

Part 1 of 15

FOR MID- AND HIGH-VOLUME LABORATORIES

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Name of instrument	ASI Evolution Automated RPR Analyzer immunoassay	ASI Infinity EIA Analyzer immunoassay	DxC 700 AU chemistry
Operational type/Model type	batch/benchtop	batch/benchtop	continuous random access/floor standing
List price/First year sold in U.S.	\$44,995/2018	\$44,995/1998	—/2016
Targeted hospital bed size/Targeted daily test volume	≥20/>100	≥20/20	—/300–2,250 samples
Company manufactures instrument	yes (also sold by Fisher Scientific, VWR)	yes (also sold by Fisher Scientific, VWR)	yes (also sold by Henry Schein, McKesson, Medline)
Other models in this family of analyzers	—	—	AU 480, AU 5800
No. of units in clinical use in U.S./Outside U.S. (countries)	4/—	80/4,350	58/100
Dimensions (H × W × D)/Instrument footprint (square feet)	19 × 36 × 22 in./6 sq. ft.	19 × 36 × 22 in./6 sq. ft.	51 × 78 × 41 in./40.1 sq. ft.
Weight empty/Weight fully loaded	78 lbs./80 lbs.	78 lbs./80 lbs.	1,046 lbs./—
Tests available on analyzer in U.S.	ASI automated rapid plasma reagin test for syphilis for diagnostic and blood donor screening	ASI infectious disease tests: VZV, EBV-VCA, rubella, CMV, EBV-NA, HSV, toxoplasma, measles, mumps; open tests from other manufacturers	complete general chemistry, proteins/serology, thyroid, esoterics, TDM, DAT panels, more
Tests not available in U.S. but available in other countries	—	—	—
Tests in development for analyzer	ASI automated RPR test for syphilis for tissue donor screening	—	—
No. of different measured assays onboard simultaneously	1 (1 can be run and calibrated at one time)	3 (3 can be run and calibrated at one time)	63 (63 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	12 (12 can be active simultaneously)	60 (60 can be active simultaneously)
Test throughput per hour/Assay run time	190 (190 tests in throughput)/sample dependent	test dependent/test dependent	1,200 (63 tests in throughput)/avg. 8 min. 37 sec.
Chemistry:			
No. of direct ion-selective electrode channels	—	—	3
Detection methods	—	—	photometry, potentiometry
Stat time until completion/specimen throughput for:	—	—	—
• Ion-selective electrode	—	—	<9 min./80 specimens per hr.
• Basic metabolic panel	—	—	<9 min./67 specimens per hr.
• Complete metabolic panel	—	—	<9 min./33 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	—	—	1 min.
Immunoassay:			
Fully automated microplate immunoassay system	yes (192 tests per unit; 48 wells per microplate)	yes	—
Methodologies supported	agglutination	enzyme immunoassay	—
Separation methodologies	none (all assays homogeneous)	coated microwell	—
Stat time until completion of a β-hCG test	—	assay dependent	—
• Typical time delay from test order to aspiration of sample	—	30 sec.	—
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approx. No. of tests per reagent set or pack/Reagent type	480 per kit or 4,800 per kit/self-contained multiuse	96 per kit/open reagent system	50–1,500 per bottle/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	no/yes	no/yes	yes (4°–12°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/no	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/60 min. or 190 specimens or 1 test/assay	yes/96 specimens or 12 tests/assays	yes/up to 125 specimens
Design of sample handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 4 cuvettes)	no/yes (can store up to 96 cuvettes)	yes/no
Min.–max. sample volume that can be aspirated at one time	2–500 μL	2 μL	1–25 μL
Min. reaction volume/Min. specimen volume/Min. dead volume	110 μL/300 μL/150 μL	2 μL/2 μL/2 μL	120 μL/1 μL plus dead volume/50 μL or 4 mm above nonsample layer
Dedicated pediatric sample cup	no	no	yes (dead volume: 50 μL)
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 12 × 100)/no	yes (tubes [in mm]: 12 × 100)/no	yes (primary and secondary tubes [in mm]: 11.5–16 diameter, 55–102 height; nested micro cups)/no
Protects against probe collision	yes	yes	no
Detects clots/liquid level/short sample	no/yes/no	no/yes/no	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	no/no/no/no	no/no/no/no	yes/yes/yes/yes
Dilutes patient samples onboard/Susceptibility to carryover	yes/0	yes (can be programmed to perform dilutions prior to analysis)/0	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	no	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	yes/yes	yes/yes	yes/yes
Analyzer requires dedicated water supply	no (.03 L/hr. consumption during operation)	no (.03 L/hr. consumption during operation)	yes (28 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/no	no (calibrants can be stored onboard)/yes	yes (calibrants are not stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—	—/—/—/—/assay dependent	1 day/14 days/14–20 days/30 days/—
Automatic programmable start/Automatic programmable shutdown	yes (2 min. avg. start-up time)/yes	yes (2 min. avg. start-up time; 2 min. warm-up time)/yes	yes/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	direct to drain or waste bottle	direct to drain or waste bottle	direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (UPC)/no	yes (UPC)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no	no	yes
Instrument can diagnose its own malfunctions	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	yes	yes	yes
UPS backup power supply/Data-management capability	no/onboard	no/onboard	no/onboard
LIS or EHR systems interfaced	—	—	Cerner, Sunquest, Aspyra, SCC Soft Computer, CPSI, Dynamic Healthcare, Antek, Siemens, McKesson, Mediatech, more
LIS interface provided/Bidirectional interface capability	no/no	no/no	yes (included in instrument price)/yes (broadcast download and host query)
Modern servicing provided/Service engineer on-site response time	no/within 48 hrs.	no/within 48 hrs.	yes/<24 hrs.
Mean time between failures	365 days (displays error codes for troubleshooting)	365 days (displays error codes for troubleshooting)	2 service calls per year avg. (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: <10 min.; weekly: <10 min.; monthly: <10 min.	daily: <10 min.; weekly: <10 min.; monthly: <10 min.	—
Maintenance records kept onboard for user/vendor	no/no	no/no	yes/no
Maintenance training demonstration module onboard	no	no	yes
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/2 days (at customer site)	yes (2 training slots)/2 days (at customer site)	yes (No. of slots contract dependent)/8–10 days (combination of vendor and customer sites)
Advanced operator training/Where advanced training is held	no/—	no/—	yes (extra charge)/customer or vendor site
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/\$6,000	yes (1 year)/\$5,000	yes (terms: contract dependent)/contract dependent
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> low cost for automation of RPR syphilis testing throughput of 190 tests per hour automated RPR test for donor screening 	<ul style="list-style-type: none"> low cost for automation open system that can automate manual tests intuitive operation and software 	<ul style="list-style-type: none"> standardization across the AU family of chemistry analyzers lower total cost of ownership due to fewer consumables and concentrated reagents most common parts can be changed in 3 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 2 of 15 FOR MID- AND HIGH-VOLUME LABORATORIES	Beckman Coulter Shallon Hagen smhagen@beckman.com Chaska, MN 952-448-4848 www.beckmancoulter.com	Binding Site Tami McCarthy tami.mccarthy@bindingsite.com San Diego, CA 858-291-4532 www.bindingsite.com	Bio-Rad Laboratories Clinical Diagnostics Group Maria Crisostomo maria_crisostomo@bio-rad.com Hercules, CA 800-224-6723 www.bio-rad.com
Name of instrument	Unicel DxI 600	Optilite	BioPlex 2200 System
Type of instrument	immunoassay	chemistry	immunoassay
Operational type/Model type	continuous random access/floor standing	continuous random access/benchtop	continuous random access/floor standing
List price/First year sold in U.S.	—/2007	\$109,500/2015	—/2006
Targeted hospital bed size/Targeted daily test volume	—/40,000–80,000 annual	>100/>50	—/—800 samples
Company manufactures instrument	yes (also sold by McKesson, Henry Schein)	no (manufactured by Thermo Fisher)	yes
Other models in this family of analyzers	Access 2, Unicel DxI 800	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—	139/177 (Spain, Germany, France, UK, Italy, Denmark, more)	—/— (Australia, Canada, Czech Republic, France, more)
Dimensions (H × W × D)/Instrument footprint (square feet)	67 × 61.5 × 37.5 in./—	24.4 × 37 × 27.6 in./7.09 sq. ft.	53 × 72 × 34 in./12.9 sq. ft.
Weight empty/Weight fully loaded	—	242 lbs./~260 lbs.	1,032 lbs./—
Tests available on analyzer in U.S.	ferritin, folate, vitamin B12, testosterone, CEA, EPO, 25(OH) vitamin D total, ostase, troponin I, CK-MB, rubella IgG, toxo IgG, AFP (ONTD), DHEA-S, AMH, TPO Ab, AFP, PSA, more	Freelite Kappa, Freelite Lambda, Hevylite IgGk and IgGλ, Hevylite IgAk and IgAλ, Hevylite IgMk and IgMλ, IgG, IgA, IgM, IgD, IgG1, IgG2, IgG3, IgG4, IgA1, IgA2, more	50 multiplex tests: autoimmune (systemic autoimmune, celiac, vasculitis, RA, APS), infectious disease (5th gen. HIV Ag-Ab, syphilis/RPR, EBV-G/M, ToRC-G/M, MMRV, HSV-1/-2), vitamin D
Tests not available in U.S. but available in other countries	—	—	—
Tests in development for analyzer	—	—	Lyme borreliosis
No. of different measured assays onboard simultaneously	50 (50 can be run and calibrated at one time)	34 (34 can be run and calibrated at one time)	50 (50 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	—	—
Test throughput per hour/Assay run time	up to 200/13–55 min.	108 (108 tests in throughput)/8–23 min. (avg. 13 min.)	up to 2,200 (up to 22 tests in throughput)/avg. 45 min. (assay dependent)
Chemistry:			
No. of direct ion-selective electrode channels	—	—	—
Detection methods	—	photometry	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	—
• Basic metabolic panel	—	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	—	—	—
Immunoassay:			
Fully automated microplate immunoassay system	—	—	no
Methodologies supported	—	—	multiplex flow (cytometric)
Separation methodologies	—	—	magnetic particle
Stat time until completion of a β-hCG test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approx. No. of tests per reagent set or pack/Reagent type	50 per pack or 100 per kit/self-contained single use	100/self-contained multiuse	assay panel dependent: HIV and vitamin D, 200; ToRC IgM, 150/self-contained multiuse
Reagents refrigerated onboard/Reagents ready to use	yes/yes	yes (8°–10°C below ambient)/yes	yes (2°–8°C)/yes
Reagent lot tracking/Reagent inventory	yes/—	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/180–240 min. or 60 specimens	yes/90 min. or 54 specimens or 180 tests/assays	yes/480 min. or 800 specimens or 9,600 tests/assays
Design of sample handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 1,000 cuvettes)	no/yes (can store up to 360 cuvettes)	no/yes (can store up to 800 cuvettes)
Min.–max. sample volume that can be aspirated at one time	5 µL minimum	2–200 µL	3–150 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—/specimen container dependent/100 µL	120 µL/assay dependent/150 µL	3 µL/tube size dependent/250 µL
Dedicated pediatric sample cup	yes (dead volume: 100 µL)	yes (dead volume: 150 µL)	no
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 12 × 75, 13 × 75, 13 × 100, 16 × 75, 16 × 100)/no	yes (tubes [in mm]: 16 × 100, 13 × 100, 13 × 75, 12 × 75)/no	yes (tubes [in mm]: 10–16 diameter, 41–100 height)/no
Protects against probe collision	—	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	no/—/—/—	no/no/no/yes	no/no/no/yes
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/<1 part per million
Automatic rerun capability	no	yes	no
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	no/no	yes/yes	yes/no
Analyzer requires dedicated water supply	no	no (2 L/hr. consumption during operation)	no (0.5 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: per lab protocol and every new lot)	yes (calibrants are not stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—	—	—/—/—/—/30 days (assay dependent)
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	yes (10 min. avg. start-up time)/—
Onboard real-time QC/Onboard software capability to review QC	—	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	—	no	yes
Waste management	—	automated collection onboard instrument	manually by user or automated collection onboard instrument, direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	—	no	no
Instrument can diagnose its own malfunctions	no (operator intervention required to order parts)	no (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	no	yes
UPS backup power supply/Data-management capability	no/onboard	yes/onboard	yes/onboard
LIS or EHR systems interfaced	—	Epic, Sunquest, Orchard, Cerner, SCC Soft Computer	Aspyra, SCC Soft Computer, Cerner, Meditech, Orchard, Schuyler House, Sunquest, more
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download)	yes (additional cost)/yes (broadcast download and host query)	no/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/—	no/next business day	yes/<24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	240 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: >10 min.; weekly: 12 min. at 5,000 tests; monthly: 17 min. at 10,000 tests	daily: 10 min.; weekly: 15 min.; monthly: 30 min.	daily: 5 min.; weekly: 30 min.; monthly: ~60 min.
Maintenance records kept onboard for user/vendor	yes/—	some records (log)/no	yes (includes audit trail of who replaced parts)/yes (includes audit trail of who replaced parts)
Maintenance training demonstration module onboard	yes	no	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/—	yes (2 training slots)/2 days (at customer site)	yes (2 training slots)/5 days (at vendor site)
Advanced operator training/Where advanced training is held	—	no/—	no/—
Warranty provided/Cost of annual service contract (24 h/7 d)	—	yes (1 year)/\$12,950	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> load on the fly consumables ProService remote diagnostic service capability 	<ul style="list-style-type: none"> reduced carryover due to disposable cuvettes dilution cascade to final result intuitive software that includes 3 different antigen excess protection methods, optimized by assay 	<ul style="list-style-type: none"> full random-access automation with innovative multiplex chemistry compatible track line connectivity option internal QC beads run simultaneously with each sample
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FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	EVOLIS System	PhD Ix	PR4100 Microplate Reader
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	batch, random access/benchtop	batch/benchtop	batch/benchtop
List price/First year sold in U.S.	—/2001	—/2012	—/2012
Targeted hospital bed size/Targeted daily test volume	—/up to 360 samples per shift	—/50–200 samples	—
Company manufactures instrument	no	yes	yes
Other models in this family of analyzers	—	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—	—	—
Dimensions (H × W × D)/Instrument footprint (square feet)	37 × 44 × 30 in./10 sq. ft.	30 × 36 × 27 in./7 sq. ft.	5.3 × 13.7 × 7.4 in./—
Weight empty/Weight fully loaded	209 lbs./—	112 lbs./—	5.7 lbs./—
Tests available on analyzer in U.S.	HIV Ag/Ab combo, HIV Ab, HIV-2 Ab, HAV total, HAV IgM, HBsAg, HBs, HBe, HBe IgM	open system: autoimmune and infectious disease assays	HIV, HBsAg, HBs, HAV, HAV IgM, HBe, HBe IgM, HCV, syphilis, measles, mumps, VZV, Lyme, toxoplasma, ANA, SSA, SSB
Tests not available in U.S. but available in other countries	HCV, toxoplasma IgG, toxoplasma IgM, rubella IgG, rubella IgM, CMV IgG, CMV IgM, HSV IgG, VZV IgG, measles IgG, more	—	—
Tests in development for analyzer	—	—	—
No. of different measured assays onboard simultaneously	4–8 (4–8 can be run and calibrated at one time)	8 enzyme immunoassay or 4 IFA (8 enzyme immunoassay or 4 IFA can be run and calibrated at one time)	—
No. of user-definable (open chemistry) channels	—	no limit	—
Test throughput per hour/Assay run time	assay dependent (4 tests in throughput)/assay dependent	assay dependent/assay dependent	—
Chemistry:			
No. of direct ion-selective electrode channels	—	—	—
Detection methods	—	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	—
• Basic metabolic panel	—	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	—	—	—
Immunoassay:			
Fully automated microplate immunoassay system	yes (96 wells per microplate)	no (96 wells per microplate)	no (96 wells per microplate)
Methodologies supported	enzyme immunoassay	enzyme immunoassay, immunofluorescence	enzyme immunoassay, immunofluorescence
Separation methodologies	coated microwell	coated microwell, glass slide (substrates: cell culture and tissue)	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	—	—	—
Approx. No. of tests per reagent set or pack/Reagent type	96/self-contained multiuse	96 (up to 8 different assays)/open reagent system	—/open reagent system
Reagents refrigerated onboard/Reagents ready to use	no/yes	no/yes	no/no (requires operator prehandling/preparation)
Reagent lot tracking/Reagent inventory	yes/yes	yes/no	no/no
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/no	liquid chemistry (open reagent system)/no
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/180 specimens or 4 tests/assays	yes/192 specimens or 8 EIA or 4 IFA tests/assays	no/—
Design of sample handling system	rack	batch, benchtop, reagent rack	batch, benchtop
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/no	no/no
Min.–max. sample volume that can be aspirated at one time	10–100 µL	1–100 µL	—
Min. reaction volume/Min. specimen volume/Min. dead volume	10 µL/10 µL/200 µL	1 µL/1 µL/150 µL	—/70 µL/—
Dedicated pediatric sample cup	no	no	no
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: up to 16 diameter, up to 100 height)/no	yes (tubes [in mm]: 12–13 diameter, 75–100 height)/no	no/no
Protects against probe collision	no	no	no
Detects clots/liquid level/short sample	yes/yes/yes	no/yes/yes	no/yes/no
Detection for hemolysis/icterus/lipemia/clots	no/no/no/no	no/no/no/no	no/no/no/no
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/—	no/—
Automatic rerun capability	no	no	no
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	yes/no	yes/no	no/no
Analyzer requires dedicated water supply	no (0.5 L/hr. consumption during operation)	no	no
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: each run)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: each run)	no (calibrants are not stored onboard)/no
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—/—/—/—/each run	—/—/—/—/each run	—
Automatic programmable start/Automatic programmable shutdown	no/no	no/no	—
Onboard real-time QC/Onboard software capability to review QC	yes/yes	no/yes	no/no
Supports multiple QC lot numbers per analyte	yes	no	no
Waste management	manually by user or automated collection onboard instrument	manually by user or automated collection onboard instrument	—
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)/no
Lab can control analyzer from remote computer	no	no	no
Instrument can diagnose its own malfunctions	no (operator intervention required to order parts)	no (operator intervention required to order parts)	no (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	no	no	no
UPS backup power supply/Data-management capability	yes/onboard	yes/onboard	no/no
LIS or EHR systems interfaced	—	—	—
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download)	no/yes (broadcast download and host query)	no/—
Modem servicing provided/Service engineer on-site response time	yes/24 hrs.	no/24 hrs.	no/—
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	—
Average scheduled maintenance time by lab personnel	daily: 5 min.; monthly: 60 min.	daily: < 5 min.; weekly: 15 min.; monthly: 30 min.	—
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/yes (includes audit trail of who replaced parts)	no/no	no/no
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/5 days (at vendor site)	yes/2 days (at customer site)	yes/— (at customer site)
Advanced operator training/Where advanced training is held	no/—	no/—	no/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> fully automated microplate system providing a high level of safety (i.e., positive sample ID) for mid to high volumes network workstations for higher throughput semi-open system with full bidirectional LIS and comprehensive range of assays 	<ul style="list-style-type: none"> open platform with assay programming wizard and capability to run IFA and EIA methods on a single instrument accurate delivery of volumes as low as 1 µL unique IFA hyperwash, resulting in lower background fluorescence 	<ul style="list-style-type: none"> comprehensive data-analysis software for full traceability LIS connectivity

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

Part 4 of 15
FOR MID- AND HIGH-VOLUME LABORATORIES

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Name of instrument	VIDAS 3	LIAISON XL	Pictus 700 (P700)
Type of instrument	immunoassay	immunoassay	chemistry
Operational type/Model type	batch, random access, continuous random access/benchmark	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.	—/2016	—/2012	\$60,190/2013
Targeted hospital bed size/Targeted daily test volume	—	>300/>200	50–250/1,000–4,000
Company manufactures instrument	yes	no	yes
Other models in this family of analyzers	VIDAS 30	LIAISON	Pictus 500 (P500)
No. of units in clinical use in U.S./Outside U.S. (countries)	—	>500/>2,700 (worldwide)	<100/>750 (Europe, Latin America, Africa, Middle East, Asia)
Dimensions (H × W × D)/Instrument footprint (square feet)	24 × 29.5 × 25.5 in./5.2 sq. ft.	59 × 59 × 36 in./14.6 sq. ft.	39.4 × 38.1 × 26.4 in./7.1 sq. ft.
Weight empty/Weight fully loaded	174.2 lbs./—	695 lbs./717 lbs.	418 lbs./478 lbs.
Tests available on analyzer in U.S.	procalcitonin, D-dimer exclusion, Lyme IgG, Lyme IgM, C. difficile GDH, C. difficile toxin A & B, measles IgG, mumps IgG, rubella IgG, varicella IgG, HCG, H. pylori, toxo IgG, more	25 hydroxyvitamin D, 1,25 dihydroxyvitamin D, intact PTH, 1-84 PTH, EBV IgM, VCA IgG, EBNA IgG, EA (D) IgG, toxo IgG, toxo IgM, rubella IgG, rubella IgM, CMV IgG, CMV IgM, more	full drugs-of-abuse menu and general chemistry
Tests not available in U.S. but available in other countries	ferritin, NT-proBNP, CK-MB, high-sensitivity troponin I, troponin I ultra, protein C, HIV DUO Ultra, HIV DUO Quick, HIV P24II, more	T3, T4, hTg, anti-hTg, anti-TPO, osteocalcin, BAP OSTASE, ferritin, calprotectin, CA 125, CA15-3, CA 19-9, AFP, more	63 barcoded clinical chemistry parameters, including substrates, electrolytes, enzymes, specific proteins
Tests in development for analyzer	—	Quantiferon-TB Gold Plus	vitamin D
No. of different measured assays onboard simultaneously	12 (total menu can be run and calibrated at one time)	25 (25 can be run and calibrated at one time)	72 (999 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	0	variable
Test throughput per hour/Assay run time	—	up to 180/17–65 min. (avg. 35 min.)	720/30–1,200 sec. (avg. 300 sec.)
Chemistry:			
No. of direct ion-selective electrode channels	—	—	3
Detection methods	—	—	photometry, potentiometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	120 sec./60 specimens per hr.
• Basic metabolic panel	—	—	450 sec./60 specimens per hr.
• Complete metabolic panel	—	—	540 sec./40 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	—	—	24 sec.
Immunoassay:			
Fully automated microplate immunoassay system	no	no	—
Methodologies supported	fluorescence, enzyme immunoassay, solid-phase receptacle pipetting device	chemiluminescence	—
Separation methodologies	—	magnetic particle	—
Stat time until completion of a B-hCG test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approx. No. of tests per reagent set or pack/Reagent type	30 or 60 tests per kit/self-contained single use	100/self-contained multiuse	50–200 per set or 400–1,800 per pack/self-contained multiuse, open reagent system
Reagents refrigerated onboard/Reagents ready to use	no/yes	yes (13°±2°C)/yes	yes (8°±2°C)/yes
Reagent lot tracking/Reagent inventory	yes/—	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry (open reagent system)/no
Separate reagent pack for each specimen/for each test run	—/yes	no/no	no/no
Walkaway capability/Walkaway duration	yes/27 specimens or 12 tests/assays	yes/360 min. or 120 specimens or 2,500 tests	yes/180 min. or 95 specimens or 1,800 tests/assays
Design of sample handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/—	no/yes (can store up to 1,000 cuvettes)	yes/yes (can store up to 160 cuvettes)
Min.–max. sample volume that can be aspirated at one time	100–200 µL	5–200 µL	2–100 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—/100–200 µL (assay dependent)/—	100 µL/assay dependent/150 µL	180 µL/22 µL/100 µL
Dedicated pediatric sample cup	—	yes (dead volume: 150 µL)	no (dead volume: 20 µL)
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 12 × 75, 13 × 75, 13 × 100, 16 × 100; Nalgene cups size: 13.5 × 38.1)/no	yes (tubes [in mm]: 6–15 internal diameter, up to 100 height)/no	yes (tubes [in mm]: 13 × 75 to 16 × 100)/no
Protects against probe collision	—	yes	yes
Detects clots/liquid level/short sample	yes/—/yes	yes/yes/yes	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	—	no/no/no/yes	no/no/no/yes
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)/30 parts per million
Automatic rerun capability	—	yes	yes
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	—	yes/no	yes/yes
Analyzer requires dedicated water supply	—	no (0.5 L/hr. consumption during operation)	no (<5 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 14 or 28 days)	no (calibrants can be stored onboard)/yes	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 7 days)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—	—/—/—/—/assay dependent	8 hr./—/7 days/14 days/—
Automatic programmable start/Automatic programmable shutdown	yes (5 min. avg. start-up time)/yes	no/no	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	manually by user or automated collection onboard instrument	automated collection onboard instrument, direct to drain	manually by user or direct to drain
Sample barcode-reading capability/Autodiscrimination	yes/—	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, EAN)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no
Lab can control analyzer from remote computer	—	yes	yes
Instrument can diagnose its own malfunctions	yes	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/Data-management capability	—/onboard	yes/onboard	yes/onboard
LIS or EHR systems interfaced	—	Orchard, Epic, Cerner, SCC Soft Computer, Sunquest	AP Visions, Medicus, Schuyler House, CGM LabDaq, more
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	no/yes (broadcast download and host query)	yes (additional cost)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/—	no/24 hrs.	no/48 hrs.
Mean time between failures	385 days (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	1 year (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	weekly: 10–15 min.	weekly: 30 min.; monthly: 60 min.	daily: 30 min.; weekly: 1 hr.; monthly: 2 hr.
Maintenance records kept onboard for user/vendor	yes/—	yes/no	no/no
Maintenance training demonstration module onboard	no	no	no
Training included with purchase/Avg. time for basic user training	yes/— (at customer site)	yes (3 training slots)/3 days (at customer site)	yes (2 training slots)/3 days (at customer site)
Advanced operator training/Where advanced training is held	—	yes/vendor site	yes (extra charge)/customer or vendor site
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/\$5,500
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • routine and emergency (stat) testing in single-dose assay format readily adaptable to batch or single test runs • easy-to-use, reliable system with mean time between failure of more than a year • specialty menu of critical care and infectious disease assays 	<ul style="list-style-type: none"> • clinical effectiveness due to large specialty test menu • ready-to-use reagents with most calibrators onboard to ensure high-quality results and reduce risk of errors • easy-to-use system; point-in-space connectivity to LAS 	<ul style="list-style-type: none"> • uninterrupted workflow • Windows-based, intuitive, user-friendly software • high-quality components for long stability and result reliability
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 6 of 15

FOR MID- AND HIGH-VOLUME LABORATORIES

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Fujirebio US
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844-544-3787 www.fujirebio-us.com

Name of instrument	EUROLabWorkstation ELISA	µTASWako i30	LUMIPULSE G1200
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	batch/benchtop	random access/benchtop	random access/floor standing
List price/First year sold in U.S.	—/2017	—/2011	\$79,000/2015
Targeted hospital bed size/Targeted daily test volume	—/>>3,000	—	500/800
Company manufactures instrument	yes (also sold by distribution partners)	no (manufactured by FUJIFILM Wako Pure Chemical Corp.)	no (manufactured by Otsuka)
Other models in this family of analyzers	—	—	—
No. of units in clinical use in U.S./Outside U.S. (countries)	—	20/400 (Canada, Germany, Japan, China, South Korea, more)	7/1,000 (Japan, Germany, France, Italy, Belgium, more)
Dimensions (H × W × D)/Instrument footprint (square feet)	~34 × 129 × 32 in./—	21.5 × 20.5 × 23.4 in./3.34 sq. ft.	57.6 × 46.8 × 31.2 in./32.45 sq. ft.
Weight empty/Weight fully loaded	992 lbs./—	157 lbs./—	727 lbs./794 lbs.
Tests available on analyzer in U.S.	—	AFP-L3 (AFP-L3% with total AFP), DCP (PIVKA-II)	procalcitonin, syphilis (TP-N), 25-OH vitamin D, FSH, LH, prolactin, TSH, CA125 II, HE4, ROMA
Tests not available in U.S. but available in other countries	—	PCT, NT-proBNP, troponin-T	AFP, CEA, CA 15-3, CA 19-9, PSA, free PSA, CYFRA, PIVKA-II, ProGRP, SMRP, PLAP, pepsinogen I, pepsinogen II, more
Tests in development for analyzer	—	—	AMH, hTau, β-amyloid 1-42, wPTH, C-peptide, more
No. of different measured assays onboard simultaneously	180 (180 can be run and calibrated at one time)	6 (6 can be run and calibrated at one time)	36 (24 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	0	—
Test throughput per hour/Assay run time	>200/—	25/—	120 (120 tests in throughput)/avg. 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	—	—	—
Immunoassay:			
Fully automated microplate immunoassay system	yes (180 tests per unit; 96 wells per microplate)	no	no
Methodologies supported	enzyme immunoassay	fluorescence	chemiluminescence
Separation methodologies	coated microwell	microcapillary gel electrophoresis	magnetic particle
Stat time until completion of a β-hCG test	—	—	25 min.
• Typical time delay from test order to aspiration of sample	—	—	none
Stat time until completion of a cTn test	—	—	—
• Typical time delay from test order to aspiration of sample	—	—	—
Approx. No. of tests per reagent set or pack/Reagent type	96/open reagent system	100/self-contained multiuse	42/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	no/yes	yes (2°–10°C)/yes	yes (2°–12°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 (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	yes/yes
Walkaway capability/Walkaway duration	yes/480 min. or 800 specimens or 1,440 tests/assays	yes/190 min. or 50 specimens or 80 tests	yes/252 min. or 100 specimens or 504 tests/assays
Design of sample handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 1,440 cuvettes)	no/no	no/no
Min.–max. sample volume that can be aspirated at one time	5–1,100 µL	3 µL minimum	10–140 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	100 µL/5 µL/75 µL	—/75 µL/72 µL	150 µL/110 µL/100 µL
Dedicated pediatric sample cup	yes (dead volume: 75 µL)	no	no
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 10–16 × 100)/no	yes (tubes [in mm]: 13 × 75, 13 × 100, 16 × 100)/no	yes (tubes [in mm]: 13–16 × 75–100)/no
Protects against probe collision	yes	yes	no
Detects clots/liquid level/short sample	—/yes/yes	yes/yes/yes	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	—	no/no/no/no	no/no/no/yes
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/1.3 parts per million	no/0.1 parts per million	yes (can be programmed to perform dilutions prior to analysis)/1 part per million
Automatic rerun capability	no	no	no
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	yes/no	no/no	yes/no
Analyzer requires dedicated water supply	no	no	no (2.1 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: each run)	yes (calibrants are not stored onboard)/no	no (calibrants are not stored onboard)/yes (recommended avg. frequency: once a month for most assays)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—/—/—/—/each run	—	—/—/—/—/once a month for most assays
Automatic programmable start/Automatic programmable shutdown	—	no/no	yes (30 min. avg. start-up time; 5 min. warm-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	no/yes	yes/yes
Supports multiple QC lot numbers per analyte	—	yes	yes
Waste management	automated collection onboard instrument, direct to drain	automated collection onboard instrument	manually by user or direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Data Matrix)/—	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ITF, EAN(JAN)-13, EAN(JAN)-18, STF(5BER), NW-7, EAN128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no
Lab can control analyzer from remote computer	yes	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	no (operator intervention is required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	no	no
UPS backup power supply/Data-management capability	yes/onboard	no/onboard	yes/onboard
LIS or EHR systems interfaced	—	—	—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (host query)	no/yes (host query)	yes (included in instrument price)/yes (broadcast download and host query)
Modern servicing provided/Service engineer on-site response time	yes/—	no/based on contract	no/24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	400 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	—	daily: 0; weekly: 0; monthly: 15 min.	daily: 15 min.; weekly: 30 min.; monthly: 45 min.
Maintenance records kept onboard for user/vendor	yes/yes	no/no	some records (syringe parts, seals, exchanges)/no
Maintenance training demonstration module onboard	yes	no	no
Training included with purchase/Avg. time for basic user training	yes (1 training slot)/1 day (at customer site)	yes/—2 days (at customer site)	yes (1 training slot)/6 hrs. (at customer site)
Advanced operator training/Where advanced training is held	yes/customer site	—	no
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/\$12,500
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> high-throughput system: >200 tests per hour for up to 15 ELISA plates and >700 samples 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 conform tracking of actions 	<ul style="list-style-type: none"> microfluidics technology; small footprint, tabletop; liver cancer risk markers small sample volume fast turnaround time 	<ul style="list-style-type: none"> unitized immunoreaction cartridge eliminates open bottle-stability concerns 30-min. time to result for all assays uninterrupted productivity—replenishes samples, reagents, and consumables on the fly

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

Part 7 of 15 FOR MID- AND HIGH-VOLUME LABORATORIES	Gold Standard Diagnostics Nicholas Garrone ngarrone@gsdx.us Davis, CA 530-759-8000 www.gsdx.us	Gold Standard Diagnostics Christina Brusca cbrusca@gsdx.us Davis, CA 530-759-8000 www.gsdx.us	Grifols David Spina david.spina@grifols.com Emeryville, CA 800-379-0957 www.diagnostic.grifols.com
Name of instrument Type of instrument	AIX1000 Agglutination Instrument immunoassay	ThunderBolt immunoassay	SQII immunoassay
Operational type/Model type List price/First year sold in U.S. Targeted hospital bed size/Targeted daily test volume Company manufactures instrument	batch/benchtop —/2016 — yes (also sold by Cardinal Health, Thermo Fisher Scientific, VWR)	batch/benchtop —/2012 250–1,000/10–500 yes (also sold by distribution partners)	batch/benchtop —/2018 ≥200/50–500 no (manufactured by Dynex)
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 (square feet) Weight empty/Weight fully loaded	— — 20.75 × 24.5 × 24 in./4.1 sq. ft. —/110 lbs.	none 150/700 2 × 2 × 2 ft./4 sq. ft. 65 lbs./66 lbs.	Dynex DS2 0/— 26 × 21 × 27 in./3.79 sq. ft. 105 lbs./~120 lbs.
Tests available on analyzer in U.S.	nontreponemal rapid plasma reagin for syphilis serology	—	30 FDA-approved AESKULISA autoimmune tests, including 13 for rheumatology, 9 for gastroenterology, 6 for thrombosis, and 2 for vasculitis; additional AESKULISA tests for research use only
Tests not available in U.S. but available in other countries Tests in development for analyzer	— —	— —	— 125 tests for research use only, covering rheumatology, thrombosis, gastroenterology, vasculitis, hepatology, more
No. of different measured assays onboard simultaneously	1 (1 can be run and calibrated at one time)	>8 (>8 can be run and calibrated at one time)	4 AESKULISA assays or 12 EIAs (4–12 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	— 100 (1 test in throughput)/—	— —/avg. 90 min.	2 (2 can be active simultaneously) —
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 agglutination none (all assays homogeneous) — — — —	yes (192 tests per unit; 96 wells per microplate) chemiluminescence, enzyme immunoassay coated microwell — — — —	yes (4–12 tests per unit; 96 wells per microplate) enzyme immunoassay coated microwell — — — —
Approx. No. of tests per reagent set or pack/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 no/no liquid chemistry (closed reagent system)/no no/no yes/90 min. or 192 specimens or 1 test/assay	—/open reagent system no/yes no/no liquid chemistry (open reagent system)/no no/yes yes/—	96/self-contained multiuse, open reagent system no/yes —/yes liquid chemistry (open reagent system)/yes no/yes yes/100 specimens or 4–12 tests/assays
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/Pierces caps on primary tubes Protects against probe collision Detects clots/liquid level/short sample Detection for hemolysis/icterus/lipemia/clots Dilutes patient samples onboard/Susceptibility to carryover	rack no/no 1–150 µL 140 µL/105 µL/200 µL no yes (tubes [in mm]: 12, 13, 16 × 75, 100)/no yes yes/yes/yes no/no/no/yes yes/—	rack no/no 1–400 µL 300 µL/1 µL/200 µL no yes (tubes [in mm]: 12, 13, 16 × 75, 100)/no yes yes/yes/yes no/no/no/no yes (can be programmed to perform dilutions prior to analysis)/— no no/no	rack no/no 10–250 µL — no yes (tubes [in mm]: 10–16 diameter × 40–100 height)/no — yes/yes/yes —/—/—/yes yes (can be programmed to perform dilutions prior to analysis)/— no yes/—
Automatic rerun capability Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	no no/no	no no/no	no yes/—
Analyzer requires dedicated water supply Autocalibration/Multipoint calibration supported	no (.045 L/hr. consumption during operation) no (calibrants are not stored onboard)/no	no yes (calibrants are not stored onboard)/yes	no no (calibrants are not stored onboard)/yes (recommended avg. frequency: per plate)
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	— no (<5 min. warm-up time)/no yes/yes no	— no/yes yes/yes no	— no/no no/yes —
Waste management Sample barcode-reading capability/Autodiscrimination Lab can control analyzer from remote computer Instrument can diagnose its own malfunctions System malfunctions can be diagnosed via remote monitoring UPS backup power supply/Data-management capability LIS or EHR systems interfaced LIS interface provided/Bidirectional interface capability Modem servicing provided/Service engineer on-site response time	automated collection onboard instrument yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no no no (operator intervention required to order parts) yes no/onboard — no/no no/24 hrs.	manually by user yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no yes yes (operator intervention required to order parts) yes —/onboard Sunquest, Orchard Harvest, CGM LabDaq, Meditech no/yes (host query) no/48 hrs.	automated collection onboard instrument yes (Interleaved 2 of 5, UPC, Codabar, Code 39, more)/yes no yes (operator intervention required to order parts) — no/onboard — yes/yes (broadcast download and host query) no/contract dependent
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/Where advanced training is held	— (displays error codes for troubleshooting) daily: <5 min.; weekly: <20 min. yes/yes no yes/2 days (at customer site) yes/vendor site	420 days (displays error codes for troubleshooting) daily: 5 min.; weekly: 30 min. some records/no yes yes/2–3 hrs. (at customer or vendor site) yes (extra charge for additional training separate from installation trip)/customer or vendor site	— (displays error codes for troubleshooting) daily: 5–10 min.; weekly: 15–20 min.; monthly: 20–30 min. no/no no yes (No. of slots contract dependent)/2 days (at customer site)
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> fully automated nontreponemal RPR screens and titers over a range of 1:1–1:256 automated processing, analysis, interpretation, and result archiving 	<ul style="list-style-type: none"> small footprint for small laboratory spaces no consumable tips and bottles; greatly reduced consumable usage and expenses easy-to-use user interface 	<ul style="list-style-type: none"> customized for AESKULISA autoimmune assays while retaining open platform capabilities high capacity with a small footprint pipetting tool controls multiple components, simplifying design and maximizing reliability
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 8 of 15

FOR MID- AND HIGH-VOLUME LABORATORIES

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Immunodiagnosics Systems
 info.us@idsplc.com
Gaithersburg, MD
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Name of instrument	Triturus	HELIOS	IDS-iSYS
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	batch/benchtop	batch/benchtop	continuous random access/benchtop
List price/First year sold in U.S.	\$79,000/1999	\$155,925/2017	—/2010
Targeted hospital bed size/Targeted daily test volume	300+/100–1,000	200–1,000/100–200	all/>600
Company manufactures instrument	yes (also sold by distribution partners)	no (manufactured by AESKU)	yes (also sold by distribution partners)
Other models in this family of analyzers	—	HELMED	— (coming this year)
No. of units in clinical use in U.S./Outside U.S. (countries)	>200/>1,700	—/≥300 (more than 34 countries)	>80/>700 (worldwide)
Dimensions (H × W × D)/Instrument footprint (square feet)	28.3 × 41.3 × 34.3 in./10 sq. ft.	28.5 × 25.6 × 29.6 in./5.25 sq. ft.	28 × 42 × 30 in./~6 sq. ft.
Weight empty/Weight fully loaded	265 lbs./—	73 lbs./—	227 lbs./~238 lbs.
Tests available on analyzer in U.S.	open system; most U.S. clinically cleared and RUO EIA procedures can be programmed: infectious diseases, autoimmune diseases, bone markers, endocrinology, hemostasis, oncology markers, hepatitis, HIV profiles	ANA HEp-2, ANCA (ethanol and formalin fixed), Crithidia luciliae (nDNA)	1,25-dihydroxy vitamin D, insulin-like growth factor-I (IGF-I), human growth hormone (hGH), insulin-like growth factor binding protein-3 (IGFBP-3), CTX-I (CrossLaps), more
Tests not available in U.S. but available in other countries	—	EMA, triple substrate	1,25 VitDXp, intact PINP, N-MID osteocalcin, Ostase BAP, TRAcP5b, salivary cortisol, ACTH, total testosterone, more
Tests in development for analyzer	—	—	cortisol, 17-beta estradiol, androstenedione, DHEA-S, more
No. of different measured assays onboard simultaneously	8 (8 can be run and calibrated at one time)	4 (4 can be run and calibrated at one time)	15 (15 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	1	—	0
Test throughput per hour/Assay run time	— (dependent on reagent methodology)/—	—	up to 120 (assay dependent)/avg. 90 tests per hr.
Chemistry:			
No. of direct ion-selective electrode channels	—	—	—
Detection methods	—	—	—
Stat time until completion/specimen throughput for:	—	—	—
• Ion-selective electrode	—	—	—
• Basic metabolic panel	—	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	—	—	—
Immunoassay:			
Fully automated microplate immunoassay system	yes (1–8 tests per unit; 96 wells per microplate)	yes	—
Methodologies supported	enzyme immunoassay	fluorescence, indirect fluorescent antibody	—
Separation methodologies	coated microwell	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	—	—	—
Approx. No. of tests per reagent set or pack/Reagent type	— (assay and vendor dependent)/open reagent system	120/self-contained multiuse	100/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	no/no (requires operator prehandling/preparation)	no/yes	yes (12°–15°C)/yes
Reagent lot tracking/Reagent inventory	—/yes	yes/no	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/no	liquid chemistry (closed reagent system)/—	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/—	no/no	no/no
Walkaway capability/Walkaway duration	yes/180 min. or 92 specimens or 8 tests/assays	yes/up to 190 specimens or 4 tests/assays	yes/120 specimens or 15 tests/assays
Design of sample handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/no	no/no	no/yes (can store up to 1,120 cuvettes)
Min.–max. sample volume that can be aspirated at one time	2 µL minimum	—	4–400 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—/300 µL/200 µL	—/assay dependent/tube dependent	assay dependent/4 µL/80 µL
Dedicated pediatric sample cup	no	no	yes (dead volume: 80 µL)
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 12–16 × 75–100)/no	yes (tubes [in mm]: 11–16 diameter × 55–100 height)/no	yes (tubes [in mm]: all sizes up to 16 × 100)/no
Protects against probe collision	—	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	no/yes/yes	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	—/—/—/yes	no/no/no/no	no/no/no/yes
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)/0	yes (can be programmed to perform dilutions prior to analysis)/—
Automatic rerun capability	no	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	no/no	yes/no	yes/no
Analyzer requires dedicated water supply	no	no	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: monthly)	no (calibrants are not stored onboard)/no	no (calibrants are not stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—	—	—/—/—/—/4–28 days
Automatic programmable start/Automatic programmable shutdown	yes (1–2 min. avg. start-up time)/yes	no (5 min. warm-up time)/no	yes (<40 min. avg. start-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	no/yes	no/yes
Supports multiple QC lot numbers per analyte	no	—	yes
Waste management	automated collection onboard instrument	automated collection onboard instrument	manually by user
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, Code 3/9, Code 2/5, Matrix 2/5, Code 11, EAN/JAN, more)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/no
Lab can control analyzer from remote computer	no	yes	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	no	yes	yes
UPS backup power supply/Data-management capability	yes/onboard	yes/no	yes/onboard
LIS or EHR systems interfaced	CHCS, Sunquest, more	—	—
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download and host query)	no/yes (host query)	no/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/within 24 hrs.	—	yes/<24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	>200 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 5–15 min.; weekly: <30 min.; monthly: 30–40 min.	daily: 15 min.; weekly: 20 min.	daily: 5 min.; weekly: 10 min.; monthly: 10 min.
Maintenance records kept onboard for user/vendor	no/no	no/—	yes (includes audit trail of who replaced parts)/no
Maintenance training demonstration module onboard	—	—	no
Training included with purchase/Avg. time for basic user training	yes/3 days (at customer site)	yes/—	yes (training slots not limited)/½ day for operator, 2 days for supervisor (at customer or vendor site)
Advanced operator training/Where advanced training is held	yes (extra charge)/vendor site	—	yes/customer and vendor sites
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/contract dependent	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • multi-batch or continuous throughput • 2 probes for high-speed processing; can use fixed probes or disposable tips; unique cross-well washing • open platform with user-defined menu, color-coded worksheets for setup 	<ul style="list-style-type: none"> • provides all-in-one IFA HEp-2, ANCA (ethanol and formalin fixed), and nDNA slide processing and reading on one platform • FDA cleared to identify 7 HEp-2 patterns plus negative results • utilizes pattern-recognition software and can estimate the endpoint titer 	<ul style="list-style-type: none"> • full walkaway automation; compact benchtop design; continuous loading with batch, random, and stat flexibility • intelligent clot management prevents measurement interruption and enhances productivity via maximized uptime • total traceability and full data transmitted to the LIS

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

Part 9 of 15	Inova Diagnostics Rachel Rosenblum rrosenblum@inovadx.com San Diego, CA 858-586-9900 www.inovadx.com	Inova Diagnostics Rachel Rosenblum rrosenblum@inovadx.com San Diego, CA 858-586-9900 www.inovadx.com	Mindray North America Peggy Chan p.chan@mindray.com Redmond, WA 425-881-0361 ext. 3305 www.mindraynorthamerica.com
Name of instrument	BIO-FLASH	QUANTA-Lyser 3000	BA-800M
Type of instrument	immunoassay	immunoassay	chemistry
Operational type/Model type	batch, random access, continuous random access/benchtop	batch/benchtop	batch, random access, discrete/floor standing
List price/First year sold in U.S.	—/2011	—/2017	\$211,000/2017
Targeted hospital bed size/Targeted daily test volume	>100/>100	>100/>100	—/1,600–6,000
Company manufactures instrument	yes	yes	yes (also sold by MedTest)
Other models in this family of analyzers	—	QUANTA-Lyser 4000	—
No. of units in clinical use in U.S./Outside U.S. (countries)	100/450 (UK, Spain, France, Germany, Italy, more)	75/25 (UK, France, Spain, Italy, Australia, Belgium)	—/2,200 (49 countries)
Dimensions (H × W × D)/Instrument footprint (square feet)	24 × 34 × 21 in./5 sq. ft.	36 × 42 × 32 in./10 sq. ft.	47 × 91 × 40 in./25.19 sq. ft.
Weight empty/Weight fully loaded	215 lbs./265 lbs.	468 lbs./—	1,430 lbs./1,654 lbs.
Tests available on analyzer in U.S.	tTG IgA, tTG IgG, DGP IgA, DGP IgG, DGP screen, aCL IgG, aCL IgM, aCL IgA, B2GP1 IgG, B2GP1 IgM, B2GP1 IgA, B2GP1-domain 1, MPO, PR3, GBM, ENA 7, RNP, more	calprotectin, intrinsic factor, ASCA IgA, IgG, GPA, h-tTG and gliadin with IgA and IgG, F actin IgA, M2EP (MIT3), gp210, sp100, PBC screen IgG/IgA, SLA, LKM-1, ANA, dsDNA, chromatin, C1q CIC, centromere, histone, Jo-1, RNP, Scl-10, more	BMP, CMP, DOA, ISE, renal, hepatic panels, vitamin D, CRP (high sensitivity), lipoprotein(a), homocysteine, lipase, microalbumin, HbA1c, β-hydroxybutyrate, microprotein
Tests not available in U.S. but available in other countries	CTD Screen Plus, ribosomal P, DFS70, HMGCR	—	cystatin C
Tests in development for analyzer	—	—	oral fluid drugs of abuse
No. of different measured assays onboard simultaneously	20 (20 can be run and calibrated at one time)	8 (8 can be run and calibrated at one time)	68 (68 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0	8 (8 can be active simultaneously)	—
Test throughput per hour/Assay run time	60 (60 tests in throughput)/30 min.	assay dependent/assay dependent	800–1,200 with ISE (68 tests in throughput)/1–15 min. (avg. 11 min.)
Chemistry:			
No. of direct ion-selective electrode channels	—	—	3
Detection methods	—	—	photometry, potentiometry, turbidimetry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	1 min./56 specimens per hr.
• Basic metabolic panel	—	—	10.45 min./80 specimens per hr. (after first hr.)
• Complete metabolic panel	—	—	13.08 min./48 specimens per hr. (after first hr.)
Typical time delay from ordering stat test until aspiration of sample	—	—	~135 sec.
Immunoassay:			
Fully automated microplate immunoassay system	no	yes (576 tests per run; 96 wells per microplate)	—
Methodologies supported	chemiluminescence	enzyme immunoassay	—
Separation methodologies	magnetic particle, bead	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	—	—	—
Approx. No. of tests per reagent set or pack/Reagent type	50 or 100/self-contained multiuse	ELISA, 96; IFA, 240/self-contained single use, open reagent system	133–500 per reagent bottle/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	yes (2°–8°C)/yes	no/yes	yes (2°–8°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/no	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed 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/150 min. or 30 specimens or 20 tests/assays	yes/4.5 hrs. or 240 specimens or 480 tests/assays	yes/~462 min. or 300 specimens or 12 test panels
Design of sample handling system	rack	rack	rack and ring
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 280 cuvettes)	no/no	yes/no
Min.–max. sample volume that can be aspirated at one time	10 μL minimum	100 μL	1.5–35 μL
Min. reaction volume/Min. specimen volume/Min. dead volume	10 μL/10 μL/50 μL	50 μL/assay dependent/200 μL	100 μL/1.5 μL/50 μL
Dedicated pediatric sample cup	yes (dead volume: 50 μL)	yes (dead volume: 50 μL)	yes (dead volume: 50 μL)
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 12 × 16)/no	yes (tubes [in mm]: 12 × 16)/no	yes (tubes [in mm]: 12 × 75, 12 × 100, 16 × 75, 16 × 100)/no
Protects against probe collision	yes	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	no/no/no/no	no/no/no/no	yes/yes/yes/yes
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/no	yes (can be programmed to perform dilutions prior to analysis)/no	yes (can be programmed to perform dilutions prior to analysis)/<1,000 parts per million
Automatic rerun capability	yes	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	yes/no	yes/yes	yes/yes
Analyzer requires dedicated water supply	no	no	yes (35 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	no (calibrants are not stored onboard)/yes (recommended avg. frequency: once per year or new lot)	no (calibrants are not stored onboard)/yes	no (calibrants can be stored onboard)/yes
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/—/—/—/once per lot	—/—/—/—/per run	8 hrs./—/7 days/14 days/—
Automatic programmable start/Automatic programmable shutdown	yes (<10 min. avg. start-up time)/yes	no (10 min. warm-up time)/no	yes/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	no	no	yes
Waste management	automated collection onboard instrument, direct to drain	automated collection onboard instrument, direct to drain	direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	yes	yes	no
Instrument can diagnose its own malfunctions	no (operator intervention required to order parts)	no (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	no	no	yes
UPS backup power supply/Data-management capability	yes/onboard	yes/onboard	yes/onboard
LIS or EHR systems interfaced	—	—	ApolloLIMS, more
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download and host query)	no/yes (host query)	no/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/24 hrs.	no/24 hrs.	no/24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	240 days (displays error codes for troubleshooting)	3 years (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	weekly: 5 min.; monthly: 15 min.	daily: 15 min.; weekly: 25 min.; monthly: 25 min.	daily: <10 min.; weekly: <1 hr.; monthly: <1 hr.
Maintenance records kept onboard for user/vendor	no/no	no/no	yes (includes audit trail of who replaced parts)/some records (parts replacement, other maintenance)
Maintenance training demonstration module onboard	no	no	yes
Training included with purchase/Avg. time for basic user training	yes (3–5 training slots)/24 hrs. (at customer site)	yes (5 training slots)/24 hrs. (at customer site)	yes (1+ training slot)/3 days (at customer site)
Advanced operator training/Where advanced training is held	yes (extra charge)/customer and vendor sites	yes (extra charge)/customer site	no/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (2 years)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> random access; continuous load; chemiluminescent; benchtop footprint completes up to 450 results per shift calibrate once per lot 	<ul style="list-style-type: none"> ability to track reagent lot number, expiration date, and identity for QUANTA Lite ELISA and NOVA Lite IFA reagents pipettes IFA mounting media uses washable probes 	<ul style="list-style-type: none"> outstanding mean time between failure of 3 years; minimal instrument downtime; autoloader may load up to 300 sample tubes at a time; total sample capacity up to 440 tubes; operators are free to perform other lab duties; scalable modular system; more
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 10 of 15

FOR MID- AND HIGH-VOLUME LABORATORIES

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Name of instrument	BS-480	VITROS 3600 Immunodiagnostic System	VITROS 4600 Chemistry System
Type of instrument	chemistry	immunoassay	chemistry
Operational type/Model type	batch, random access, discrete/floor standing	batch, random access, continuous random access, discrete/floor standing	batch, random access, continuous random access, discrete/floor standing
List price/First year sold in U.S.	\$120,000/2015	—/2008	—/2011
Targeted hospital bed size/Targeted daily test volume	—/800–2,000	—/150–1,300	—/1,000–4,500
Company manufactures instrument	—	yes (also sold by distribution partners)	yes (also sold by distribution partners)
Other models in this family of analyzers	—	VITROS ECIQ Immunodiagnostic System	VITROS 350 Chemistry System, VITROS 5,1 FS Chemistry System
No. of units in clinical use in U.S./Outside U.S. (countries)	30/2,242 (52 countries)	>200/>400 (North America, Central and South America, Europe, Africa, Asia, Japan, China)	>250/>500 (North America, Central and South America, Europe, Africa, Asia, Japan, China)
Dimensions (H x W x D)/Instrument footprint (square feet)	45 x 46 x 28 in./35 sq. ft.	65 x 84 x 35 in./19.4 sq. ft.	53 x 92 x 33 in./21.4 sq. ft.
Weight empty/Weight fully loaded	661 lbs./753 lbs.	1,740 lbs./—	1,400 lbs./—
Tests available on analyzer in U.S.	BMP, CMP, DOA, ISE, renal, hepatic panels, vitamin D, CRP (high sensitivity), lipoprotein(a), homocysteine, lipase, microalbumin	—	—
Tests not available in U.S. but available in other countries	cystatin C, HbA1c, β-hydroxybutyrate, microprotein	—	—
Tests in development for analyzer	oral fluid drugs of abuse	VITROS NephroCheck, high-sensitivity troponin	kappa light chain, lambda light chain, D-dimer, cystatin C, tricyclic antidepressants
No. of different measured assays onboard simultaneously	78 (78 can be run and calibrated at one time)	31 (31 can be run and calibrated at one time)	82 (82 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	—	0	20 (20 can be active simultaneously)
Test throughput per hour/Assay run time	400–560 with ISE/1–14 min.	189/16–73 min. (avg. 30 min.)	845/2–8 min. (avg. 5 min.)
Chemistry:			
No. of direct ion-selective electrode channels	3	—	3
Detection methods	photometry, potentiometry, turbidimetry	—	colorimetric rate, potentiometric, immunorate, turbidimetric
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	4.2 min./56 specimens per hr.	—	2.5 min./up to 505 tests per hr.
• Basic metabolic panel	11.72 min./40 specimens per hr. (after first hr.)	—	6 min./up to 675 tests per hr.
• Complete metabolic panel	14.42 min./30 specimens per hr. (after first hr.)	—	7.5 min./up to 700 tests per hr.
Typical time delay from ordering stat test until aspiration of sample	~135 sec. when running; ~244 sec. in standby mode	—	1 min.
Immunoassay:			
Fully automated microplate immunoassay system	—	no	—
Methodologies supported	—	direct enhanced chemiluminescence	—
Separation methodologies	—	coated microwell	—
Stat time until completion of a β-hCG test	—	24 min.	—
• Typical time delay from test order to aspiration of sample	—	1 min.	—
Stat time until completion of a cTn test	—	18 min.	—
• Typical time delay from test order to aspiration of sample	—	1 min.	—
Approx. No. of tests per reagent set or pack/Reagent type	160–500 per reagent bottle/self-contained single use	100/self-contained multiuse	60/self-contained multiuse, open reagent system
Reagents refrigerated onboard/Reagents ready to use	yes (2°–10°C)/yes	yes (10°C)/yes	yes (10°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes	dry chemistry, liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/143 min. or 87 specimens or 14 test panels (may vary)	yes/120 min. or 90 specimens or 3,100 tests/assays	yes/120 min. or 160 specimens or 8,940 tests/assays
Design of sample handling system	ring	circular routine sampling center	circular routine sampling center
Uses washable cuvettes/Uses disposable cuvettes	yes/no	no/no	no/yes (can store up to 348 cuvettes)
Min.–max. sample volume that can be aspirated at one time	1.5–45 µL	2–200 µL	2–200 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	120 µL/1.5 µL/50 µL	—/10 µL/35 µL	—/2 µL/35 µL
Dedicated pediatric sample cup	yes (dead volume: 50 µL)	no	—
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 12 x 75, 12 x 100, 13 x 75, 13 x 100)/no	yes (tubes [in mm]: 10.25 x 45, 12 x 75, 12 x 100, 13 x 75, 13 x 100, 16 x 75, 16 x 100, more)/no	yes (tubes [in mm]: 10.25 x 45, 12 x 75, 12 x 100, 13 x 75, 13 x 100, 16 x 75, 16 x 100, more)/no
Protects against probe collision	yes	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	yes/yes/yes/yes	yes/yes/yes/yes	yes/yes/yes/yes
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/<.05%	yes (can be programmed to perform dilutions prior to analysis)/0	yes (can be programmed to perform dilutions prior to analysis)/0
Automatic rerun capability	yes	yes	yes
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	yes/yes	yes/no	yes/no
Analyzer requires dedicated water supply	yes (20 L/hr. consumption during operation)	no (no water consumption during operation)	no (no water consumption during operation)
Autocalibration/Multipoint calibration supported	yes (ISE only; calibrants can be stored onboard)/yes	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days)	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: at lot change)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	8 hrs./—/7 days/14 days/—	—/—/—/28 days	6 mos./6 mos./6 mos./6 mos./—
Automatic programmable start/Automatic programmable shutdown	yes (15 min. avg. start-up time; 1 min. warm-up time)/no	—	—
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	direct to drain	automated collection onboard instrument	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, UPC, Codabar, Code 39, Code 128, ISBT 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/yes
Lab can control analyzer from remote computer	no	no	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	yes
UPS backup power supply/Data-management capability	yes/onboard	yes/onboard	yes/onboard
LIS or EHR systems interfaced	Merge, CGM LabDaq, ApolloLIMS, Comtron	—	—
LIS interface provided/Bidirectional interface capability	no/yes	yes (additional cost)/yes (broadcast download and host query)	yes (additional cost)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/24 hrs.	yes/4 hrs.	yes/4 hrs.
Mean time between failures	5.05 years (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: 1 hr. 5 min. hands on, 55 min. automated; monthly: 25 min.	daily: <10 min; weekly: 30 min.; monthly: 20 min.	daily: <10 min; weekly: 20 min.; monthly: 20 min.
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/some records (parts replacement, other maintenance)	yes (includes audit trail of who replaced parts)/no	yes (includes audit trail of who replaced parts)/no
Maintenance training demonstration module onboard	yes	yes	yes
Training included with purchase/Avg. time for basic user training	yes (1+ training slot)/3 days (at customer site)	yes (2 training slots)/5 days (at customer and vendor sites)	yes (2 training slots)/5 days (at customer and vendor sites)
Advanced operator training/Where advanced training is held	no/—	yes (extra charge)/vendor site	yes (extra charge)/vendor site
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (2 years)/—	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	• auto startup; auto rerun; autodilution; sample probe clot detection; probe vertical/horizontal collision protection; reagent probe bubble detection; empty reagent detection; on-the-fly reagent loading; reflexive test add-on; serum index; mask chemistry; multi-lot reagent onboard; more	• Intellicheck technology process checks reduce misreported results and provide real-time quality status and traceability • single-use disposable tips for sample and reagent metering eliminate sample and reagent carryover • MicroSensor technology detects HIL and turbidity without using reagents or additional sample and time	• Intellicheck technology process checks reduce misreported results and provide real-time quality status and traceability • single-use disposable tips for sample and reagent metering eliminate sample and reagent carryover • MicroSensor technology detects HIL and turbidity without using reagents or additional sample and time

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

Part 11 of 15	Ortho Clinical Diagnostics Lori Schrider uscustomerservice@orthoclinicaldiagnostics.com Raritan, NJ 800-828-6316 www.orthoclinicaldiagnostics.com	Randox Laboratories David Ferguson evidenceseries@randox.com Crumlin, County Antrim, Ireland 0044 28 9442 2413 www.randox.com/evidence/	Randox Laboratories Graeme McNeill graeme.mcneill@randox.com Kearneysville, WV 304-728-2890 www.randox.com
Name of instrument	VITROS 5600 Integrated System	Evidence	RX imola
Type of instrument	combination chemistry/immunoassay	immunoassay	chemistry
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	batch/floor standing	discrete/benchtop
List price/First year sold in U.S.	—/2008	—/2012	—/2006
Targeted hospital bed size/Targeted daily test volume	—/1,000–4,500	—	75/>750
Company manufactures instrument	yes (also sold by distribution partners)	yes (also sold by distribution partners)	yes
Other models in this family of analyzers	—	Evidence Evolution, Evidence Investigator, Evidence MultiSTAT 8/27	RX misano, RX monaco, RX daytona +, RX modena 19/920 (>120 countries)
No. of units in clinical use in U.S./Outside U.S. (countries)	>1,000/>1,000 (North America, Central and South America, Europe, Africa, Asia, Japan, China)	66.9 × 78.7 × 39.4 in./—	27 × 38 × 23 in./44.28 sq. ft.
Dimensions (H × W × D)/Instrument footprint (square feet)	68 × 110 × 35 in./26.7 sq. ft.	1,330 lbs./—	331 lbs./340 lbs.
Weight empty/Weight fully loaded	2,360 lbs./—	—	—
Tests available on analyzer in U.S.	—	acetaminophen, amphetamine, barbiturates, bath salts, benzodiazepine, benzylpiperazines, buprenorphine, cannabinoids, carbamazepine, chloral hydrate metabolite, cocaine metabolite	acetic acid, acid phosphatase, aldolase, albumin, alkaline phosphatase, ALT GPT, ammonia, amylase (pancreatic) apo A-1, apo B, AST, barbiturates, benzodiazepines, direct bilirubin, more adiponectin, alkaline phosphatase, alpha-A-antitrypsin, amylase, ASO, B2 microglobulin, bile acids, total bilirubin, calcium, ceruloplasmin, chloride, cholinesterase, CK-MB, CK-NAC, more
Tests not available in U.S. but available in other countries	—	—	none
Tests in development for analyzer	VITROS NephroCheck, high-sensitivity troponin, more	—	60 (60 can be run and calibrated at one time)
No. of different measured assays onboard simultaneously	107 (107 can be run and calibrated at one time)	21 (21 can be run and calibrated at one time)	15 (0 can be active simultaneously)
No. of user-definable (open chemistry) channels	20 (20 can be active simultaneously)	0	560, including ISE (50 tests in throughput)/5–10 min. (avg. 6 min.)
Test throughput per hour/Assay run time	945/2–73 min. (avg. 8 min.)	3,960/—	—
Chemistry:			
No. of direct ion-selective electrode channels	3	—	3
Detection methods	colorimetric rate, potentiometric, immunorate, turbidimetric, direct enhanced chemiluminescence	—	potentiometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	2.5 min./up to 505 tests per hr.	—	13 min. 15 sec./80 specimens per hr.
• Basic metabolic panel	6 min./up to 675 tests per hr.	—	13 min. 43 sec./80 specimens per hr.
• Complete metabolic panel	7.5 min./up to 700 tests per hr.	—	13 min. 15 sec./67 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	1 min.	—	30 sec.
Immunoassay:			
Fully automated microplate immunoassay system	no	no	—
Methodologies supported	direct enhanced chemiluminescence	chemiluminescence	—
Separation methodologies	coated microwell	—	—
Stat time until completion of a β-hCG test	24 min.	—	—
• Typical time delay from test order to aspiration of sample	1 min.	—	—
Stat time until completion of a cTn test	18 min.	—	—
• Typical time delay from test order to aspiration of sample	1 min.	—	—
Approx. No. of tests per reagent set or pack/Reagent type	50–100/self-contained multiuse, open reagent system	180 or 360/self-contained multiuse, open reagent system	200/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	yes (10°C)/yes	yes (2°–8°C)/yes	yes (8°–15°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	dry chemistry, liquid chemistry (open reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/120 min. or 90 specimens or 11,440 tests/assays	yes/100 min. or 180 specimens or 3,960 tests/assays	yes/70 min. or 40 specimens or 10 tests/assays
Design of sample handling system	circular routine sampling center	carousel	ring
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 348 cuvettes for MicroTip assays)	no/no	yes/no
Min.–max. sample volume that can be aspirated at one time	2–200 µL	7–150 µL	1.5–35 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—/2 µL/35 µL	—/7 µL/500 µL (test tube)	150 µL/1.5 µL/150 µL
Dedicated pediatric sample cup	no	yes (dead volume: 250 µL)	yes (dead volume: 100 µL)
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 10.25 × 45, 12 × 75, 12 × 100, 13 × 75, 13 × 100, 16 × 75, 16 × 100, more)/no	—/no	yes (tubes [in mm]: 17 × 38)/no
Protects against probe collision	yes	no	yes
Detects clots/liquid level/short sample	yes/yes/yes	no/yes/yes	yes/yes/no
Detection for hemolysis/icterus/lipemia/clots	yes/yes/yes/yes	no/no/no/no	yes/yes/yes/no
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/0	no/—	yes (can be programmed to perform dilutions prior to analysis)/0
Automatic rerun capability	yes	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	yes/no	—	yes/yes
Analyzer requires dedicated water supply	no (no water consumption during operation)	no (10 L/hr. consumption during operation)	yes (18 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: at lot change)	— (calibrants are not stored onboard)/yes	no (calibrants can be stored onboard)/yes (recommended avg. frequency: 14 days)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	6 mos./6 mos./6 mos./6 mos./28 days	—	1 day/7 days/7 days/14 days/28 days
Automatic programmable start/Automatic programmable shutdown	—	yes (13 min. avg. start-up time)/yes	yes (5–10 min. avg. start-up time; 30 min. warm-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	—/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	automated collection onboard instrument	manually by user or automated collection onboard instrument	direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, ISBT 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, Code 93)/—	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no	—	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	—	yes
UPS backup power supply/Data-management capability	yes/onboard	—/onboard	no/onboard
LIS or EHR systems interfaced	—	—	—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	yes (included in instrument price)/yes (host query)	no/yes (host query)
Modem servicing provided/Service engineer on-site response time	yes/4 hrs.	—/<24 hrs. (contract dependent)	no/within 24 hrs.
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	2 per 3 years (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: <10 min.; weekly: 30 min.; monthly: 20 min.	daily: 5 min.; weekly: 10 min.; monthly: 30 min.	daily: 5 min.; weekly: 15 min.; monthly: 1 hr.
Maintenance records kept onboard for user/vendor	yes (includes audit trail of who replaced parts)/no	no/no	no/no
Maintenance training demonstration module onboard	no	yes	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/5 days (at customer and vendor sites)	yes (1 training slot per service contract)/5 days (site depends on contract)	yes (1 training slot)/3 days (at customer site)
Advanced operator training/Where advanced training is held	yes (extra charge)/vendor site	yes/site depends on contract	yes (extra charge)/customer site
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • Intellichem technology process checks reduce misreported results and provide real-time quality status and traceability • single-use disposable tips for sample and reagent metering eliminates sample and reagent carryover • MicroSensor technology detects HIL and turbidity without using reagents or additional sample and time 	<ul style="list-style-type: none"> • biochip enables simultaneous analysis of multiple analytes in single sample • maximum throughput of 3,960 tests per hour • unreported tests retrieved retrospectively; arrays contain multiple tests applicable to forensic toxicology and workplace 	<ul style="list-style-type: none"> • large test menu • stat sample capabilities • benchtop analyzer
<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 FOR MID- AND HIGH-VOLUME LABORATORIES	Roche Diagnostics Ryan Dempsey ryan.dempsey@roche.com Indianapolis, IN 800-428-5074 us.diagnostics.roche.com	Roche Diagnostics Ryan Dempsey ryan.dempsey@roche.com Indianapolis, IN 800-428-5074 us.diagnostics.roche.com	Sekisui Diagnostics Marketing Department questions@sekisui-dx.com Lexington, MA 781-652-7800 www.sekisuidiagnostics.com
Name of instrument	cobas 6000 analyzer series	cobas 8000 modular analyzer series	SK500 Clinical Chemistry System
Type of instrument	combination chemistry/immunoassay	combination chemistry/immunoassay	chemistry
Operational type/Model type	random access, continuous random access/floor standing	random access, continuous random access/floor standing	random access/floor standing
List price/First year sold in U.S.	—/2006	—/2010	\$84,500/2016
Targeted hospital bed size/Targeted daily test volume	~100/1,000–4,000	>100/>4,000	—/600–1,200
Company manufactures instrument	no (manufactured by Hitachi High-Technologies)	no (manufactured by Hitachi High-Technologies)	no
Other models in this family of analyzers	chemistry: cobas c 501; immunoassay: cobas e 601	chem.: cobas c 701, c 702, c 502; immuno.: cobas e 801, e 602	—
No. of units in clinical use in U.S./Outside U.S. (countries)	>1,600/>14,000 (56 countries)	>400/> 5,000 (49 countries)	—
Dimensions (H × W × D)/Instrument footprint (square feet)	51 × 74–196 × 41 in./34.62 sq. ft. for 2-module configuration	40–53 × 99–294 × 45 in./~66.35 sq. ft. for 3-module config.	45 × 41.5 × 29.5 in./8.5 sq. ft.
Weight empty/Weight fully loaded	830–1,990 lbs./830–1,990 lbs.	1,150–5,485 lbs./1,150–5,485 lbs.	662 lbs./700 lbs.
Tests available on analyzer in U.S.	more than 180 tests for anemia, DAT, coagulation, diabetes, cardiac markers, more	more than 180 tests for anemia, diabetes, cardiac markers, more	iron, total bilirubin, LDL, HDL, creatinine, AST, phosphorus, ALP, glucose, urea (BUN), calcium, albumin, ALT, more
Tests not available in U.S. but available in other countries	immunoassay: anti-HTLV-III, CA 27-24, CMV IgG avidity, more	immunoassay: anti-HTLV-III, CA 27-24, CMV IgG avidity, more	TPLA, RPR, HbA1c
Tests in development for analyzer	chemistry: acid phosphatase total serum/nonprostatic serum, more	chemistry: acid phosphatase total serum/nonprostatic serum, more	drugs of abuse
No. of different measured assays onboard simultaneously	immunoassay: 17-OH progesterone, active B12, anti-HBe, more	immunoassay: 17-OH progesterone, active B12, anti-HBe, more	39 (39 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	chemistry: 6 acetylmorphine, alpha 2 microglobulin, EDDP, more	chemistry: 6 acetylmorphine, alpha 2 microglobulin, EDDP, more	36 (36 can be active simultaneously)
Test throughput per hour/Assay run time	up to 151 (up to 148 can be run and calibrated at one time)	up to 283 (>300 can be run and calibrated at one time)	580 (39 tests in throughput)/1–11.5 min.
	20 (all can be active simultaneously)	40 (all can be active simultaneously)	
	up to 2,170 (2,170 tests in throughput)/ISE: 12 sec.; chemistry: 3–10 min. in 1-min. steps; immunoassay: 9–27 min. (avg. 18 min.)	up to 9,800 (9,800 tests in throughput)/ISE: 12 sec.; chemistry: 3–10 min. in 1-min. steps; immunoassay: 9–27 min. (avg. 18 min.)	
Chemistry:			
No. of direct ion-selective electrode channels	3	3	3
Detection methods	photometry, potentiometry	photometry, potentiometry	photometry, potentiometry
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	4.5 min./133 specimens per hr.	4.5 min./600 specimens per hr.	11 min./60 specimens per hr.
• Basic metabolic panel	7 min./up to 240 specimens per hr.	7 min./600 specimens per hr.	12 min./58 specimens per hr.
• Complete metabolic panel	10 min./up to 110 specimens per hr.	10 min./600 specimens per hr.	13 min./32 specimens per hr.
Typical time delay from ordering stat test until aspiration of sample	<1 min.	<1 min.	1 min.
Immunoassay:			
Fully automated microplate immunoassay system	no	no	—
Methodologies supported	electrochemiluminescence	electrochemiluminescence	—
Separation methodologies	magnetic particle	magnetic particle	—
Stat time until completion of a β-hCG test	9 min.	9 min.	—
• Typical time delay from test order to aspiration of sample	42 sec.	24 sec.	—
Stat time until completion of a cTn test	9 min.	9 min.	—
• Typical time delay from test order to aspiration of sample	42 sec.	24 sec.	—
Approx. No. of tests per reagent set or pack/Reagent type	up to 800 per pack (chemistry), up to 200 per pack (immunoassay)/self-contained multiuse	up to 3,000 per pack (chemistry), up to 300 per pack (immunoassay)/self-contained multiuse	— (variable)/open reagent system
Reagents refrigerated onboard/Reagents ready to use	yes (5°–12°C [chemistry], 20°±3°C [immunoassay])/yes	yes (5°–15°C [chemistry], 6°–10°C [immunoassay])/yes	yes (8°–12°C)/yes
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/yes	liquid chemistry (open reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/75 min. or 150 samples or 1,500 tests/assays	yes/45 min. or 300 samples or 3,000 tests/assays	yes/270 min. or 72 specimens or 39 tests/assays
Design of sample handling system	5-position rack	5-position rack	ring
Uses washable cuvettes/Uses disposable cuvettes	yes (for chemistry)/yes (can store up to 1,008 cuvettes for immunoassay)	yes (for chemistry)/yes (can store up to 1,575 cuvettes for immunoassay depending on configuration)	yes/no
Min.—max. sample volume that can be aspirated at one time	1–35 µL	1–60 µL	1–20 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	100 µL (chemistry), 160–200 µL (immunoassay)/1.5 µL (chemistry) 4–10 µL (immunoassay)/500 or 1,000 µL (tube dependent)	100 µL (chemistry), 120 µL (immunoassay)/1 µL/container dependent	100 µL/101 µL/100 µL
Dedicated pediatric sample cup	yes (dead volume: 50 µL)	yes (dead volume: 50 µL)	yes (dead volume: 50 µL)
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 13 × 75, 13 × 100, 16 × 75, 16 × 100, more)/no	yes (tubes [in mm]: 13 × 75, 13 × 100, 16 × 75, 16 × 100, more)/no	yes (tubes [in mm]: 12.4 × 75, 12.4 × 100, 15.4 × 75, 15.4 × 100)/no
Protects against probe collision	yes	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	yes/yes/yes/yes	yes/yes/yes/yes	yes/yes/yes/yes
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/<1 part per million (chemistry), 0 (immunoassay)	yes (can be programmed to perform dilutions prior to analysis)/<1 part per million (chemistry), 0 (immunoassay)	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/concentrated to rerun out-of-linear-range low results	yes/yes	yes/yes	yes/no
Analyzer requires dedicated water supply	yes (10 L/hr. consumption during operation for chemistry, 12 L/hr. for immunoassay)	yes (10–36 L/hr. consumption during operation for chemistry, 12–30 L/hr. for immunoassay)	yes (13 L/hr. consumption during operation)
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 24 hrs. [ISE], once per lot [chemistry], up to 56 days per lot [immunoassay])	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 24 hrs. [ISE], once per lot [chemistry], up to 56 days per lot [immunoassay])	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 20 days)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	24 hrs./once per lot/42 days per lot/once per lot/up to 56 days per lot	24 hrs./once per lot/42 days per lot/once per lot/up to 84 days per lot	24 hrs./—/—/20 days/—
Automatic programmable start/Automatic programmable shutdown	yes/yes	yes (up to 6.5 min. start-up time)/yes	yes (15 min. avg. start-up time; 1–3 min. warm-up time)/yes
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	no/yes
Supports multiple QC lot numbers per analyte	yes	yes	yes
Waste management	direct to drain	direct to drain	direct to drain
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128, GS1-128, GS1-Databar, Code 93)/no
Lab can control analyzer from remote computer	yes	yes	no
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	yes	yes	no
UPS backup power supply/Data-management capability	yes/onboard	yes/onboard	no/onboard
LIS or EHR systems interfaced	—	—	CGM LabDaq, Cerner
LIS interface provided/Bidirectional interface capability	yes (included in instrument price)/yes (broadcast download and host query)	yes (included in instrument price)/yes (broadcast download and host query)	yes (additional cost)/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	yes/<8 hrs.	yes/<8 hrs.	no/contract dependent
Mean time between failures	— (displays error codes for troubleshooting)	— (displays error codes for troubleshooting)	210 days (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 4 min.; weekly: 20 min.; monthly: 45 min. (all hands-on time)	daily: 4–5 min.; weekly: 20 min.; monthly: 72 min. (all hands-on time)	daily: 5 min.; weekly: 5 min.; monthly: none
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)	user defined/no
Maintenance training demonstration module onboard	yes	yes	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/varies at customer site, 5 days at vendor site	yes (4 training slots)/varies at customer site, 5 days at vendor site	yes (2 training slots)/3 days (at customer site)
Advanced operator training/Where advanced training is held	yes/vendor site	yes/vendor site	yes (extra charge)/customer site
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/configuration dependent	yes (1 year)/configuration dependent	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • broad test menu: more than 180 assays on 1 integrated platform • 283 days mean time between repair visits (global average) • flexible, scalable design: available in 7 unique configurations 	<ul style="list-style-type: none"> • 172 days mean time between repair visits (global average) • high reagent onboard and calibration stability; no reagent prep; on-the-fly loading • broad test menu: more than 180 assays on 1 integrated platform 	<ul style="list-style-type: none"> • minimal floorspace required with 580 tests per hour • instrument-specific and open-system reagents available • small reaction volumes maximize reagent tests per kit and reduce water consumption
<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	Siemens Healthineers John Dabney john.dabney@siemens.com Tarrytown, NY 847-229-3711 https://usa.healthcare.siemens.com/laboratory-diagnostics	Siemens Healthineers Joe Amodeo joseph.amodeo@siemens-healthineers.com Deerfield, IL 847-229-3711 https://usa.healthcare.siemens.com/laboratory-diagnostics	Siemens Healthineers Joe Amodeo joseph.amodeo@siemens-healthineers.com Deerfield, IL 847-229-3711 https://usa.healthcare.siemens.com/laboratory-diagnostics
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument Type of instrument	ADVIA Centaur XPT Immunoassay System immunoassay	Atellica Sci combination chemistry/immunoassay	Dimension EXL with LM Integrated Chemistry System combination chemistry/immunoassay
Operational type/Model type	random access/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 daily 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 (square feet) Weight empty/Weight fully loaded	—/2016 ≥300/500 yes (also sold by Direct, McKesson, Henry Schein) ADVIA Centaur CP, ADVIA Centaur XP immunoassay systems ≥100/≥1,100 (>60 countries) 66 × 77 × 41 in./21.92 sq. ft. 1,289 lbs./1,289 lbs.	—/2017 mid-volume/>750,000 annual yes (also sold by McKesson, Henry Schein) CHC 930 (chemistry), IM 1300 and IM 1600 (immuno) <100/<100 (<25 countries) 57.7 × 166.9 × 57.1 in./48.9 sq. ft. 3,320 lbs./—	\$291,000/2009 mid- and high-volume/<2,000 yes (also sold by McKesson, Henry Schein) Dimension EXL 200 Integrated Chemistry System >2,000/>2,000 (>65 countries) 48 × 99 × 52 in./25.1 sq. ft. 1,095 lbs./1,095 lbs.
Tests available on analyzer in U.S. Tests not available in U.S. but available in other countries Tests in development for analyzer	allergy, anemia, autoimmune, bone metabolism, cardiac, diabetes, hepatitis, HIV, immunosuppressant drugs, more — —	>90 chemistry assays, including alanine aminotransferase, alkaline phosphatase, ammonia, amylase, calcium, more AFP, aHAVT, aHbCM, aHbS2, HbCT, PSA ACTH, active B12, AMH, anti-CCP, anti-HBe, androstenedione, calcitonin, CMV IgG, CMV IgM, EBV-EBNA IgG, more up to 112 10 (chemistry), 0 (immunoassay) up to 1,800 (chemistry), up to 220 (immunoassay)/ 18 sec.—54 min. (assay dependent)	— — —
No. of different measured assays onboard simultaneously No. of user-definable (open chemistry) channels Test throughput per hour/Assay run time	30 (300 can be run and calibrated at one time) 0 up to 240 (up to 240 tests in throughput)/~18 min. to first result, 15 sec. thereafter	up to 112 10 (chemistry), 0 (immunoassay) up to 1,800 (chemistry), up to 220 (immunoassay)/ 18 sec.—54 min. (assay dependent)	91 (91 can be run and calibrated at one time) 15 (15 can be active simultaneously) up to 624 (up to 187 electrolyte, 167 heterogeneous immunoassay, 440 photometric tests in throughput)/ 45 sec.—32 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	— — — — —	none photometry, turbidimetric, integrated multisensor technology, EMIT, PETINIA ~2 min./— ~10 min. with glucose oxidase, 7 min. with glucose hexokinase/— ~10 min./— 60 sec. maximum	3 indirect photometry, potentiometry, turbidimetric, EMIT/advanced LOCI chemiluminescence, PETINIA, ACMA, more 2.9 min./62 specimens per hr. 4.0 min./62 specimens per hr. 9.3 min./82 specimens per hr. <24 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	no chemiluminescence, acridinium ester magnetic particle 18 min. 15 sec. 18 min. 15 sec.	no chemiluminescence, acridinium ester magnetic particle — — ~10 min. ~60 sec.	no chemiluminescence none (all assays homogeneous) ~16 min. <24 sec. ~16 min. <24 sec.
Approx. No. of tests per reagent set or pack/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	50–250, some 500/self-contained multiuse yes (4°C)/yes yes/yes liquid chemistry (closed reagent system)/yes no/no yes/280 min. or 180 specimens or 840 tests/assay	50–5,000/self-contained multiuse, open reagent system yes (4°–8°C)/yes yes/yes liquid chemistry (open reagent system)/yes no/no yes/up to 5 hrs. or 440 specimens or 112 tests/assays	15–360/self-contained multiuse yes (2°–8°C)/yes yes/yes liquid chemistry (open reagent system)/yes no/no yes/60 specimens or >2,000 tests/assays
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/Pierces caps on primary tubes Protects against probe collision Detects clots/liquid level/short sample Detection 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/concentrated to rerun out-of-linear-range low results	rack no/yes (can store up to 1,000 cuvettes) 10–200 µL 450 µL/10 µL/50 µL no yes (tubes: 1–10 mL, micro)/no yes yes/yes/yes no/no/no/yes yes (can be programmed to perform dilutions prior to analysis)/0 (uses disposable sample tips) yes yes/no	sample handler multiple rack drawer yes for chemistry/yes for immunoassay (can store 336 cuvettes for chemistry) 2 µL (chemistry), 10 µL (immunoassay) assay dependent/assay dependent/container dependent no yes (tubes [in mm]: 12 × 75 to 16 × 100)/no no yes/yes/yes yes/yes/yes/yes yes (can be programmed to perform dilutions prior to analysis)/ 0 (immunoassay), <0.1 parts per million (chemistry) yes yes/no	segmented sample wheel, rack no/yes (can store up to 12,000 cuvettes) 2–60 µL 2 µL/2 µL/30 µL yes (dead volume: 30 µL) yes (tubes: 5–10 mL, more)/no no yes/yes/yes yes/yes/yes/yes yes (can be programmed to perform dilutions prior to analysis)/<1 part per million 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	no (2.5 L/hr. consumption during operation) no (calibrants are not stored onboard)/yes (recommended avg. frequency: 28 days [assay dependent]) —/28 days (assay dependent)/—/28 days (assay dependent) yes (always ready, no warm-up time)/no no/yes yes	yes (33 L/hr. consumption during operation for chemistry, 6 L/hr. for immunoassay) yes (calibrants are stored onboard)/yes (recommended avg. fre- quency: 28–183 days for chemistry, 14–91 days for immunoassay) autocalibration every 4 hrs./28–63 days/40–180 days/up to 180 days/14–91 days no/no yes/yes yes	yes (up to 5 L/hr. consumption during operation) yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 60–90 days) autocalibration every 2 hrs./30 days/30 days/30–90 days (assay specific)/30–90 days (assay specific) no/no yes/yes yes
Waste management Sample barcode-reading capability/Autodiscrimination Lab can control analyzer from remote computer Instrument can diagnose its own malfunctions System malfunctions can be diagnosed via remote monitoring UPS backup power supply/Data-management capability LIS or EHR systems interfaced LIS interface provided/Bidirectional interface capability Modem servicing provided/Service engineer on-site response time	auto. collection onboard instrument, direct to drain, more yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes no yes (operator intervention required to order parts) yes yes/onboard (optional add-on: Siemens Centralink DMS) Cerner, Meditech, SCC Soft Computer, Sunquest, more yes (additional cost)/yes (broadcast download and host query) yes/contract dependent	manually by user or direct to drain yes (Interleaved 2 of 5, Code 39, Code 128)/yes yes yes (operator intervention required to order parts) yes yes/onboard (optional add-on: Siemens Centralink DMS) — yes (incl. in price)/yes (broadcast download and host query) yes/5 hrs. avg.	direct to drain yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes no yes (operator intervention required to order parts) yes yes/onboard (optional add-on: Siemens Centralink DMS) — yes (additional cost)/yes (broadcast download and host query) yes/2–8 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/Where advanced training is held Warranty provided/Cost of annual service contract (24 h/7 d)	— (displays error codes for troubleshooting) daily: 0; weekly: 4–10 min.; monthly: 15 min. yes (includes audit trail of who replaced parts)/some (maintenance log with prepopulated and free text event descriptions) yes yes (2 training slots)/~3 days (at customer and vendor sites) yes (cost dependent on contract)/vendor site yes (1 year)/—	3 mos. (displays error codes for troubleshooting) daily: <5 min.; weekly: 20 min. max.; monthly: 25 min. max. yes (includes audit trail of who replaced parts)/yes (includes audit trail of who replaced parts) yes yes (3 training slots)/6.5 days (at customer and vendor sites) yes/customer and vendor site yes (1 year)/—	— (displays error codes for troubleshooting) daily: 5 min.; weekly: 10 min.; monthly: 15 min. yes (no audit trail of who replaced parts)/no no yes (2 training slots)/3 days (at customer and vendor sites) yes (extra charge)/vendor site yes (contract dependent)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> on-the-fly loading and unloading of samples, reagents, supplies automated daily maintenance; no monthly cleaning procedures; no daily start-up procedure up to 240 tests per hour; stat port allows priority sampling at any time; disposable sample tips; automated clot management 	<ul style="list-style-type: none"> patented sample transportation (Atellica Magline) and unique sample/tube characterization automated and user features—calibration, QC, maintenance, reagent management, lab metric calculations onboard sample aliquot for automated repeat and re-dilutions 	<ul style="list-style-type: none"> true integration of chemistry and immunoassay in one analyzer 5 min. daily hands-on maintenance 10 min. guideline-compliant troponin-I assay
<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	Siemens Healthineers John Dabney john.dabney@siemens.com Tarrytown, NY 847-229-3711 https://usa.healthcare.siemens.com/laboratory-diagnostics	Thermo Fisher Scientific Nicole Ramsey nicole.ramsey@thermofisher.com Portage, MI 800-346-4364 www.thermofisher.com/phadia-systems	Thermo Fisher Scientific/BRAHMS info.brahms@thermofisher.com Hennigsdorf, Germany +49(0)33028830 www.thermoscientific.com/kryptor
FOR MID- AND HIGH-VOLUME LABORATORIES			
Name of instrument	Immuliite 2000 XPI Immunoassay System	Phadia 250 Laboratory System	B-R-A-H-M-S KRYPTOR compact PLUS
Type of instrument	immunoassay	immunoassay	immunoassay
Operational type/Model type	batch, random access, continuous random access, discrete/floor standing	continuous random access, discrete/floor standing	batch, random access, continuous random access/benchtop
List price/First year sold in U.S.	—/2009	—/2004	\$56,400/2015
Targeted hospital bed size/Targeted daily test volume	>200/250	—/20,000–95,000 per year	—
Company manufactures instrument	yes (also sold by Direct, McKesson, Henry Schein)	yes	yes
Other models in this family of analyzers	—	Phadia 1000, Phadia 2500, Phadia 5000 laboratory systems	BRAHMS KRYPTOR, BRAHMS KRYPTOR compact
No. of units in clinical use in U.S./Outside U.S. (countries)	≥160/≥2,200 (>75 countries)	>271/>2,135 (>25 countries)	—/>700 (worldwide)
Dimensions (H × W × D)/Instrument footprint (square feet)	47 × 60 × 30 in./12.5 sq. ft.	73 × 50 × 30 in./54 sq. ft.	24 × 29 × 29 in./4.59 sq. ft.
Weight empty/Weight fully loaded	800 lbs./800 lbs.	485 lbs./—	119 lbs./—
Tests available on analyzer in U.S.	3gAllergy specific, total IgE, ferritin, folic acid, RBC folate, vitamin B12, calcitonin, PYRILINKS-D, high-sensitivity CRP, myoglobin, troponin I, CMV IgG, CMV IgM, herpes I & II IgG, more	hundreds of ImmunoCAP-specific IgE allergens and allergen components, ImmunoCAP-total IgE, ECP and tryptase; EIIA autoimmune products include thyroid (anti-TG, anti-TPO), more	BRAHMS PCT sensitive
Tests not available in U.S. but available in other countries	AlaTOP allergy screen, allergen-specific IgG, allergen-specific IgG4, ECP, osteocalcin, CK-MB, D-dimer, NT-proBNP, IL-2R, more	EIIA CTD screen (15 ENAs), EIIA Pm/Scl, EIIA anti IgA, EIIA calprotectin, EIIA ASCA IgG and IgA, EIIA Rib-P, RF IgG, more	BRAHMS: copeptin proAVP, MR-proANP, anti-Tgn, anti-TPOn, AFP, CA 15-3, CA 19-9, CA 125 II, CEA, CgA II, CYFRA 21-1, more
Tests in development for analyzer	—	—	—
No. of different measured assays onboard simultaneously	24 (unlimited number can be run and calibrated at one time)	6 (6 can be run and calibrated at one time)	8 (8 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	none	0	—
Test throughput (per hour)/Assay run time	200 (200 tests in throughput)/35–65 min.	60 (~350 results per 8-hr. shift)/ImmunoCAP: 100 min.—8 hrs.; EIIA: 114 min.—8 hrs.	60 max. (up to 60 tests in throughput)/9–59 min.
Chemistry:			
No. of direct ion-selective electrode channels	—	—	—
Detection methods	—	—	—
Stat time until completion/specimen throughput for:			
• Ion-selective electrode	—	—	—
• Basic metabolic panel	—	—	—
• Complete metabolic panel	—	—	—
Typical time delay from ordering stat test until aspiration of sample	—	—	—
Immunoassay:			
Fully automated microplate immunoassay system	no	no	yes (1 test per well; 96 wells per microplate)
Methodologies supported	chemiluminescence, bead	fluorescence immunoassay	fluorescence
Separation methodologies	centrifugation	fiber matrix filter, coated microwell	none (all assays homogeneous)
Stat time until completion of a β-hCG test	35 min.	—	34 min.
• Typical time delay from test order to aspiration of sample	18 sec.	—	1 min.
Stat time until completion of a cTn test	35 min.	—	—
• Typical time delay from test order to aspiration of sample	18 sec.	—	—
Approx. No. of tests per reagent set or pack/Reagent type	200/self-contained multiuse	— (variable)/self-contained multiuse	50–100/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	yes (4°C)/yes	yes (2°–8°C, some at room temperature)/some are ready to use	yes (2°–8°C)/some are ready to use
Reagent lot tracking/Reagent inventory	yes/yes	yes/yes	yes/yes
Reagent form/Reagents barcoded	liquid chemistry (closed reagent system)/yes	liquid chemistry (closed reagent system)/yes	liquid chemistry, reconstitutes onboard, dilutes concentrated reagents (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/no	no/no	no/no
Walkaway capability/Walkaway duration	yes/240 min. or 90 specimens or 1,000 tests/assays	yes/100 min.	yes/220 min. max. or 64 specimens max. or 96 max. tests/assay (assay dependent)
Design of sample handling system	rack	rack	rack
Uses washable cuvettes/Uses disposable cuvettes	no/yes (can store up to 1,000 cuvettes)	no/no	no/no
Min.–max. sample volume that can be aspirated at one time	5–600 µL	ImmunoCAP: 40 µL min.; EIIA: 50 µL min.	8–70 µL
Min. reaction volume/Min. specimen volume/Min. dead volume	—/5 µL/50 µL	ImmunoCAP: 40 µL/40 µL/200 µL; EIIA: 50 µL/20 µL/200 µL	150 µL/sample tube and assay dependent/tube dependent
Dedicated pediatric sample cup	yes (dead volume: 50 µL)	no	yes (dead volume: 75 µL)
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 12–16 diameter, 75–100 height; 10 × 50 micro sample tubes)/no	yes (tubes [in mm]: 10–17 diameter, 50–105 height)/no	yes (primary and secondary tubes [in mm]: 11–17 diameter, 60–110 height)/no
Protects against probe collision	no	yes	yes
Detects clots/liquid level/short sample	yes/yes/yes	yes/yes/yes	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	no/no/no/yes	no/no/no/yes	yes/yes/yes/yes
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis)/<3 parts per million	yes (can be programmed to perform dilutions prior to analysis)/—	yes (can be programmed to perform dilutions prior to analysis)/≤2 parts per million
Automatic rerun capability	yes	no	yes
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	yes/no	yes/no	yes/yes
Analyzer requires dedicated water supply	no	no (1 L/hr. consumption during operation)	no
Autocalibration/Multipoint calibration supported	yes (calibrants are not stored onboard)/yes (recommended avg. frequency: 1–4 weeks [assay dependent])	yes (calibrants can be stored onboard)/yes (recommended avg. frequency: 28 days)	no (calibrants are not stored onboard)/yes (recommended avg. frequency: 5–15 days)
Typical calibration frequency for ISE/therapeutic drugs/drugs of abuse/general chemistries/immunoassays	—/2 weeks/—/—/1–4 weeks (assay dependent)	—/—/—/—/28 days	—/—/—/—/5–15 days
Automatic programmable start/Automatic programmable shutdown	yes (4 min. avg. start-up time)/yes	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	yes	yes	yes
Waste management	manually by user	automated collection onboard instrument, 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)/yes	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128, 123)/no	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no	no	yes
Instrument can diagnose its own malfunctions	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)	yes (operator intervention required to order parts)
System malfunctions can be diagnosed via remote monitoring	no	yes	yes
UPS backup power supply/Data-management capability	yes/onboard (optional add-on: Siemens Centralink DMS)	yes/onboard	yes/onboard
LIS or EHR systems interfaced	—	Antek LabDaq, Cerner, Epic Beaker, GE, McKesson, Meditech, NetLIMS, Orchard Harvest, SCC Soft Computer, Seacoast, more	—
LIS interface provided/Bidirectional interface capability	yes (additional cost)/yes (broadcast download and host query)	yes/yes (broadcast download or host query)	yes (additional cost)/yes (host query)
Modern servicing provided/Service engineer on-site response time	yes/2–8 hrs.	no/24 business hrs.	yes/M–F total breakdown: 26 hrs., workaround: 72 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: 5–10 min.; weekly: 20 min.; monthly: 20–30 min.	daily: 5 min.; weekly: 10 min.; monthly: 3 hrs.	daily: <3 min.; weekly: <3 min.; monthly: <5 min.
Maintenance records kept onboard for user/vendor	no/no	some records (daily, weekly, and monthly maintenance data)/no	yes (no audit trail of who replaced parts)/yes (no audit trail of who replaced parts)
Maintenance training demonstration module onboard	yes	no	no
Training included with purchase/Avg. time for basic user training	yes (2 training slots)/3 days (at customer and vendor sites)	yes (2 training slots)/4 days (at vendor site)	yes (1 training slot)/1.5–2 days (at customer site)
Advanced operator training/Where advanced training is held	yes (cost dependent on contract)/vendor site	yes/vendor site	yes (extra charge)/vendor site
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—	yes (1 year)/—	yes (1 year)/contract dependent
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> extensive routine and specialty immunoassay menu; includes menu of >300 allergens provides opportunity to reduce sendouts and boost revenue reagent onboard stability (90 days) 	<ul style="list-style-type: none"> ability to run allergy and autoimmunity in the same run 	<ul style="list-style-type: none"> Nobel Prize-winning TRACE measuring principle automated timely dilution management no additional washing steps
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Part 15 of 15

FOR MID- AND HIGH-VOLUME LABORATORIES**Tosoh Bioscience**

Kathleen Campbell kathleen.campbell@tosoh.com
South San Francisco, CA
650-636-8198 www.tosohbioscience.us

Name of instrument	AIA 900
Type of instrument	immunoassay
Operational type/Model type	random access/floor standing
List price/First year sold in U.S.	—/2011
Targeted hospital bed size/Targeted daily test volume	—/500–1,500 per month
Company manufactures instrument	no (manufactured by Tosoh Japan; also sold by McKesson, Henry Schein, Fisher HealthCare, Medline, more)
Other models in this family of analyzers	AIA 360, AIA 2000
No. of units in clinical use in U.S./Outside U.S. (countries)	—/— (Japan, Europe)
Dimensions (H × W × D)/Instrument footprint (square feet)	49.09 × 35.04 × 26.18 in. (loader), 49.09 × 50.79 × 26.18 in. (9-tray sorter), 49.09 × 59.84 × 26.18 in. (19-tray sorter)/—
Weight empty/Weight fully loaded	404 lbs. (loader), 562 lbs. (9-tray sorter), 602 lbs. (19-tray sorter)/—
Tests available on analyzer in U.S.	TSH, FT4, T3, T4, T-uptake, FT3, TPOAb, TgAb, bhCG, estradiol, FSH, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, b-2-microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, more
Tests not available in U.S. but available in other countries	BNP, HbSAg, HbSAb, HbCAg, HbCAb, HbEA, cTnI third generation, PSA II, TrAb, HCVAb, free PSA, wPTH, more
Tests in development for analyzer	precepsin
No. of different measured assays onboard simultaneously	45 (45 can be run and calibrated at one time)
No. of user-definable (open chemistry) channels	0
Test throughput per hour/Assay run time	90 (90 tests in throughput)/—
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
Methodologies supported	fluorescence
Separation methodologies	bead
Stat time until completion of a β-hCG test	18 min.
• Typical time delay from test order to aspiration of sample	—
Stat time until completion of a cTn test	18 min.
• Typical time delay from test order to aspiration of sample	—
Approx. No. of tests per reagent set or pack/Reagent type	100/self-contained single use
Reagents refrigerated onboard/Reagents ready to use	no/yes
Reagent lot tracking/Reagent inventory	no/no
Reagent form/Reagents barcoded	dry chemistry (closed reagent system)/yes
Separate reagent pack for each specimen/for each test run	no/yes
Walkaway capability/Walkaway duration	yes/90 min. or 45 specimens or 45 tests/assays
Design of sample handling system	trays
Uses washable cuvettes/Uses disposable cuvettes	no/no
Min.–max. sample volume that can be aspirated at one time	10–125 μL
Min. reaction volume/Min. specimen volume/Min. dead volume	150 μL/500 μL (tube), 100 μL (cup)/500 μL
Dedicated pediatric sample cup	no
Primary tube sampling/Pierces caps on primary tubes	yes (tubes [in mm]: 13 × 75, 13 × 100)/no
Protects against probe collision	yes
Detects clots/liquid level/short sample	yes/yes/yes
Detection for hemolysis/icterus/lipemia/clots	no/no/no/yes
Dilutes patient samples onboard/Susceptibility to carryover	yes (can be programmed to perform dilutions prior to analysis, with extra pipette tips)/0
Automatic rerun capability	no
Sample volume can be diluted to rerun out-of-linear-range high results/concentrated to rerun out-of-linear-range low results	no/yes
Analyzer requires dedicated water supply	no
Autocalibration/Multipoint calibration supported	no (calibrants are stored onboard)/yes (recommended avg. frequency: 90 days)
Typical calibration frequency for ISE/therapeutic drugs/ drugs of abuse/general chemistries/immunoassays	—/—/—/—/90 days
Automatic programmable start/Automatic programmable shutdown	no/no
Onboard real-time QC/Onboard software capability to review QC	yes/no
Supports multiple QC lot numbers per analyte	yes
Waste management	automated collection onboard instrument
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Codabar, Code 39, Code 128)/yes
Lab can control analyzer from remote computer	no
Instrument can diagnose its own malfunctions	yes
System malfunctions can be diagnosed via remote monitoring	no
UPS backup power supply/Data-management capability	yes/no
LIS or EHR systems interfaced	Sunquest, SCC Soft Computer, Cerner
LIS interface provided/Bidirectional interface capability	no/yes (broadcast download and host query)
Modem servicing provided/Service engineer on-site response time	no/24 hrs. by phone
Mean time between failures	— (displays error codes for troubleshooting)
Average scheduled maintenance time by lab personnel	daily: 10 min.; weekly: 15 min.; monthly: 15 min.
Maintenance records kept onboard for user/vendor	no/no
Maintenance training demonstration module onboard	—
Training included with purchase/Avg. time for basic user training	yes/2.5 days (at vendor site)
Advanced operator training/Where advanced training is held	no/—
Warranty provided/Cost of annual service contract (24 h/7 d)	yes (1 year)/—
Distinguishing features (supplied by company)	<ul style="list-style-type: none"> • no interference from biotin • interchangeable reagents per system; flexible options for each size of lab • dry reagents for 90-day calibration stability for most assays

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

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