor standing	batch, random access, continuous random access, discrete/floor standing	discrete/benchtop
List price/First year sold in U.S. Targeted hospital bed size/Targeted test volume	—/2022 —/daily: 960; monthly: 28,000	\$60,190/2013 50–250/daily: 1,000–4,000; monthly: 30,000–120,000; annual: 365,000–1,460,000	—/2018 —/daily: > 50; monthly: > 800; annual: > 10,000
Company manufactures instrument Other models in this family of analyzers No. of units in clinical use in U.S./Outside U.S. (countries)	yes (also sold by distribution partners) — 50/50 (Czech Republic)	— Pictus 500 (P500) < 100/> 750 (Europe, Latin America, Africa, Middle East, Asia)	no (manufactured by Tokyo Boeki) DZ-Lite 3000 Plus 30/4 (Canada, Caribbean, Philippines)
Dimensions (H × W × D)/Instrument footprint Weight empty/Weight fully loaded No. of different measured assays onboard simultaneously No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	52 × 27 × 85 in. (excludes monitor)/— 611 lbs./611 lbs. — — 120/8–15 min.	39.4 × 38.1 × 26.4 in./7.1 sq. ft. 418 lbs./478 lbs. 72 (up to 72 can be run and calibrated at one time) — 720/30–1,200 sec. (avg. 300 sec.)	22 × 32 × 26 in./5.8 sq. ft. 240 lbs./— 36 (36 can be run and calibrated at one time) 100 (100 can be active simultaneously) up to 270 (assay dependent)/5–23 min. (avg. 10 min.)
Chemistry: No. of direct ion-selective electrode channels Detection methods Stat time until completion/specimen throughput for: • Ion-selective electrode • Basic metabolic panel • Complete metabolic panel Typical time delay from ordering stat test until aspiration of sample	— — — — — —	3 photometry, potentiometry 2 min./60 specimens per hr. 7.5 min./60 specimens per hr. 9 min./50 specimens per hr. 24 sec.	0 photometry — — — —
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 chemiluminescence bead — — — —	— — — — — —	— — — — — —
Approximate No. of tests per reagent set/Reagent type	15/open reagent system	50–200 per set, 400–1,800 per pack/self-contained multiuse, open reagent system	—/open reagent system
Reagents refrigerated onboard/Reagents ready to use Reagent lot tracking/Reagent inventory Reagent form/Reagents barcoded Separate reagent pack for each specimen/for each test run Walkaway capability/Walkaway duration	no/yes yes/yes liquid chemistry (open reagent system)/yes no/no yes/10–15 min.	yes (8° ±2°C)/yes yes/yes liquid chemistry (open reagent system)/no no/no yes/180 min. or 95 specimens or 1,800 tests	yes (2°–8°C)/yes yes/yes liquid chemistry (open reagent system)/yes no/yes yes/60 min. or 45 specimens or 36 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	rack yes/yes (can store up to 500 cuvettes) 10–300 µL 10 µL/—/— no no no/no no no no/yes/— hemolysis, icterus, lipemia, clots not available yes (can be programmed to perform dilutions prior to analysis)/—	rack yes/yes (can store up to 160 cuvettes) 2–100 µL 180 µL/22 µL/100 µL yes (dead volume: 20 µL) yes yes/no no yes yes/yes/yes detection for clots; hemolysis, icterus, lipemia not available yes (can be programmed to perform dilutions prior to analysis)/30 parts per million	ring yes (can store up to 60 cuvettes)/no 2–25 µL 140 µL/2 µL/100 µL no yes yes/no no yes yes/yes/yes detection for hemolysis, icterus, lipemia, clots yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability Sample volume can be diluted to rerun out-of-linear-range high results Sample volume can be concentrated to rerun out-of-linear-range low results	yes yes yes	yes yes yes	yes yes yes
Analyzer requires dedicated water supply Autocalibration/Multipoint calibration supported	no yes (calibrants can be stored onboard)/yes	no (< 3 L/hr. consumption during operation) yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 7 days) 8 hr./—/7 days/14 days/14 days	yes (3.5 L/hr consumption during operation) no (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent) —
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays 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/yes yes/yes yes automated collection onboard instrument	no/no yes/yes yes manually by user or direct to drain	yes/yes no/yes yes manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Data Matrix, QR code)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/—
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	yes yes yes yes onboard/—	yes yes (operator intervention required to order parts) yes yes onboard/AP Visions, Medicus, CGM Schuylab, Labtrack, CGM LabDaq, Medytox	no yes (operator intervention required to order parts) no no onboard/yes
LIS interface provided/Bidirectional interface capability Modem servicing provided/Service engineer on-site response time	no/no yes/—	yes (additional cost)/yes (broadcast download and host query) no/48 hrs.	no/yes (host query) no/—
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)	— (displays error codes for troubleshooting) — yes/yes (both include audit trail of who replaced parts) no yes/3–5 days (at customer or vendor site) yes (at customer or vendor site)/yes yes/—	1 year (displays error codes for troubleshooting) daily: 30 min.; weekly: 1 hr.; monthly: 2 hr. no/no no yes (2 training slots)/3 days (at customer site) yes (at customer or vendor site)/yes yes (1 year)/\$5,500	— (displays error codes for troubleshooting) daily: 10 min.; weekly: 30 min.; monthly: 15 min. no/no no yes (2–3 training slots)/1–2 days (at customer site) yes (at customer or vendor site)/yes (1 day: \$2,400; 2 days: \$3,600) yes (1 year)/—
Distinguishing features (supplied by company)	• dispense cartridge technology allows the use of flash and glow detection systems • modular reagent cartridges used for flexible assay design • intelligent reagent racks with integrated stirring mechanism; intuitive software for optimized assay development	• uninterrupted workflow • Windows-based, intuitive, user-friendly software • high-quality components for long stability and result reliability	• compact benchtop chemistry analyzer with ready-to-use reagents for diagnostic testing and monitoring • requires less maintenance; no external water, waste, or cooling unit required • supports up to four-part reagent assays
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>	[†] all information listed was provided to CAP TODAY in 2025; company did not provide updated information by 2026 entry deadline	[†] all information listed was provided to CAP TODAY in 2025; company did not provide updated information by 2026 entry deadline	

Part 7 of 15	Dynex Technologies Global Customer Service customerservice@dynex.com Chantilly, VA 800-288-2354 www.dynex.com	EUROIMMUN Medizinische Labordiagnostika Product Management Auto. automation-pm@euroimmun.de Luebeck, Germany +49 451 2032-0 www.euroimmun.com	EUROIMMUN Medizinische Labordiagnostika Product Management Auto. automation-pm@euroimmun.de Luebeck, Germany +49 451 2032-0 www.euroimmun.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument Type of instrument	Agility Automated ELISA System immunoassay	EUROLabWorkstation ELISA immunoassay	EUROLabWorkstation IFA immunoassay
Operational type/Model type	batch/benchtop	batch/benchtop	batch/benchtop
List price/First year sold in U.S. Targeted hospital bed size/Targeted test volume	—/2012 —	—/2017 —/> 3,000	—/2019 —/up to 3,000
Company manufactures instrument Other models in this family of analyzers (No. of units in clinical use in U.S./Outside U.S. (countries))	yes DSX —/425 (worldwide)	yes (also sold by EUROIMMUN US) — —	yes (also sold by EUROIMMUN US) — —
Dimensions (H × W × D)/Instrument footprint Weight empty/Weight fully loaded No. of different measured assays onboard simultaneously	47 × 47 × 30.25 in./12.5 sq. ft. 560 lbs./— up to 12 SmartKit reagent packs (up to 12 can be run and calibrated at one time)	~34 × 129 × 32 in./— ~760 lbs./~990 lbs. 180 (180 can be run and calibrated at one time)	~34 × 115 × 32 in./— ~760 lbs./~990 lbs. 75 (75 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	— (up to 12 can be active simultaneously) assay dependent (up to 1,536 tests per run)/assay dependent	— > 200 (assay dependent)/—	— > 200 (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 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	yes (up to 12 tests per unit; 96 wells per microplate) enzyme immunoassay coated microwell — — — —	yes (180 tests per unit; 96 wells per microplate) enzyme immunoassay coated microwell — — — —	no fluorescence BIOCHIPS on indirect immunofluorescence slides — — — —
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	—/open system with self-contained multiuse SmartKit no (23° ±4°C)/yes yes/yes liquid chemistry (open reagent system)/yes no/yes yes/up to 1,152 specimens or up to 1,152 tests	96/open reagent system no/yes yes/yes liquid chemistry (open reagent system)/yes no/no yes/up to 480 min. or 800 specimens or 1,440 tests	up to 1,200/self-contained multiuse no/yes yes/yes liquid chemistry (closed reagent system)/yes no/no yes/up to 360 min. or ~700 specimens or 750 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	rack no/no 10–300 µL 10 µL/—/— no yes yes/yes (17 × 100 mm) no no yes/yes/yes detection for clots; hemolysis, icterus, lipemia not available yes (can be programmed to perform dilutions prior to analysis)/no carryover no yes no	rack no/yes (can store up to 1,440 cuvettes) 5–1,100 µL 100 µL/5 µL/75 µL yes (dead volume: 75 µL) yes yes/yes (10–16 × 100 mm) no yes yes/yes/yes detection for clots yes (can be programmed to perform dilutions prior to analysis)/1.3 parts per million no yes no	rack no/no 5–1,100 µL 100 µL/5 µL/75 µL yes (dead volume: 75 µL) yes yes/yes (10–16 × 100 mm) no yes yes/yes/yes detection for clots yes (can be programmed to perform dilutions prior to analysis)/1.3 parts per million no yes no
Analyzer requires dedicated water supply Autocalibration/Multipoint calibration supported Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays Automatic programmable start/Automatic programmable shutdown Onboard real-time QC/Onboard software capability to review QC Supports multiple QC lot numbers per analyte Waste management	no no (calibrants are not stored onboard)/yes (recommended avg. frequency: assay dependent) —/assay dependent/assay dependent/—/assay dependent no/no yes/yes yes automated collection onboard instrument	no no/yes (recommended avg. frequency: each run) —/—/—/—/each run — yes/yes — automated collection onboard instrument or direct to drain	no no/— —/—/—/—/assay dependent — yes/yes — automated collection onboard instrument or 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	yes (UPC, Codabar, Code 39, Code 128, Code 93)/yes no yes (operator intervention required to order parts) yes yes onboard/Clinisys, Oracle Health	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Data Matrix)/— yes yes (operator intervention required to order parts) yes yes onboard/—	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Data Matrix)/— yes yes (operator intervention required to order parts) yes yes onboard/—
LIS interface provided/Bidirectional interface capability Modern servicing provided/Service engineer on-site response time	no/yes (host query) no/24 hrs.	yes (additional cost)/yes (host query) yes/—	yes (additional cost)/yes (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)	200 days (displays error codes for troubleshooting) daily: 10 min.; weekly: 5 min. no/no no no/3 days (at customer site) yes (at customer site)/yes	— (displays error codes for troubleshooting) — yes/yes yes yes (1 training slot)/1 day (at customer site) yes (at customer or vendor site)/—	— (displays error codes for troubleshooting) — yes/yes yes yes (1 training slot)/1 day (at customer site) yes (at customer or vendor site)/—
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>	• increases productivity—full walkaway processing from beginning of testing with up to 12 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	• 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	• 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

Part 8 of 15	FUJIFILM Healthcare Americas Corp. Amador Alejo amador.alejo@fujifilm.com Lexington, MA 877-714-1924 www.ivd.fujimed.com	Fujirebio Diagnostics Christopher Joynes joynesc@fdi.com Malvern, PA 844-544-3787 www.fujirebio.com	Gold Standard Diagnostics gsd.sales@us.goldstandarddiagnostics.com Davis, CA 530-759-8000 https://clinical.goldstandarddiagnostics.com/us
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	µTASWako i30	LUMIPULSE G1200	AIX1000 Agglutination Instrument
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	random access/benchtop	continuous random access/floor standing	batch/benchtop
List price/First year sold in U.S.	—/2011	\$175,000/2016	—/2016
Targeted hospital bed size/Targeted test volume	—	> 50/daily: 1,000; monthly: 20,000; annual: 240,000	—
Company manufactures instrument	no (manufactured by FUJIFILM Wako Pure Chemical Corp.)	no (manufactured by Otsuka)	yes (also sold by Cardinal Health, Thermo Fisher Scientific, VWR)
Other models in this family of analyzers	—	—	AIX1000 2.0, AIX1000 2.1
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)	>60/~1,500 (Japan, Germany, France, Italy, Belgium)	—
Dimensions (H × W × D)/Instrument footprint	21.5 × 20.5 × 23.4 in./3.34 sq. ft.	57.6 × 47.2 × 31.5 in./35 sq. ft.	17.7 × 25.2 × 22.5 in./4.1 sq. ft.
Weight empty/Weight fully loaded	157 lbs./—	727 lbs./794 lbs.	62 lbs./~110 lbs.
No. of different measured assays onboard simultaneously	6 (6 can be run and calibrated at one time)	36 (24 can be run and calibrated at one time)	2 (2 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	—	—
Test throughput per hour/Assay run time	25/—	120 (120 tests in throughput)/30 min.	128 (128 tests in throughput)/75 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	chemiluminescence	agglutination
Separation methodologies	microcapillary gel electrophoresis	magnetic particle	none necessary
Stat time until completion of a β-hCG test	—	30 min.	—
• Typical time delay from test order to aspiration of sample	—	none	—
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approximate No. of tests per reagent set/Reagent type	100/self-contained multiuse	42/self-contained single use	480/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes (2°–10°C)/yes	yes (2°–10°C)/yes	no/—
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	no/no
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/no	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/yes	no/no
Walkaway capability/Walkaway duration	yes/190 min. or 50 specimens or 80 tests	yes/55 min. or 100 specimens or 155 tests	yes/20–90 min.
Design of sample-handling system	rack	rack	universal slide-in racks
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/no	no/no
Min.–max. sample volume that can be aspirated at one time	3 µL minimum	10–140 µL	1–150 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—/75 µL/72 µL	150 µL/110 µL/100 µL	105 µL/300 µL/150 µL
Dedicated pediatric sample cup	no	no	no
Primary tube sampling	yes	yes	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/yes	yes/yes	yes/yes (12–16 × up to 100 mm)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	yes	no	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	no/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	hemolysis, icterus, lipemia, clots not available	detection for clots; hemolysis, icterus, lipemia not available	hemolysis, icterus, lipemia, clots not available
Dilutes patient samples onboard/Susceptibility to carryover	no/0.1 parts per million	yes (can be programmed to perform dilutions prior to analysis)/1 part per million	yes/—
Automatic rerun capability	yes	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results	yes	yes	no
Sample volume can be concentrated to rerun out-of-linear-range low results	no	no	no
Analyzer requires dedicated water supply	no	no (2.1 L/hr. consumption during operation)	no (0.045 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/—	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 30 days)	—
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—	—/—/—/—/30 days	—
Automatic programmable start/Automatic programmable shutdown	no/no	yes (5 min. warm-up time)/yes	no (< 5 min. start-up time)/no
Onboard real-time QC/Onboard software capability to review QC	no/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	no
Waste management	automated collection onboard instrument	manually by user or direct to drain	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ITF, EAN/JAN-13, EAN/JAN-18, STF(5BER), EAN-128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, NW7, Standard 2 of 5)/no	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, 1D, 2D)/yes
Lab can control analyzer from remote computer	no	no	yes
Instrument can diagnose its own malfunctions	no (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	no	no	yes
UPS backup power supply	no	yes	no
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/SCC Soft Computer	onboard/—
LIS interface provided/Bidirectional interface capability	no/yes (host query)	yes (included in instrument price)/yes (broadcast download and host query)	yes/yes
Modem servicing provided/Service engineer on-site response time	no/based on contract	no/24 hrs.	—
Mean time between failures	— (displays error codes for troubleshooting)	>300 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 0; weekly: 0; monthly: 15 min.	daily: 15 min.; weekly: 30 min.; monthly: 45 min.	daily: < 5 min.; weekly: < 20 min.; monthly: < 5 min.
Maintenance records kept onboard for user/vendor	no/—	no/no	yes/yes
Maintenance training demonstration module onboard	no	yes (2 training slots per module)	no
Training included with purchase/Avg. time for basic user training	yes/~2 days (at customer site)	yes/8 hrs. (at customer site)	yes (minimum 1 training slot)/2 days (at customer site or online)
Advanced operator training/Extra charge for follow-up or advanced training	—	yes (at customer site)/yes (\$2,500 [post-instrument install])	yes/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/\$14,950	yes (1 year)/—
Distinguishing features (supplied by company)	• microfluidics technology; small footprint–tabletop • liver cancer risk biomarkers (AFP-L3, DCP) for hepatocellular carcinoma surveillance (in vitro diagnostic use) • small sample volume; fast turnaround time	• unitized test cartridge (14 tests/cartridge) reduces reagent waste and eliminates cross contamination • continuous access loading and unloading of samples, reagents, and consumables without operational interruption • 30-min. time to result for all assays	• extra high titer capability on 2.1 model; run screens and titers out to 1:2048 • universal slide-in racks accommodate a variety of tube sizes for easier and faster sample loading • automated processing, analysis, interpretation, and result and image archiving; 90 min. walkaway time for 192 specimens
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 9 of 15		Gold Standard Diagnostics gsd.sales@us.goldstandarddiagnostics.com Davis, CA 530-759-8000 https://clinical.goldstandarddiagnostics.com/us		HORIBA Susan Behnke medical-marketing.us@horiba.com Irvine, CA 888-903-5001 www.horiba.com/us/en/medical/		HORIBA Brooke Bradley medical-marketing.us@horiba.com Canton, MI 734-487-8300 www.horiba.com	
FOR MID- AND HIGH-VOLUME LABORATORIES							
Name of instrument Type of instrument		ThunderBolt immunoassay		Yumizen C1200 chemistry		Yumizen C560 chemistry	
Operational type/Model type List price/First year sold in U.S. Targeted hospital bed size/Targeted test volume Company manufactures instrument		batch/benchtop —/2011 — yes (also sold by distribution partners)		continuous random access/floor standing \$179,800/2020 < 300/daily: 9,520; monthly: 17,000; annual: 2 million yes (manufactured by HORIBA ABX SAS; also sold by distribution partners) Yumizen C1200 AL —		random access, discrete/floor standing \$110,000/2023 < 275/daily: 3,000; monthly: 60,000; annual: 720,000 yes (also sold by distribution partners)	
Other models in this family of analyzers No. of units in clinical use in U.S./Outside U.S. (countries)		Bolt —/— (Australia, Austria, Belgium, Bolivia, Brazil, Canada, Chile, Colombia, Czech Republic, England, Finland, more)				Yumizen C230, Yumizen C240 —	
Dimensions (H × W × D)/Instrument footprint Weight empty/Weight fully loaded No. of different measured assays onboard simultaneously No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time		22 × 39 (includes laptop) × 22.5 in./6.09 sq. ft. 62 lbs./110 lbs. up to 24 (with limitations) — dependent on assay incubation times (192 tests in throughput)/20 min.–4 hr. (avg. 2 hr.)		44 × 48 × 33.5 in./— 992 lbs./— 45 (45 can be run and calibrated at one time) 100 (100 can be active simultaneously) 1,200 (45 plus 3 ISE tests in throughput)/3–15 min.		45 × 46 × 28 in./35 sq. ft. 661 lbs./— 81 (up to 81 can be run and calibrated at one time) up to 50 (50 can be active simultaneously) 560/1–10 min. (avg. 8 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 photometry, potentiometry, enzyme immunoassay, immunoturbidimetry 2.4 min./200 specimens per hr. 12 min./60 specimens per hr. 12 min./58 specimens per hr. 81 sec.		3 photometry, potentiometry ~4.2 min./~56 specimens per hr. ~7.7 min./~53 specimens per hr. ~10.5 min./~50 specimens per hr. ~135 sec.	
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		yes (192 tests per unit; 96 wells per microplate) chemiluminescence, enzyme immunoassay coated microwell — — — —		— — — — — —		— — — — — —	
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		96/open reagent system no (room temperature–40°C)/variable; reagent specific yes/no liquid chemistry (open reagent system)/no no/yes yes/dependent on reagent		500–2,200/self-contained multiuse, open reagent system yes (2°–8°C)/variable; reagent specific yes/yes liquid chemistry (open reagent system)/yes no/no yes/dependent on reagent		160–500 (reagent dependent)/open reagent system yes (2°–10°C)/variable; reagent specific yes/yes liquid chemistry (open reagent system)/yes no/no yes/143 min. or 87 specimens or 14 test panels	
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		slide-in racks no/no 1–300 µL 25 µL/151 µL/150 µL no yes yes/yes hemolysis, icterus, lipemia, clots not available		84 sample continuous loading ring, optional autoloading rack yes/no (can store up to 231 cuvettes) 1–25 µL 80 µL/—/200 µL for primary tube sampling yes (dead volume: 50 µL) yes yes/yes detection for hemolysis, icterus, lipemia, clots		ring yes/no (can store up to 90 cuvettes) 1.5–45 µL 120 µL/75 µL (test dependent)/70 µL yes (dead volume: 70 µL) yes yes/— no yes yes/yes/yes detection and quantitation for hemolysis, icterus, lipemia; detection for clots yes (can be programmed to perform dilutions prior to analysis)/500 parts per million yes yes yes	
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		yes (can be programmed to perform dilutions prior to analysis)/assay specific no yes yes		yes/— yes yes —		yes (can be programmed to perform dilutions prior to analysis)/500 parts per million 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		no no (calibrants are not stored onboard)/yes (recommended avg. frequency: per batch) —/—/—/—/per batch no (5 min. start-up time)/no yes/yes yes manually by user		yes (average of 20 L/hr. consumption during operation) yes (calibrants can be stored onboard [ISE])/yes (recommended avg. frequency: with each test kit) daily/for QC failure/for QC failure/per test kit/— yes (40 min. start-up time)/yes yes/yes no direct to drain		yes (average of 20 L/hr. consumption during operation) yes (calibrants can be stored onboard)/yes (assay dependent) 8 hrs./as needed/as needed/14 days/— yes/yes yes/yes yes automated collection onboard instrument or 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, UPC, Codabar, Code 39, Code 128, Code 93, more)/yes no yes (operator intervention required to order parts) yes no onboard/— no/yes (host query) no/48 hrs.		yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, EAN)/— no yes (operator intervention required to order parts) yes no onboard/CGM Labdaq no/yes (broadcast download and host query) no/< 24 hrs.		yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/— no yes (operator intervention required to order parts) yes yes (optional) onboard/CGM Labdaq, Clinisys, Apollo, Paracelsus no/yes (host query) no/1 business day	
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)		— (displays error codes for troubleshooting) daily: 5 min.; weekly: 15 min.; monthly: 20 min. yes/some records (dye tests and calibrations) no yes/4 hrs. (at customer or vendor site) yes (at customer or vendor site)/yes (contract dependent) yes (1 year from shipment date)/—		122 days (displays error codes for troubleshooting) daily: 10–15 min. (walkaway); weekly: 20–30 min.; monthly: < 60 min. no/no no yes (1 training slot)/3 days (at vendor or customer site) yes (at vendor site)/yes yes (contract dependent)/—		— (displays error codes for troubleshooting) daily: < 5 min.; weekly: 1 hr.; monthly: 25 min. yes (includes audit trail of who replaced parts)/some records (log) yes yes/3 days (online and at customer site) no/— yes (1 year)/—	
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>		• open architecture: program any EIA or CLIA protocol; fully customizable with flexible and intuitive software • space saving: high capacity (192 samples) in a 2 × 2 ft. footprint • cost saving: low instrument price point with no routine consumables required		• microvolume technology for improved cost efficiency • big lab automation in a small footprint; processes 1,200 tests per hour with ion-selective electrodes • 100 programmable applications; optional autoloader		• 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	

Part 10 of 15	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	QuidelOrtho Laura Osborne laura.osborne@quidelortho.com Raritan, NJ 800-828-6316 www.quidelortho.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument Type of instrument	VITROS 3600 Immunodiagnostic System immunoassay	VITROS 4600 Chemistry System chemistry	VITROS XT 7600 Integrated System combination 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, continuous random access, discrete/floor standing
List price/First year sold in U.S. Targeted hospital bed size/Targeted test volume	—/2008 150–4,500/daily: > 200; monthly: > 5,000; annual: > 60,000	—/2011 150–4,500/daily: 600–3,000; monthly: 17,000–85,000; annual: 200,000–1.5 million	—/2018 150–4,500/daily: 600–3,000; monthly: 17,000–85,000; annual: 200,000–4 million
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)	no (manufactured by Nypro Engineering and Technology group service; also sold by Cardinal, McKesson, more)
Other models in this family of analyzers No. of units in clinical use in U.S./Outside U.S. (countries)	VITROS ECI/ECiQ Immunodiagnostic System > 150/> 690 (North, Central, and South America, more)	VITROS 350 Chemistry System, VITROS XT 3400 Chemistry System > 160/> 980 (North, Central, and South America, more)	VITROS 5600 Integrated System > 460/> 400 (North, Central, and South America, more)
Dimensions (H × W × D)/Instrument footprint Weight empty/Weight fully loaded No. of different measured assays onboard simultaneously No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	65 × 84 × 35 in./19.4 sq. ft. 1,740 lbs./— 31 (31 can be run and calibrated at one time) 0 189/16–73 min. (avg. 30 min.)	53 × 92 × 33 in./21.4 sq. ft. 1,400 lbs./— 82 (82 can be run and calibrated at one time) 20 (20 can be active simultaneously) 845/2.5–20 min. (avg. 5 min.)	68 × 110 × 34.9 in./26.7 sq. ft. 2,360 lbs./— 150 (150 can be run and calibrated at one time) 20 (20 can be active simultaneously) 1,320/2.5–73 min. (avg. 7 min.)
Chemistry: No. of direct ion-selective electrode channels Detection methods	— —	3 photometry, potentiometry, colorimetric, turbidimetric	3 photometry, potentiometry, turbidimetric, direct enhanced chemiluminescence
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	— — — —	5 min./126 tests per hr. 6 min./84 tests per hr. 7.5 min./50 tests per hr. 1 min.	5 min./126 tests per hr. 6 min./95 tests per hr. 7.5 min./74 tests per hr. 1 min.
Immunoassay: Fully automated microplate immunoassay system Methodologies supported	no chemiluminescence, enzyme immunoassay, direct enhanced chemiluminescence coated microwell	— —	no chemiluminescence, enzyme immunoassay, direct enhanced chemiluminescence coated microwell
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	24 min. 1 min. 18 min. 1 min.	— — — —	24 min. 1 min. 18 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	50–100/self-contained multiuse yes (10°C)/yes yes/yes — (closed reagent system)/yes no/no yes/120 min. or 90 specimens or 3,100 tests	60/self-contained single use, open reagent system yes (10°C)/yes yes/yes dry chemistry, liquid chemistry (open reagent system)/yes no/no yes/120 min. or 160 specimens or 8,940 tests	50–100/varies for chemistry and immunoassay yes (10°C)/yes yes/yes dry chemistry, liquid chemistry (open reagent system)/yes no/no yes/—
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	circular routine sampling center no/no 2–200 µL —/10 µL/35 µL yes (dead volume: 35 µL) yes yes/yes (micro sample cups, 10.25 × 45 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, 13 × 100 mm, 16 × 75 mm, 16 × 100 mm) no yes yes/yes/yes detection and quantitation for hemolysis, icterus, lipemia; detection for clots	continuous load and unload, circular routine sample center no/yes (can store up to 348 cuvettes) 2–200 µL 0 µL/2 µL/35 µL yes (dead volume: 35 µL) yes yes/yes (micro sample cups, 10.25 × 45 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, 13 × 100 mm, 16 × 75 mm, 16 × 100 mm) no yes yes/yes/yes detection and quantitation for hemolysis, icterus, lipemia; detection for clots	continuous load and unload, circular routine sample center no/yes (can store up to 348 cuvettes) 2–200 µL 0 µL/2 µL/35 µL yes (dead volume: 35 µL) yes yes/yes (micro sample cups, 10.25 × 45 mm, 12 × 75 mm, 12 × 100 mm, 13 × 75 mm, 13 × 100 mm, 16 × 75 mm, 16 × 100 mm) no yes yes/yes/yes detection and quantitation for hemolysis, icterus, lipemia; detection for 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	yes (can be programmed to perform dilutions prior to analysis)/0 yes yes no	yes (can be programmed to perform dilutions prior to analysis)/0 yes yes yes	yes (can be programmed to perform dilutions prior to analysis)/0 yes yes yes
Analyzer requires dedicated water supply Autocalibration/Multipoint calibration supported	no (no water consumption during operation) no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days) —/—/—/28 days	no (no water consumption during operation) no (calibrants are not stored onboard)/yes (recommended avg. frequency: 6 mos. or lot change for most chemistry assays) 6 mos./6 mos./6 mos./6 mos./—	no (no water consumption during operation) no (calibrants are not stored onboard)/yes (recommended avg. frequency: 6 mos. or lot change for most chemistry assays) 6 mos./6 mos./6 mos./6 mos./28 days
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays Automatic programmable start/Automatic programmable shutdown Onboard real-time QC/Onboard software capability to review QC Supports multiple QC lot numbers per analyte Waste management	no/no yes/yes yes manually by user	no/no yes/yes yes manually by user	no/no yes/yes yes manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/—	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, more)/yes
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	no yes (operator intervention required to order parts) yes yes yes onboard/— yes (additional cost)/yes (broadcast download and host query) yes/4 hrs.	no yes (operator intervention required to order parts) yes yes yes onboard/— yes (additional cost)/yes (broadcast download and host query) yes/4 hrs.	no yes (operator intervention required to order parts) yes yes yes onboard/— yes (additional cost)/yes (broadcast download and host query) yes/4 hrs.
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	— (displays error codes for troubleshooting) daily: < 10 min.; weekly: 30 min.; monthly: 20 min. yes (includes audit trail of who replaced parts)/no yes yes (2 training slots)/5 days (at customer site)	— (displays error codes for troubleshooting) daily: 5 min.; weekly: 30 min.; monthly: 20 min. yes (includes audit trail of who replaced parts)/no yes yes (2 training slots)/5 days (at customer site)	— (displays error codes for troubleshooting) daily: < 10 min.; weekly: 30 min.; monthly: 20 min. yes (includes audit trail of who replaced parts)/no yes yes (2 training slots)/5 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 (1 year)/depends on plan selected	yes/depends on plan selected
Distinguishing features (supplied by company)	• 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	• 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	• XT MicroSlide runs two tests on one slide, increasing productivity and fulfilling 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
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 11 of 15	Randox Laboratories Graeme McNeill graeme.mcneill@randox.com Kearneysville, WV 304-728-2890 www.randox.com	Roche Diagnostics Brianna Frederick brianna.frederick@roche.com Indianapolis, IN 800-428-5074 go.roche.com/cobasproUSA	Sebia Marketing info-ai.us@sebia.com Branchburg, NJ 908-526-3744 www.sebia.com
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument Type of instrument	RX imola chemistry	cobas pro integrated solutions combination chemistry/immunoassay	dIFine P30 Processor 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) Dimensions (H × W × D)/Instrument footprint	discrete/benchtop —/2006 75/daily: > 750; monthly: > 22,500; annual: > 270,000 yes RX misano, RX monaco, RX daytona +, RX modena 34/> 1,000 (> 120 countries) 27 × 38 × 23 in./44.28 sq. ft.	random access, continuous random access/floor standing —/2019 150/daily: > 150; monthly: > 2,000; annual: > 750,000–4.5 million no (manufactured by Hitachi High-Technologies) cobas pure integrated solutions > 1,000/> 5,000 (> 40 countries)	batch/benchtop — annual: > 5,000 no — —
Weight empty/Weight fully loaded No. of different measured assays onboard simultaneously	331 lbs./340 lbs. 60 (60 can be run and calibrated at one time)	4,564.2 lbs./4,564.2 lbs. chem: 73 (73 can be run and calibrated at one time); immuno: 48 (48 can be run and calibrated at one time)	220 lbs./— 30 (30 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	15 (0 can be active simultaneously) 560, including ISE (50 tests in throughput)/5–10 min. (avg. 6 min.)	10 (10 can be active simultaneously) up to 6,400 (varies by module)/chem: 4.5–10 min. (avg. 10 min.); immuno: 9–27 min. (avg. 18 min.)	— assay dependent/—
Chemistry: No. of direct ion-selective electrode channels Detection methods Stat time until completion/specimen throughput for: • Ion-selective electrode • Basic metabolic panel • Complete metabolic panel Typical time delay from ordering stat test until aspiration of sample	3 potentiometry 13 min. 15 sec./80 specimens per hr. 13 min. 43 sec./80 specimens per hr. 13 min. 15 sec./67 specimens per hr. 30 sec.	3 indirect photometry, potentiometry 4.5 min. for ISE, 10 min. with CO2/600 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 ~10 min. 1 min. ~10 min. 1 min.	no fluorescence IFA slide well washing — — — —
Approximate No. of tests per reagent set/Reagent type	200/self-contained single use	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	80–240/open reagent system no/yes yes/yes liquid chemistry (open reagent system)/yes no/yes yes/240 specimens or 30 tests
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	yes (8°–15°C)/yes yes/yes liquid chemistry (closed reagent system)/yes no/no yes/70 min. or 40 specimens or 10 tests	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	no/yes yes/yes liquid chemistry (open reagent system)/yes no/yes yes/240 specimens or 30 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	ring yes (can store up to 90 cuvettes)/no 1.5–35 µL 150 µL/1.5–35 µL/150 µL yes (dead volume: 100 µL) yes — no yes yes/yes/no detection and quantitation for hemolysis, icterus, lipemia; clots not available	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: 30 µL) yes yes/yes (11 × 102 mm [chem], 13 × 102 mm [immuno])	rack no/no 10–1,000 µL — yes yes yes/no
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	yes (can be programmed to perform dilutions prior to analysis)/ no carryover yes yes yes	yes (can be programmed to perform dilutions prior to analysis)/ <1 part per million (chemistry), no carryover (immunoassay) yes yes yes	yes (can be programmed to perform dilutions prior to analysis)/— no no no
Analyzer requires dedicated water supply	yes (18 L/hr. consumption during operation)	yes (32 L/hr. consumption during operation for chemistry, 30 L/hr. for immunoassay)	no
Autocalibration/Multipoint calibration supported	no (calibrants can be stored onboard)/yes (recommended avg. frequency: 14 days)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: once per lot [chem], up to 84 days per lot [immuno])	no (calibrants are not stored onboard)/no
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	1 day/7 days/7 days/14 days/28 days yes (9 min. warm-up time)/yes —/yes yes direct to drain	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	— no/no yes/yes no automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination Lab can control analyzer from remote computer Instrument can diagnose its own malfunctions System malfunctions can be diagnosed via remote monitoring UPS backup power supply Data-management capability/LIS or EHR systems interfaced	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes yes yes (operator intervention required to order parts) yes no onboard/—	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, Oracle Health, Epic, more yes (incl. in price)/yes (broadcast download and host query) yes/—	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no yes yes (operator intervention required to order parts) yes yes onboard/yes
LIS interface provided/Bidirectional interface capability Modem servicing provided/Service engineer on-site response time	yes (included in instrument price)/yes (host query) no/within 24 hrs.	yes (incl. in price)/yes (broadcast download and host query) yes/—	no/yes (host query) no/within 24 hrs.
Mean time between failures	2 per 3 years (displays error codes for troubleshooting)	c 503 module: 220 days; e 801 module: avg. 220 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel Maintenance records kept onboard for user/vendor Maintenance training demonstration module onboard Training included with purchase/Avg. time for basic user training	daily: 5 min.; weekly: 15 min.; monthly: 1 hr. no/no no yes (1 training slot)/3 days (at customer site)	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 customer and vendor sites)/yes (cost varies by contract)	daily: performed automatically; weekly: 5 min.; monthly: 10 min. no/no no yes (2 training slots)/3 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training Warranty provided/Cost of annual service contract (24 h/7 d)	yes (at customer site)/yes yes (1 year)/—	yes (at customer and vendor sites)/yes (cost varies by contract) yes (1 year)/varies by contract	yes (at customer site)/no yes (1 year)/—
Distinguishing features (supplied by company)	• large and extensively dedicated test menu • stat sample capabilities • benchtop analyzer	• 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	• processes up to 240 samples and 30 IFA slides with a small footprint • fully automated—performs dilution, incubation, washing, mounting, and coverslipping • reliable traceability of samples, reagents, and slides owing to integrated barcode readers
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 12 of 15	Siemens Healthineers Tony Gaglio anthony.gaglio@siemens-healthineers.com Tarrytown, NY 800-888-7436 www.siemens-healthineers.com/en-us	Siemens Healthineers Emmanuel Quiazon emmanuel.quiazon@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
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	Atellica Solution	Atellica CI Analyzer	IMMULITE 2000 XPi Immunoassay System
Type of instrument	combination chemistry/immunoassay	combination chemistry/immunoassay	immunoassay
Operational type/Model type	batch, random access, continuous random access/floor standing	batch, random access, continuous random access/floor standing	batch, random access, continuous random access/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, Cardinal)	yes (also sold by McKesson, Henry Schein, Medline, Cardinal)	yes (also sold by McKesson, Henry Schein, Medline, Cardinal)
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)	—	—	> 300/> 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.	63.3 × 80.0 × 36.8 in./20.4 sq. ft.	72 × 63 × 36 in. (incl. monitor)/15.8 sq. ft.
Weight empty/Weight fully loaded	chem: 1,036 lbs.; immuno: 1,265 lbs./—	1,675 lbs./—	890 lbs./—
No. of different measured assays onboard simultaneously	chem: up to 70 (up to 70 can be run and calibrated at one time); immuno: up to 42 (up to 42 can be run and calibrated at one time)	chem: up to 50 (up to 50 can be run and calibrated at one time); immuno: up to 20 (up to 20 can be run and calibrated at one time)	24 (1 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	25 (25 can be active simultaneously)	25 (25 can be active simultaneously)	none
Test throughput per hour/Assay run time	2,240 (up to 1,800 chem, up to 440 immuno tests in throughput)/18 sec.–54 min. (assay dependent)	1,120 (up to 1,000 chem, up to 120 immuno tests in throughput)/24 sec.–54 min. (assay dependent)	up to 200 (up to 24 tests in throughput)/35–125 min. (assay dependent)
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 sec./—	—
• 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	6–60 sec. maximum	6–60 sec. maximum	—
Immunoassay:			
Fully automated microplate immunoassay system	no	no	no
Methodologies supported	chemiluminescence, enzyme immunoassay, acridinium ester chemiluminescence	chemiluminescence, enzyme immunoassay, acridinium ester chemiluminescence	chemiluminescence, enzyme immunoassay
Separation methodologies	magnetic particle	magnetic particle	bead, centrifugation
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	6–60 sec.	6–60 sec.	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	6–60 sec.	6–60 sec.	18 sec.
Approximate No. of tests per reagent set/Reagent type	50–8,000 (assay dependent)/self-contained multiuse, open reagent system	50–8,000 (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°–8°C)/yes	yes (2°–8°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/300 min. or 9,000 tests (chem), 450 min. or 1,200 tests (immuno)	yes/120 min. or 2,000 tests (chem), 240 tests (immuno)	yes/60–300 min.
Design of sample-handling system	multiple rack drawer, single sample transport	multiple rack drawer, single sample transport	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)	yes/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)	4–50 µL (chem), 10–100 µL (immuno)	5–600 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	assay dependent/assay dependent/container dependent	assay dependent/assay dependent/container dependent	—/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	yes/yes (12–16 × 75–100 mm; 10 × 50 mm micro sample tubes)
Pierces caps on primary tubes	no	no	no
Protects against probe collision	no	no	no
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection and quantitation for hemolysis, icterus, lipemia; detection for clots	detection and quantitation for hemolysis, icterus, lipemia; detection for 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)/—	yes (can be programmed to perform dilutions prior to analysis)/
Automatic rerun capability	yes	yes	< 3 parts per million
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 (up to 33 L/hr. consumption during operation for chemistry, up to 6 L/hr. for immunoassay)	yes (up tp 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 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: 1–4 weeks [assay dependent])
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	4 hrs./28–63 days/40–180 days/up to 180 days/up to 91 days	4 hrs./28–63 days/40–180 days/up to 180 days/up to 91 days	—/2 weeks/—/—/1–4 weeks (assay dependent)
Automatic programmable start/Automatic programmable shutdown	yes/yes	yes/yes	— (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	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, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	yes	yes	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply	yes	yes	no
Data-management capability/LIS or EHR systems interfaced	onboard, optional add-on (Siemens Atellica Data Manager)/ Meditech, Clinisys, Oracle Health, Labdaq, Epic Beaker, more	onboard, optional add-on (Siemens Atellica Data Manager)/ Meditech, Clinisys, Oracle Health, Labdaq, Epic Beaker, more	onboard/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/5 hrs. avg.	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: 15 min.; monthly: 15 min.	daily: < 5 min.; weekly: < 10 min.; monthly: < 15 min.	daily: 15 min.; weekly: 20 min.; monthly: 45 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 or vendor site)	yes (3 training slots)/6.5 days (at customer or vendor site)	yes (2 training slots)/2 days (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at vendor site)/yes	yes (at vendor site)/yes	yes (at customer 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)	• individual sample carriers provide intelligent sample routing; integrated automation for decapping, sealing • dedicated high-capacity refrigerated, covered calibration and QC materials onboard with automatic deployment • microvolume sample technology for CC; IA controlled temperature requires no recalibration if laboratory ambient temp. changes	• individual sample carriers provide intelligent sample routing; integrated automation for decapping, sealing • dedicated high-capacity refrigerated, covered calibration and QC materials onboard with automatic deployment • microvolume sample technology for CC; IA controlled temperature requires no recalibration if laboratory ambient temp. changes	• extensive routine and specialty immunoassay menu; includes menu of more than 300 allergens • specialty testing provides opportunity to reduce send-out test costs and boost revenue • reagent onboard stability of 90 days; automated daily maintenance reduces hands-on time and start-up delays
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 13 of 15	Thermo Fisher Scientific/BRAHMS kryptor.analyzer@thermofisher.com Hennigsdorf, Germany +49(0)33028830 www.thermoscientific.com/kryptor	Thermo Fisher Scientific John Karr john.karr@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 Type of instrument	B-R-A-H-M-S KRYPTOR GOLD immunoassay	Phadia 250 Laboratory System immunoassay	AIA-900 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.	90/18–40 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	—
Methodologies supported	fluorescence, enzyme immunoassay	fluoroenzyme immunoassay	fluorescence enzyme immunoassay (FEIA)
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, EliA 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	9–40 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), 9 µL (EliA)/—/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, Oracle Health, Epic, GE TriplerG, McKesson, Meditech, NetLims, more	optional add-on (Tosoh 501RP+)/—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	—/yes (broadcast download and host query)	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	yes/Mon.–Fri.: 26 hrs. at total breakdown, 72 hrs. at 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)	• 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	• 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	• 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 14 of 15	Tosoh Bioscience info.diag.am@tosoh.com Grove City, OH 800-248-6764 www.diagnostics.us.tosohbioscience.com	Werfen AID.marketing.na@werfen.com San Diego, CA 858-586-9900 www.werfen.com	Werfen 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 (FEIA)	fluorescence	chemiluminescence
Separation methodologies	—	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/Clinisys, Oracle Health, MedLab, SCC Soft Computer, SchuyLab, IDEAS, more	onboard/Oracle Health, Clinisys, 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 hrs.	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)	• 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	• 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	• improves laboratory workflow and productivity; eliminates batching and reagent waste with stable onboard reagents • provides simultaneous random-access processing of all isotypes 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
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CHEMISTRY AND IMMUNOASSAY ANALYZERS

Part 15 of 15	
FOR MID- AND HIGH-VOLUME LABORATORIES	Werfen AID.marketing.na@werfen.com San Diego, CA 858-586-9900 www.werfen.com
Name of instrument	QUANTA-Lyser 3000†
Type of instrument	immunoassay
Operational type/Model type	batch/benchtop
List price/First year sold in U.S.	—/2017
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)	—
Dimensions (H × W × D)/Instrument footprint	36.6 × 45.3 × 32 in./—
Weight empty/Weight fully loaded	462 lbs./—
No. of different measured assays onboard simultaneously	12–22 (12–22 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	— (12–22 can be active simultaneously)
Test throughput per hour/Assay run time	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 (1 test per well; 96 wells per microplate)
Methodologies supported	enzyme immunoassay
Separation methodologies	coated microwell
Stat time until completion of a β-hCG test	—
• Typical time delay from test order to aspiration of sample	—
Stat time until completion of a cTn test	—
• Typical time delay from test order to aspiration of sample	—
Approximate No. of tests per reagent set/Reagent type	96–240/open reagent system
Reagents refrigerated onboard/Reagents ready to use	no/yes
Reagent lot tracking/Reagent inventory	yes/no
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/yes
Walkaway capability/Walkaway duration	yes/300 min. or 240 specimens or 540 tests
Design of sample-handling system	rack
Uses washable cuvettes/Uses disposable cuvettes	no/no
Min.–max. sample volume that can be aspirated at one time	5–1,000 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	30 µL/5 µL/200 µL
Dedicated pediatric sample cup	no
Primary tube sampling	yes
Accommodates most standard tube sizes/Accepts nonstandard tube sizes	yes/no
Pierces caps on primary tubes	no
Protects against probe collision	no
Detects clots/liquid level/short sample	yes/yes/yes
Detection or quantitation for hemolysis, icterus, lipemia, clots	detection for clots; hemolysis, icterus, lipemia not available
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	no
Sample volume can be diluted to rerun out-of-linear-range high results	no
Sample volume can be concentrated to rerun out-of-linear-range low results	no
Analyzer requires dedicated water supply	no
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: per run) —/—/—/—/per run
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	
Automatic programmable start/Automatic programmable shutdown	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes
Supports multiple QC lot numbers per analyte	no
Waste management	automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, EAN, EAN-128)/no
Lab can control analyzer from remote computer	no
Instrument can diagnose its own malfunctions	no (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	no
UPS backup power supply	yes
Data-management capability/LIS or EHR systems interfaced	onboard/—
LIS interface provided/Bidirectional interface capability	—/yes (host query)
Modem servicing provided/Service engineer on-site response time	—/24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 10 min.; weekly: 30 min.; monthly: none
Maintenance records kept onboard for user/vendor	some records/some records
Maintenance training demonstration module onboard	no
Training included with purchase/Avg. time for basic user training	yes/3 hrs. (at customer site)
Advanced operator training/Extra charge for follow-up or advanced training	yes (at customer or vendor site)/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes/—
Distinguishing features (supplied by company)	• four independent washable probes with two dual probes for individual IFA well washing and mounting media dispensing • reagent integrity and positive patient identification managed through reagent and patient barcode scanning • 240 sample capacity open IFA/ELISA system with 70 reagent and control positions allow for maximum walkaway time
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