

Automated immunoassay analyzers

Part 1 of 21	Abbott Diagnostics Shar Batley sharon.batley@abbott.com 100 Abbott Park Road, CP1-4, Abbott Park IL, 60064 847-938-2348 www.abbottdiagnostics.com	Abbott Diagnostics Shar Batley sharon.batley@abbott.com 100 Abbott Park Road, CP1-4, Abbott Park IL, 60064 847-938-2348 www.abbottdiagnostics.com	Abbott Diagnostics Shar Batley sharon.batley@abbott.com 100 Abbott Park Road, CP1-4, Abbott Park IL, 60064 847-938-2348 www.abbottdiagnostics.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	ARCHITECT i1000SR/2008/U.S. U.S., Japan/U.S., Europe 639/3,410 continuous random access/floor-standing/robotic sample handler allows batch, random access, continuous access and reagent loading and unloading 49 × 59 × 30/14.7	ARCHITECT i2000/1998, i2000SR/2003, i4000SR/2007/U.S. U.S., Japan/U.S., Europe 498/6,527 batch, random access, continuous random access/floor-standing/track and LAS 48 × 61 × 49/20.3, i2000, 48 × 68 × 44/22.7 per module	ARCHITECT ci4100 (2009), ci8200 (2003), ci16200 (2007)/U.S. U.S., Japan/U.S., Europe 318/655 (c4000), 364/1,875 (c8000), 35/474 (c16000) batch, random access, continuous random access/floor-standing/robotic sample handler uses multi-dimensional sample handling 48 × 127 × 49/43.2
Tests available on instrument in U.S. Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Tests in development Tests not available on other manufacturers' analyzers	HIV Ag/Ab Combo, vitamin D, vitamin B12, folate, HE-4, CA 125, CA 15-3, CA 19-9 XR, CEA, Free PSA, Total PSA, BNP, CK-MB, troponin-I, DHEA-S, estradiol, FSH, hCG (Total B-hCG), LH, progesterone, prolactin, SHBG, anti-HAV IgM, Anti-HBc IgM, anti-HCV, anti-CCP, C-peptide, cortisol, ferritin, homocysteine, insulin, intact PTH, digoxin, phenobarbital, phenytoin, theophylline, valproic acid, vancomycin, anti-Tg, anti-TPO, many others HAVAB, testosterone AFP, ProGRP, NGAL, anti-HAV IgG, anti-HBc, anti-HBs, HBsAg, HBsAg confirmatory, others AFP, anti-HAV IgG, anti-HBc, NGAL, carbamazepine, fentamicin, methotrexate, Tg —	HIV Ag/Ab Combo, vitamin D, vitamin B12, folate, HE-4, CA 125, CA 15-3, CA 19-9 XR, CEA, Free PSA, total PSA, BNP, CK-MB, myoglobin, troponin-I, DHEA-S, estradiol, FSH, hCG (total B-hCG), LH, progesterone, prolactin, SHBG, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-HBs, anti-HCV, HBsAg, HBsAg confirmatory, C-peptide, cortisol, ferritin, homocysteine, insulin, intact PTH, digoxin, phenobarbital, phenytoin, theophylline, many others HAVAB, testosterone AFP, anti-HAV IgG, NGAL, proGRP, MPO, SCC, anti-HAV IgG, anti-HBe, HBeAg, CMV IgG, CMV IgG avidity, others anti-HAV IgG, methotrexate, Tg —	HIV Ag/Ab Combo, vitamin D, vitamin B12, folate, HE-4, CA 125, CA 15-3, CA 19-9 XR, CEA, free PSA, total PSA, BNP, CK-MB, troponin-I, DHEA-S, estradiol, FSH, hCG (Total B-hCG), LH, progesterone, prolactin, SHBG, anti-HAV IgM, anti-HBc IgM, anti-HCV, anti-CCP, C-peptide, cortisol, ferritin, homocysteine, insulin, intact PTH, digoxin, phenobarbital, phenytoin, theophylline, valproic acid, vancomycin, anti-Tg, anti-TPO, many others HAVAB, testosterone AFP, proGRP, NGAL, anti-HAV IgG, anti-HBc, anti-HBs, HBsAg, HBsAg confirmatory, many others anti-HAV IgG, methotrexate, Tg —
Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate	— — —	no — —	— — —
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum specimen volume required Minimum sample vol. aspirated precisely at once/Minimum dead volume Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead volume Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result and reaspiration of sample for rerun Autocalibration or autocalibration alert Number of calibrators required for each analyte Calibrants can be stored onboard/Average calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	chemiluminescence/magnetic particle 25 25 none 25/25-100 —/30 days tracked in hours/yes yes yes yes/assay No., reagent serial No., lot No., test per kit, exp. onboard stability time, others no/<0.1 ppm 3 hours/65/25 no/liquid yes/360 no/— 60 µL 60 µL/50 µL yes/no no/— 50 decibels during normal operation, 62 decibels maximum no/— yes/pediatric, 5, 7, 10 mL tubes and sample cups/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no <20 seconds yes 2-6 point curve no/calibration required with new lot yes/yes from 2 levels for qualitative to 3 levels every 24 hours yes/yes no/no/6.5 minutes	Chemiflex (enhanced chemiluminescence) with 5 flexible protocols/magnetic microparticle 25 25 — 25/100-test and 500-test per kit —/30 days tracked in hours/yes yes yes yes/assay No., reagent serial No., lot No., tests per kit, exp. date, onboard stability time, master calibration curve no/<0.1 ppm 300/135/12,500 no/liquid yes/1,200 no/— 50 µL 150 µL/50 µL for all tube types yes/no no/— 48-70 decibels no/— yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no <20 seconds yes 2-6 point curve no/calibration required with new lot yes/yes (up to 4 curves/analyte) 3 levels every 24 hours for quantitative, 2 levels for qualitative yes/yes —/no/10 minutes	photometric, potentiometric, and Chemiflex (enhanced chemiluminescence)/— 80-93, based on analyzer 80-93, based on analyzer 220 93/50-1,700 CC: 3/28 IA: 30 days tracked in hours/yes yes yes yes/assay name, reagent No., lot No., tests per kit, expiration date, others open system/SmartWash technology 300/367/>75,000 yes/liquid disposable and semi-permanent glass/1,200 or 165/330 yes/as needed, 1-year minimum 2 µL 50 µL/— yes/yes yes/25 L per hour (ci8200)/52 L per hour (ci16200) 48-70 decibels no/— yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes no/no <20 seconds yes 2 or 6 point no/IA: calibration with new lot, CC: 28 days yes/yes from 2 levels after calibration, to 3 per 24 hours yes/yes —/no/10 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspiration of sample Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface LIS interfaces up and running in active user sites LIS interface operates simultaneously with running assays Bidirectional interface capability Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) without operator On-site response time of service engineer Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	15.6 minutes <20 seconds up to 100 are 1-step stat TDMs TPH/— yes/yes onboard/no all major LIS vendors yes yes (broadcast download and host query) yes yes/yes/yes yes yes, AbbottLink per negotiated contract 26 weeks/per negotiated contract daily: 10 minutes; weekly: 17 minutes; monthly: 90 minutes yes/yes	15.6 minutes <20 seconds 67/200 tests per hour yes/yes onboard/no all major LIS vendors yes yes (broadcast download and host query) yes yes/yes/yes yes, AbbottLink per negotiated contract 13 weeks/per negotiated contract daily: 16 minutes; weekly: <10 minutes; monthly: none (for both manual and auto procedures) yes/yes	<15.6 minutes <20 seconds 267/800 (c4000), 400/1200 (c8000), 600/1800 (c16000), 33/100 (i1000sr), 67/200 (i2000sr) yes/yes onboard/no all major LIS vendors yes yes (broadcast download and host query) no yes/yes/yes yes, AbbottLink per negotiated contract 26 weeks (c4000), 26 weeks (i1000sr) 23 weeks (c8000), 13 weeks (i2000sr), 18weeks (c16000) (per negotiated contract)/— daily: <15 minutes; weekly: <35 minutes; monthly: 15 minutes (for manual and automated procedures) yes/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided with purchase/Advanced operator training	\$125,000/40-250 tests per day flexible options available yes/yes	\$169,500/>200 immunoassay tests per day flexible options available yes/yes	\$375,000/200-500 immunoassay tests per day flexible options available yes/yes
Distinguishing features (supplied by vendor)	streamlined workload management, continuous access to reagents, samples, and supplies, 65 samples load cap., 13 universal bay, seven customizable priority bays, refrigerated reagent carousel with 25 × 100 test kit sizes, reagents stable onboard up to 30 days, priority tests, 15.6-minute turnaround time on stat assays	Chemiflex technology delivers excellent sensitivities and extended linearities, RSH allows priority and routine samples to be processed simultaneously without compromising stats; refer to operations manual for operational precautions, limitations, and hazards; class 1 laser product	integration of CC and IA without compromising stat turnaround time, results, or throughput because of patented SmartWash technology, which minimizes carryover to <0.1 ppm, reagent capacity of 93 assays, with sample load up to 367; refer to operations manual for operational precautions, limitations, and hazards

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

Automated immunoassay analyzers

Part 2 of 21	Alere Karen Davis-Fleischer Karen.Davis-Fleischer@alere.com 2 Research Way, Princeton, NJ 08540 877-441-7440 www.alere.com	Alere Karen Davis-Fleischer Karen.Davis-Fleischer@alere.com 2 Research Way, Princeton, NJ 08540 877-441-7440 www.alere.com	Awareness Technology Inc. Jamie Raistano (US), Walter Arenas (Intl) info@awaretech.com 1935 SW Martin Hwy., Palm City, FL 34990 772-283-6540 www.awaretech.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	DS2/2007/U.S. U.S./U.S. — batch/benchttop/rack 27 x 21 x 26/4	DSX/2004/U.S. U.S./U.S. approx. 500/— batch/benchttop/rack 32 x 42 x 36/7	ChemWell/1998/U.S. U.S./open system 50+/3,000+ batch, random access/benchttop/rack 16 x 34 x 20/4
Tests available on instrument in U.S.	ID: chlamydia, CMV, EBV-EA, EBNA, EBV-VCA, <i>H. Pylori</i> , HSV, legionella, lyme, measles, mumps, myco, rubella, syphilis, toxo, VZV; AI: ANCA, ANA, CCP, ASCA, beta 2, cardios, dsDNA, ENA, gliadin, histone, Jo-1, mitochondria, MPO, PR-3, RF, ribosomal P, Scl-70, SM, SM/RNP, SS-A, SS-B, TPO, TG, TTG; osteo: NTx. bladder cancer-NMP22; enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leukocyte	ID: chlamydia, CMV, EBV-EA, EBNA, EBV-VCA, <i>H. Pylori</i> , HSV, legionella, lyme, measles, mumps, myco, rubella, syphilis, toxo, VZV; AI: ANCA, ANA, CCP, ASCA, beta 2, cardios, dsDNA, ENA, gliadin, histone, Jo-1, mitochondria, MPO, PR-3, RF, ribosomal P, Scl-70, SM, SM/RNP, SS-A, SS-B, TPO, TG, TTG; osteo: NTx. bladder cancer-NMP22; enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leukocyte	unlimited—open system
Tests not available in U.S. but submitted for clearance	—	—	—
Tests not available in U.S. but available in other countries	—	—	unlimited—open system
Tests in development	—	—	—
Tests not available on other manufacturers' analyzers	enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leukocyte	enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leukocyte	—
Fully automated microplate system	yes	yes	yes
Number of each analyte performed in separate disposable unit	1 analyte per well, multiple analytes per well	1 analyte per well, multiple analytes per well	up to 12
Number of wells in microplate	96 (minimum: 1; maximum: 96)	96 (minimum: 1; maximum: 96)	minimum strip, 8; maximum full plate, 96
Methods supported/Separation methods	enzyme immunoassay/coated microwell	enzyme immunoassay/coated microwell	EIA/coated microwell
No. of different measured assays onboard simultaneously	24	48	up to 12
No. of different assays programmed, calibrated at once	24	48	unlimited
No. of user-definable (open) channels	unlimited	unlimited	unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	18/24	24/48	27/assay dependent
Shortest/Median onboard reagent stability/Refrigerated onboard	8 hours/1 day/no	8 hours/1 day/no	assay dependent/assay dependent/yes (10°C below ambient)
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	placed directly on system	placed directly on system	yes
Reagents bar coded/Information in bar code	no/—	no/—	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/0	no/0	no/0
Walkaway capacity in minutes/Specimens/Tests-assays	120 minutes/98/24	120 minutes/98/48	assay dependent/96/12
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	yes/liquid	yes/liquid
Uses disposable cuvettes/Maximum number stored	no/—	no/—	yes/96
Uses washable cuvettes/Replacement frequency	no/—	no/—	yes/assay dependent
Minimum specimen volume required	10 µL	10 µL	2 µL
Minimum sample vol. aspirated precisely at once/Minimum dead volume	10 µL/50 µL	5 µL/50 µL	2 µL/—
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/no	no/no
Requires dedicated water system/Water consumption	no/—	no/—	no/—
Noise generated	—	—	—
Has dedicated pediatric sample cup/Dead volume	no/—	no/—	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/primary, pouroff/no	yes/primary, pouroff/no	yes/12 x 100 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	no/—
Bar-code placement per CLSI standard Auto2A	yes	yes	—
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures No. of tests remaining/Short sample detection	no/yes	no/yes	no/no
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	yes/no	yes/no	no/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no	yes/no
Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	no/no	yes/yes
Time between initial result and reaspiration of sample for rerun	—	—	assay dependent
Autocalibration or autocalibration alert	no	no	no
Number of calibrators required for each analyte	analyte dependent	analyte dependent	assay dependent
Calibrants can be stored onboard/Average calibration frequency	no/within each run	no/within each run	yes/assay dependent
Multipoint calib. supported/Multiple calibs. stored for same assay	no/no	no/no	yes/yes
How often QC required	with every assay	with every assay	shortest interval: each run; longest: daily
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	no/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/5 minutes	yes/yes/5 minutes	yes/yes/2 minutes
Stat time to completion of β-hCG test	—	—	assay dependent
Time delay from ordering stat test to aspiration of sample	—	—	30 seconds
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	—/—	—	assay dependent/—
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	onboard/yes (additional cost)	onboard/yes (included)
LIS interfaces up and running in active user sites	Cerner, Millenium, Sunquest, Soft, Mysis, etc.	Cerner, Millenium, Sunquest, Soft, Mysis, etc.	—
LIS interface operates simultaneously with running assays	yes	yes	no
Bidirectional interface capability	yes (host query)	yes (host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	no	no	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/no	no/yes/no	yes/yes/yes
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	24 hrs	24 hours	within 48 hours
Mean time between failures/To repair failures	— (recently launched)/—	4 months/2 hours	—
Average time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 20 minutes; monthly: 20 minutes	daily: 10 minutes; weekly: 20 minutes; monthly: 20 minutes	daily: <10 minutes; weekly: <10 minutes; monthly: <10 minutes
Onboard maintenance records/Maintenance training demo module	no/no	no/no	no/no
List price/Targeted bed size or daily volume	\$48,200/<350 beds	\$76,660/>350 beds	\$25,000/up to 500 tests per day
Annual service contract cost (24 hours/7 days)	\$9,000	\$10,000	\$4,000
Training provided with purchase/Advanced operator training	3 days on site/yes	3 days on site/no	3 days on site/no
Distinguishing features (supplied by vendor)	combined with the Inverness ELISA product line and the ability to automate enteric assays and front-end dilute Inverness Athena assays, the DS2 provides an efficient, open, fully automated solution for customers looking for laboratory automation	open DSX platform enables customers to run many ELISA-based assays; modular design allows users to customize system to unique needs; work list load wizard for easy set up; shows graphically where to place reagents, samples, and plates at beginning of each run; complete daily maintenance in less than 5 minutes, including removal of consumables and rinsing washer	ability to perform general biochemistries; optional reagent cooling module

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

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Part 3 of 21	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Boulevard, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Boulevard, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Boulevard, Brea, CA 92821 714-961-3140 www.beckmancoulter.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	Access/Access 2 Immunoassay System/2001/U.S. U.S./U.S., France, Ireland >2,000/>2,500 continuous random access/benchtop/rack	UniCel Dxl 600 Access Immunoassay System/2007/U.S. U.S./U.S., France, Ireland >200/>150 continuous random access/floor-standing/rack, direct track sampling	UniCel Dxl 800 Access Immunoassay System/2003/U.S. U.S./U.S., France, Ireland >500/>1,000 continuous random access/floor-standing/rack, direct track sampling
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	18.5 × 39 × 24/6.5	67 × 61.5 × 37.5/16.02	67 × 67.5 × 37.5/17.6
Tests available on instrument in U.S.	cortisol, total IgE, EPO, ferritin, folate, intrinsic factor Ab, sTfR, vitamin B12, intact PTH, ostase, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total βhCG, unconjugated estriol, fast hTSH, free T3, total T4, thyroglobulin, TPOAb, PSA, free PSA, BR-GI-OV monitors, and many others	cortisol, total IgE, EPO, ferritin, folate, intrinsic factor Ab, sTfR, vitamin B12, intact PTH, ostase, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total βhCG, unconjugated estriol, fast hTSH, free T3, total T4, thyroglobulin, TPOAb, PSA, free PSA, BR-GI-OV monitors, and many others	cortisol, total IgE, EPO, ferritin, folate, intrinsic factor Ab, sTfR, vitamin B12, intact PTH, ostase, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total βhCG, unconjugated estriol, fast hTSH, free T3, total T4, thyroglobulin, TPOAb, PSA, free PSA, BR-GI-OV monitors, and many others
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	HAV Ab, HAV IgM, HbC Ab, HbC IgM, HBs Ab, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM vitamin D, PIGF, sFit-1	HAV Ab, HAV IgM, HbC Ab, HbC IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM vitamin D, PIGF, sFit-1	HAV Ab, HAV IgM, HbC Ab, HbC IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM vitamin D, PIGF, sFit-1
Tests in development Tests not available on other manufacturers' analyzers	—	—	—
Fully automated microplate system Number of each analyte performed in separate disposable unit	no —	no —	no —
Number of wells in microplate	—	—	—
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard	chemiluminescence/magnetic particle 24 24 0 24/100 tests per kit; 50 tests per cartridge 336 hours/28 days/yes (3°–10°C)	chemiluminescence/magnetic particle 50 50 — 50/100 and 300 tests per kit; 50 tests per cartridge 336 hours/28 days/yes (3°–10°C)	chemiluminescence/magnetic particle 50 50 0 50/100 and 300 tests per kit; 50 tests per cartridge 336 hours/28 days/yes (3°–10°C)
Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code	yes yes yes/specific cartridge ID, expiration date, lot No., unique reagent pack ID No.	yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration	yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	no/<10 ppm up to 180 based on consumable capacity/60/assay dependent	yes/<10 ppm 180 to 240 based on consumable capacity/60/assay dependent	yes/<10 ppm 180 to 240 based on consumable capacity/120/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum specimen volume required Minimum sample vol. aspirated precisely at once/Minimum dead volume Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead volume Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/liquid yes/294 no/— specimen container dependent 5 µL/100 µL no/no no/— <70 decibels yes/100 µL yes/12 × 75, 13 × 75 and 100, 16 × 75 and 100/no	no/liquid yes/1,000 no/— specimen container dependent 5 µL/80 µL no/no no/— <65 decibels yes/100 µL yes/12 × 75, 13 × 75 and 100, 16 × 75 and 85 and 100 mm/no	no/liquid yes/>1,000 no/— specimen container dependent 5 µL/160 µL no/no no/— <60 decibels yes/100 µL yes/12 × 75, 13 × 75 and 100, 16 × 75, 85, and 100 mm/no
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result and reaspiration of sample for rerun Autocalibration or autocalibration alert Number of calibrators required for each analyte Calibrants can be stored onboard/Average calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes no yes/yes yes yes/yes (Access 2 only) no/no no/no no/no 36 seconds no assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes no yes/yes yes yes/yes no/no yes/yes no/no 36 seconds yes assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes no yes/yes yes yes/yes no/no yes/yes no/no 36 seconds yes assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode
Stat time to completion of β-hCG test Time delay from ordering stat test to aspiration of sample Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface	15 minutes ≥36 seconds 33/100 (36 seconds) yes/yes onboard/yes (included or additional cost—negotiable)	15 minutes 18 seconds —/200 (18 seconds) yes/yes onboard/yes (included in instrument price and additional cost)	15 minutes 18 seconds ≤133/≤400 (9–18 seconds) yes/yes onboard/yes (included or additional cost—negotiable)
LIS interfaces up and running in active user sites	all major LIS vendors	all major LIS vendors	all major LIS vendors
LIS interface operates simultaneously with running assays Bidirectional interface capability Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) without operator On-site response time of service engineer Mean time between failures/To repair failures Average time to complete maintenance by lab personnel	yes yes (broadcast download and host query) no no/no/no no per negotiated service contract — daily: 15 minutes; weekly: 30 minutes	yes yes (broadcast download and host query) yes, Beckman Coulter automation systems yes/yes/yes no per negotiated contract — daily: <10 minutes	yes yes (broadcast download and host query) yes, Beckman Coulter automation systems yes/yes/yes no per negotiated contract — daily: <10 minutes
Onboard maintenance records/Maintenance training demo module	yes (Access 2 only)/online help with maintenance instructions	yes/online help with maintenance instructions	yes/online help with maintenance instructions
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided with purchase/Advanced operator training	\$149,800/all volumes and hospital sizes per negotiated contract yes/yes (Access 2 only)	\$199,500/200–300 beds or 100–300 tests per day per negotiated contract yes/yes	\$325,000/300+ beds or >400 tests per day per negotiated contract yes/yes
Distinguishing features (supplied by vendor)	ability to network up to four Access 2 systems using one LIS interface with remote diagnostics; fully automated user-defined reflex testing; continuous random-access benchtop analyzer	integrates with UniCel DxC chemistry systems; uses chemiluminescent technology; allows operators to load consumables on the fly, without interacting with the system; offers ProService remote diagnostic service capability	high-throughput immunoassay analyzer; integrates with UniCel DxC chemistry systems; uses chemiluminescent technology; allows operators to load consumables on the fly, without interacting with the system; offers ProService remote diagnostic service capability

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

Automated immunoassay analyzers

Part 4 of 21	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Boulevard, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Boulevard, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Boulevard, Brea, CA 92821 714-961-3140 www.beckmancoulter.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed	UniCel DxC 600i Synchron Access Clinical System/2006/ U.S.	UniCel Dxl 660i Synchron Access Clinical System/2009/ U.S.	UniCel DxC 680i Synchron Access Clinical System/2009/ U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S., France, Ireland	U.S./U.S., France, Ireland	U.S./U.S., France, Ireland
No. of units in clinical use in U.S./Outside U.S.	>449/150	44/21	3/6
Operational type/Model type/Sample handling system	continuous random access/floor-standing/rack-closed tube	continuous random access/floor-standing/rack-closed- tube	continuous random access/floor-standing/rack-closed- tube
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	62 × 128 × 48/42.7	68 × 147 × 48/49	68 × 153 × 48/51
Tests available on instrument in U.S.	cortisol, total IgE, EPO, ferritin, folate, intrinsic factor Ab, sTfR, vitamin B12, intact PTH, ostase, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total βhCG, unconjugated estriol, fast hTSH, free T3, total T4, thyroglobulin, TPOAb, PSA, free PSA, BR-GI-OV monitors, and many others	cortisol, total IgE, EPO, ferritin, folate, intrinsic factor Ab, sTfR, vitamin B12, intact PTH, ostase, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total βhCG, unconjugated estriol, fast hTSH, free T3, total T4, thyroglobulin, TPOAb, PSA, free PSA, BR-GI-OV monitors, and many others	cortisol, total IgE, EPO, ferritin, folate, intrinsic factor Ab, sTfR, vitamin B12, intact PTH, ostase, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total βhCG, unconjugated estriol, fast hTSH, free T3, total T4, thyroglobulin, TPOAb, PSA, free PSA, BR-GI-OV monitors, and many others
Tests not available in U.S. but submitted for clearance	—	—	—
Tests not available in U.S. but available in other countries	HAV Ab, HAV IgM, HbCAb, HbC IgM, HbSAb, HbSAg, HbSAg confirmatory, CMV IgG, CMV IgM, others	HAV Ab, HAV IgM, HbCAb, HbC IgM, HbSAb, HbSAg, HbSAg confirmatory, CMV IgG, CMV IgM, rubella IgM	HAV Ab, HAV IgM, HbCAb, HbC IgM, HbSAb, HbSAg, HbSAg confirmatory, CMV IgG, CMV IgM, rubella IgM
Tests in development	vitamin D, PIGF, sFit-1	vitamin D, PIGF, sFit-1	vitamin D, PIGF, sFit-1
Tests not available on other manufacturers' analyzers	—	—	—
Fully automated microplate system	no	no	no
Number of each analyte performed in separate disposable unit	—	—	—
Number of wells in microplate	—	—	—
Methods supported/Separation methods	chemiluminescence, enzyme immunoassay/magnetic particle	chemiluminescence, enzyme immunoassay/magnetic particle	chemiluminescence, enzyme immunoassay/magnetic particle
No. of different measured assays onboard simultaneously	89	115	115
No. of different assays programmed, calibrated at once	89	115	115
No. of user-definable (open) channels	100	100	100
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	89/100 tests per kit (immunoassay); 300 tests per container (general chemistry)	115/100 tests per kit (immunoassay); 300 tests per container (general chemistry)	115/100 tests per kit (immunoassay); 300 tests per container (general chemistry)
Shortest/Median onboard reagent stability/Refrigerated onboard	336 hours/28 days/yes (3°–10°C)/yes	336 hours/28 days/yes (3°–10°C)	336 hours/28 days/yes (2°–10°C)
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	yes	yes	yes
Reagents bar coded/Information in bar code	yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration	yes/specific cartridge ID, No. of available tests, expiration date, lot No. calibration expiration, within lot calibration	yes/specific cartridge ID, No. of available tests, expiration date, lot No. calibration expiration, within lot calibration
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/<10 ppm	yes/<10 ppm	yes/<10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	60/76/assay dependent	60/76/assay dependent	60/76/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	closed/liquid	closed/liquid
Uses disposable cuvettes/Maximum number stored	yes/125	yes/125	yes/125
Uses washable cuvettes/Replacement frequency	yes/—	yes/—	yes/—
Minimum specimen volume required	container dependent	container dependent	container dependent
Minimum sample vol. aspirated precisely at once/Minimum dead volume	3 μL/20 μL (general chemistry)	3 μL/20 μL (general chemistry)	3 μL/20 μL (general chemistry)
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes	yes/yes
Requires dedicated water system/Water consumption	yes/16 L per hour	yes/up to 16 L per hour	yes/up to 16 L per hour
Noise generated	—	—	—
Has dedicated pediatric sample cup/Dead volume	yes/—	yes/—	yes/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13 × 75 and 100, 15 × 75 and 92, 16 × 100 mm/yes	yes/13 × 75 and 100, 15 × 92 and 75, 16 × 100 mm/yes	yes/13 × 75 and 100, 15 × 75 and 92, 16 × 100 mm/yes
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per CLSI standard Auto2A	yes	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	yes/yes	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes (general chemistry)	yes/yes (general chemistry)	yes/yes (general chemistry)
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes	yes/yes
Sample volume can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	yes/yes	yes/yes	yes/yes
Time between initial result and reaspiration of sample for rerun	chemistry dependent	chemistry dependent	chemistry dependent
Autocalibration or autocalibration alert	—	—	—
Number of calibrators required for each analyte	assay dependent	assay dependent	assay dependent
Calibrants can be stored onboard/Average calibration frequency	no/28 days	no/28 days	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes	yes/yes
How often QC required	24 hours	24 hours	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/remains in ready mode	no/no/remains in ready mode	no/no/remains in ready mode
Stat time to completion of β-hCG test	15 minutes	15 minutes	15 minutes
Time delay from ordering stat test to aspiration of sample	1 minute (general chemistry)	1 minute (general chemistry)	1 minute (general chemistry)
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	90/720 (40 seconds) (general chemistry)	90/720 (40 seconds) (general chemistry)	90/720 (40 seconds) (general chemistry)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	optional add-on/yes (additional cost)	—/—	—/—
LIS interfaces up and running in active user sites	all major LIS vendors	—	—
LIS interface operates simultaneously with running assays	yes	yes	yes
Bidirectional interface capability	yes (broadcast download and host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	yes, Beckman Coulter automation systems	yes, Beckman Coulter automation systems	yes, Beckman Coulter automation systems
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/validate for the DxC 600i	yes/yes/yes	yes/yes/validate for the DxC 600i
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	per negotiated service contract	per negotiated service contract	per negotiated service contract
Mean time between failures/To repair failures	—	—	—
Average time to complete maintenance by lab personnel	—	—	—
Onboard maintenance records/Maintenance training demo module	yes/online help with maintenance instructions	yes/online help with maintenance instructions	yes/online help with maintenance instructions
List price/Targeted bed size or daily volume	\$325,000/moderate volume, <300 samples per day	\$575,000/high volume, 300–750 samples per day	\$610,000/high volume, 300–750 samples per day
Annual service contract cost (24 hours/7 days)	per negotiated contract	per negotiated contract	per negotiated contract
Training provided with purchase/Advanced operator training	yes/yes	yes/yes	yes/yes
Distinguishing features (supplied by vendor)	performs parallel processing of immunoassay and chemistry tests on one system; ClozCap technology (closed-tube aliquot and closed-tube sampling) eliminates manual processes; chemistry reagent packs are identical across the UniCel family of systems; offers ProService remote diagnostic service capability	performs parallel processing of immunoassay and chemistry tests; ClozCap technology (closed-tube aliquot and closed-tube sampling) eliminates manual processes; chemistry reagent packs are identical across the UniCel family of systems; offers ProService remote diagnostic service capability	performs parallel processing of immunoassay and chemistry tests; ClozCap technology (closed-tube aliquot and closed-tube sampling) eliminates manual processes; chemistry reagent packs are identical across the UniCel family of systems; offers ProService remote diagnostic service capability
Note: a dash in lieu of an answer means company did not answer question or question is not applicable			

Automated immunoassay analyzers

Part 5 of 21	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Boulevard, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Boulevard, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Binding Site Maureen Zetmeisl maureen.zetmeisl@thebindingsite.com 5889 Oberlin Drive, Suite 101, San Diego, CA 92121 800-633-4484 www.thebindingsite.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	UniCel DxI 860i Synchron Access Clinical System/2009/U.S. U.S./U.S., France, Ireland 6/6 continuous random access/floor-standing/rack-closed-tube 68 × 155 × 48/51.7	UniCel DxI 880i Synchron Access Clinical System/2008/U.S. U.S./U.S., France, Ireland 28/59 continuous random access/floor-standing/rack-closed-tube 68 × 161 × 48/53.7	SPA PLUS (Specialist Protein Analyzer)/2007/Japan Japan/United Kingdom — batch, random access/two-sample carousels (45 samples, 30 primary tubes, 15 non-bar-coded sample tubes/cups) 20.5 × 31.5 × 25.2/14
Tests available on instrument in U.S. Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Tests in development Tests not available on other manufacturers' analyzers	cortisol, total IgE, EPO, ferritin, folate, intrinsic factor Ab, sTfR, vitamin B12, intact PTH, ostease, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total βhCG, unconjugated estriol, fast hTSH, free T3, total T4, thyroglobulin, TPOAb, PSA, free PSA, BR-GI-OV monitors, and many others — HAV Ab, HAV IgM, HbCAb, HbC IgM, HbSAb, HbSAg, HbSAg confirmatory, CMV IgG, CMV IgM, rubella IgM	cortisol, total IgE, EPO, ferritin, folate, intrinsic factor Ab, sTfR, vitamin B12, intact PTH, ostease, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total βhCG, unconjugated estriol, fast hTSH, free T3, total T4, thyroglobulin, TPOAb, PSA, free PSA, BR-GI-OV monitors, and many others — HAV Ab, HAV IgM, HbCAb, HbC IgM, HbSAb, HbSAg, HbSAg confirmatory, CMV IgG, CMV IgM, rubella IgM	freelite kappa (free kappa light chain), freelite lambda (free lambda light chain), albumin, beta-2-microglobulin, IgG, IgA, IgM, IgD, IgG1, IgG2, IgG3, IgG4, cystatin C, C3, C4, IgA1, IgA2, T. tox plasma screen only (RUO), haptoglobin, prealbumin — CH50, hevlite IgG kappa and lambda, hevlite IgA kappa and lambda, hevlite IgM kappa and lambda, albumin CSF, IgG CSF, IgA CSF, IGM CSF, transferrin, microalbumin, C1 inactivator alpha-1-antitrypsin, alpha-1-acid-glycoprotein, alpha-2-macroglobulin, ASO, ceruloplasmin, CRP, rheumatoid factor —
Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate	no — —	no — —	no — —
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum specimen volume required Minimum sample vol. aspirated precisely at once/Minimum dead volume Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead volume Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result and reaspiration of sample for rerun Autocalibration or autocalibration alert Number of calibrators required for each analyte Calibrants can be stored onboard/Average calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	chemiluminescence, enzyme immunoassay/magnetic particle 120 120 100 120/100 tests per kit (immunoassay); 300 tests per container (general chemistry) 336 hours/28 days/yes (2°–10°C) yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration yes/<10 ppm 60/112/assay dependent closed/liquid yes/125 yes/— container dependent 3 μL/20 μL (general chemistry) yes/yes yes/up to 16 L per hour — yes/— yes/13 × 75 and 100, 15 × 75 and 92, 16 × 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes chemistry dependent — assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode	chemiluminescence, enzyme immunoassay/magnetic particle 120 120 100 120/100 tests per kit (immunoassay)/300 tests per container (general chemistry) 336 hrs/28 days/yes (2°–10°C) yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration yes/<10 ppm 60/112/assay dependent closed/liquid no/125 yes/— container dependent 3 μL/20 μL (general chemistry) yes/— yes/up to 16 L per hour — yes/— yes/13 × 75 and 100, 15 × 75 and 92, 16 × 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes (general chemistry) yes/— yes/yes chemistry dependent — assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode	turbidimetry 24 — — 24/100 672 hours/30 days/yes yes yes yes/— no/— ~60/45/assay dependent closed/liquid no/60 yes/— 150 μL 3 μL/150 μL yes/no no/3.5 L — no/— yes/most tube sizes, including 12 × 75 mm/no yes (Codabar, codes 39 and 128)/— yes no yes/yes yes no/no no/no yes/— yes/yes <10 min yes 6 no/— yes/yes — yes/no no/no/<15 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspiration of sample Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface LIS interfaces up and running in active user sites LIS interface operates simultaneously with running assays Bidirectional interface capability Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) without operator On-site response time of service engineer Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	15 minutes 1 minute (general chemistry) 90/720 (40 seconds) (general chemistry) yes/yes — — yes yes (broadcast download and host query) yes, Beckman Coulter automation systems yes/yes/yes no per negotiated service contract — — yes/online help with maintenance instructions	15 minutes 1 minute (general chemistry) 90/720 (40 seconds) (general chemistry) yes/yes — — yes yes (broadcast download and host query) yes, Beckman Coulter automation systems yes/yes/yes no per negotiated service contract — — yes/online help with maintenance instructions	— — 35/106 (10.5 minutes incubation) yes/yes optional add-on/no Cerner, Soft Computer Concepts, Cyberlab, Sunquest, Mediatech, Data Innovations Middleware, Creative Computing Applications Inc., Rubicon yes yes (broadcast download and host query) no no/no/no no 24 hours 258 days, with 2 scheduled preventative maintenance visits/4 hours on site daily: <10 minutes; weekly: <10 minutes; monthly: <15 min. no/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided with purchase/Advanced operator training	\$615,000/high to very high volume, 500–1,500 samples per day per negotiated contract yes/yes	\$650,000/high to very high volume, 750–2,250 samples per day — —	— — 5 days (includes installation)/yes
Distinguishing features (supplied by vendor)	parallel processing of immunoassay and chemistry tests; ClozCap technology (closed-tube aliquot and sampling) eliminates manual processes; chemistry reagent packs identical across the UniCel family of systems; offers ProService remote diagnostic service capability	performs parallel processing of immunoassay and chemistry tests; ClozCap technology eliminates manual processes; chemistry reagent packs are identical across the UniCel family of systems; offers ProService remote diagnostic service capability	low maintenance; prozone detection, autodilution; dual compartment reaction cuvettes, air pressure mixing system and extensive washing processes; ideal for latex assays
Note: a dash in lieu of an answer means company did not answer question or question is not applicable			

Automated immunoassay analyzers

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See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	VIDAS Immunoassay Analyzer/1991/U.S. Italy/France 2,200/25,000 batch, random access/benchtop/—	PR4100 Microplate Reader/2012/Austria Austria/US 3/10 batch/benchtop/—	PhD Ix System/2012/France France/US — batch/benchtop/reagent rack
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	Vidas 30 system: 16 × 32 × 2/4.5; MiniVidas system: 21 × 21 × 17/4	—	30 × 36 × 27/16
Tests available on instrument in U.S.	procalcitonin, TSH, FT4, T4, T3, total PSA, HCG, LH, FSH, estradiol 2, prolactin, progesterone, testosterone, ferritin, D-dimer, troponin I, NT pro BNP, CKMB, C. difficile toxin A&B, measles IgG, mumps IgG, rubella IgG, varicella zoster virus IgG, LYME IgG & IgM, chlamydia & chlamydia blocking, Helicobacter pylori, toxo competition, toxo IgG, toxo IgM, toxo IgG avidity, rotavirus, CMVM, CMVG, digoxin, others	HIV, HBsAg, HBs, HAV, HAV IgM, HBc, HBc IgM, HCV, syphilis, measles, mumps, VZV, lyme, toxoplasma, ANA, SSA, SSB	open system, method file consists of autoimmune and infectious disease assays, both EIA and IFA methodologies
Tests not available in U.S. but submitted for clearance	—	—	—
Tests not available in U.S. but available in other countries	HBs Ag, anti HBs-total, anti-HBc total, anti-HBc IgM, anti-HBe, HAV IgG, anti-HAV total, HIV duo, myoglobin, others	—	—
Tests in development	vitamin D	—	—
Tests not available on other manufacturers' analyzers	all assays for use on Vidas instruments only	—	—
Fully automated microplate system	no	no	no
Number of each analyte performed in separate disposable unit	1 test per strip	—	—
Number of wells in microplate	—	96 (minimum: 1; maximum: 8)	96 (minimum: 1; maximum: 96)
Methods supported/Separation methods	fluorescence, EIA/EIA coated, solid phase receptacle pipetting device	enzyme immunoassay/coated microwell	fluorescence, enzyme immunoassay/coated microwell
No. of different measured assays onboard simultaneously	MiniVidas: 12; Vidas: 30	—	8 EIA or 4 IFA
No. of different assays programmed, calibrated at once	total menu	—	8 EIA or 4 IFA
No. of user-definable (open) channels	0	—	no limit
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	unit dose format 30 or 60/—	—	up to 8 different assays sets of components/96
Shortest/Median onboard reagent stability/Refrigerated onboard	—/—/no	—/—/no	4 hours/—/no
Multiple reagent configurations supported	no	no	yes
Reagent container placed directly on system for use	placed directly on system	—	placed directly on system
Reagents bar coded/Information in bar code	yes/assay name, lot No., calibration, expiration	—	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover	—	yes/—
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/12–30/12–30	—	—/192/8 EIA or 4 IFA
System is open (home-brew methods can be used)/Liquid or dry system	no/dry	yes/dry	yes/liquid
Uses disposable cuvettes/Maximum number stored	no/—	no/—	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—	—
Minimum specimen volume required	100–200 µL, dependent on assay	70 µL	150 µL
Minimum sample vol. aspirated precisely at once/Minimum dead volume	100 µL, dependent on assay/—	—	1 µL/150 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no	yes/no
Requires dedicated water system/Water consumption	no/—	no/—	no/—
Noise generated	—	—	—
Has dedicated pediatric sample cup/Dead volume	no/—	no/—	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/—/no	no/—/—	yes/12–13 mm diameter and 75–100 mm height/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/no	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/no	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per CLSI standard Auto2A	no	—	yes
Onboard test auto inventory (determines volume in container)	no	—	no
Measures No. of tests remaining/Short sample detection	no/no	—	no/no
Auto detection of adequate reagent or specimen	no	—	yes
Clot detection/Reflex testing capability	no/no	—	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	—	no/no
Dilution of patient samples onboard/Automatic rerun capability	no/no	—	yes/no
Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	—	no/no
Time between initial result and reaspiration of sample for rerun	—	—	—
Autocalibration or autocalibration alert	yes	—	no
Number of calibrators required for each analyte	—	—	assay dependent
Calibrants can be stored onboard/Average calibration frequency	no/14 or 28 days, assay dependent	—	no/each run
Multipoint calib. supported/Multiple calibs. stored for same assay	no/yes	—	yes/no
How often QC required	shortest interval: 8 hours, longest: 24 hours	—	each run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	—	no/no
Automatic shutdown/Startup is programmable/Startup time	no/no/always remains ready	—	no/no/<5 minutes
Stat time to completion of β-hCG test	30 minutes	—	—
Time delay from ordering stat test to aspiration of sample	no delay	—	—
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	—/Vidas: 20; MiniVidas: 8; Vidas: 60; MiniVidas: 24	—	assay dependent/—
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	—	no/no
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	—	onboard/—
LIS interfaces up and running in active user sites	Misys, Medtech, McKesson, Advanced Lab Systems, Citation, Cerner, Dawning, Geneysis, Compulab, others	—	—
LIS interface operates simultaneously with running assays	yes	—	yes
Bidirectional interface capability	yes (broadcast download)	—	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	no	—	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes	—	no/no/no
Can order (via modem) malfunctioning part(s) without operator	no	—	no
On-site response time of service engineer	within 24 hours	—	24 hours
Mean time between failures/To repair failures	Vidas: 860 days/MiniVidas: 1,200 days	—	—
Average time to complete maintenance by lab personnel	weekly: 10–15 minutes	—	daily: <5 minutes; weekly: 15 minutes; monthly: 30 minutes
Onboard maintenance records/Maintenance training demo module	yes (includes audit trail)/—	—	no/no
List price/Targeted bed size or daily volume	—	—	\$68,000/all bed sizes
Annual service contract cost (24 hours/7 days)	—	—	\$6,700
Training provided with purchase/Advanced operator training	—	—	2 days on site/no
Distinguishing features (supplied by vendor)	routine batch testing as well as emergency stat testing; ELISA methodology; dual-function combination solid phase and pipetting device results in no fluid contact with instrument or sample carryover; single-dose assay format readily adaptable to batch or single test runs	—	open platform with assay programming wizard; bi-direction LIS with broadcast download, capable of running IFA and EIA; accurate down to 1 µL, IFA hyperwash for cleaner backgrounds, precise well-to-well timing; networking capabilities for multiple workstations

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

Automated immunoassay analyzers

Part 7 of 21	Bio-Rad Laboratories Clinical Diagnostics Group Tom Williamson tom_williamson@bio-rad.com 4000 Alfred Nobel Drive, Hercules, CA 94547 510-926-5470 www.bio-rad.com	Bio-Rad Laboratories Clinical Diagnostics Group Mary Borick mary_borick@bio-rad.com 4000 Alfred Nobel Drive, Hercules, CA 94547 510-741-4791 www.bio-rad.com	Bio-Rad Laboratories Clinical Diagnostics Group Greg Stewart greg.stewart@bio-rad.com 4000 Alfred Nobel Drive, Hercules, CA 94547 510-724-7000 www.bio-rad.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	BioPlex 2200/2006/Australia Australia/U.S. 137/38 continuous random access/floor standing/rack 58 x 72 x 34/12	PhD System/2000/Belgium France/U.S. 270/685 batch/benchtop/rack 35 x 66 x 35/16	EVOLIS/2001/Germany Germany/U.S. 275/1,350 batch/benchtop/rack 37 x 44 x 30/10
Tests available on instrument in U.S.	ANA Screen, anti-dsDNA (quant.), anti-SS-A, anti-SS-B, anti-SmRNP, anti-Sm, anti-RNP, anti-Scl-70, anti-Jo-1, anti-centromere B, anti-chromatin, anti-ribosomal P, EBV-nuclear antigen IgG, EBV-viral capsid antigen IgG, EBV-early antigen diffuse IgG, EBV-viral capsid antigen IgM, heterophile antibodies, anti-GBM IgG, anti-MPO IgG, anti-PR3 IgG, syphilis IgG, toxoplasma gondii IgG, others	autoimmune and infectious disease	—
Tests not available in U.S. but submitted for clearance	—	—	—
Tests not available in U.S. but available in other countries	—	—	HIV Ab, HIV Ab/Ag, HIV Ag, HBsAg, HBe Ab, HCV Ab, HTLV-1, anti-HBs, toxo IgG, toxo IgM, rubella IgG, EBV VCA IgG, EBV VCA IgM, EBV EAD, EBV EBNA, others
Tests in development	gastrointestinal disease, vitamin D, lyme, HIV, hepatitis	—	infectious disease and autoimmune panels
Tests not available on other manufacturers' analyzers	heterophile antibodies	—	—
Fully automated microplate system	no	no	yes
Number of each analyte performed in separate disposable unit	—	—	—
Number of wells in microplate	—	minimum strip: 1; maximum full plate: 96	minimum strip: 1; maximum full plate: 96
Methods supported/Separation methods	bead flow cytometric (multiplex)/magnetic particle	EIA and IFA/coated microwell or slide	EIA/coated microwell
No. of different measured assays onboard simultaneously	440	8 EIA or 4 IFA	4-8
No. of different assays programmed, calibrated at once	440	8 EIA or 4 IFA	4-8
No. of user-definable (open) channels	—	no limit	contact Bio-Rad representative
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	440/100	8/192	4/96
Shortest/Median onboard reagent stability/Refrigerated onboard	720 hours/30 days/yes (2°-8°C)	4 hours/—/no	30 minutes/assay dependent/—
Multiple reagent configurations supported	no	no	yes
Reagent container placed directly on system for use	yes	requires operator prehandling/preparation	yes
Reagents bar coded/Information in bar code	yes/kit type, lot number, kit serial number	no/—	yes/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/2 ppm	yes/—	no/no (disposable tips)
Walkaway capacity in minutes/Specimens/Tests-assays	480 minutes/280/17,600	—/192/—	varies by assay/180/4
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	yes/liquid	no/liquid
Uses disposable cuvettes/Maximum number stored	yes/800	no/—	microplates/—
Uses washable cuvettes/Replacement frequency	no/—	no/—	microplates/—
Minimum specimen volume required	5 µL	1 µL specimen	0.2 µL
Minimum sample vol. aspirated precisely at once/Minimum dead volume	5 µL/70 µL	1 µL/150 µL	10 µL/200 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/no
Requires dedicated water system/Water consumption	no/0.5 L per hour	no/—	no/—
Noise generated	<67 decibels	—	60 decibels
Has dedicated pediatric sample cup/Dead volume	no/—	no/—	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10-16 mm diameter, 41-100 mm height/no	yes/micro-100 mm height/no	yes/up to 16 mm diameter, up to 100 mm height/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/no	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/no
Bar-code placement per CLSI standard Auto2A	yes	yes	no
Onboard test auto inventory (determines volume in container)	yes	no	yes
Measures No. of tests remaining/Short sample detection	yes/yes	no/no	no/no
Auto detection of adequate reagent or specimen	yes	yes	no
Clot detection/Reflex testing capability	yes/yes	no/no	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no	yes/no
Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	—	no/no	no/no
Time between initial result and reaspiration of sample for rerun	—	—	—
Autocalibration or autocalibration alert	yes	no	no
Number of calibrators required for each analyte	assay dependent	1-5	assay dependent
Calibrants can be stored onboard/Average calibration frequency	no/30 days	no/each run	no/with each run
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/no	yes/no
How often QC required	24 hours	each run	user determined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	no/no	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/yes/10 minutes	no/no/5 minutes	no/no/5 minutes
Stat time to completion of β-hCG test	—	—	—
Time delay from ordering stat test to aspiration of sample	—	—	—
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	100/100/36 seconds	—	assay dependent/—
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	no/no	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/no	onboard/no	onboard/yes
LIS interfaces up and running in active user sites	Misys/Sunquest, CSI, Data Innovations, Meditech, Cerner Classic/Millennium, Rubicon, Soft	—	available
LIS interface operates simultaneously with running assays	yes	yes	yes
Bidirectional interface capability	yes	yes	yes (broadcast download)
Interface available (or will be) to auto specimen handling system	no	no	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	no/no/no	yes/no/no
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	—	<24 hours	24 hours
Mean time between failures/To repair failures	—	12 months/3.5 hours	—
Average time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 30 minutes	daily: 5 minutes; weekly: 15 minutes; monthly: 30 minutes	daily: 5 minutes; monthly: 60 minutes
Onboard maintenance records/Maintenance training demo module	yes/no	no/no	yes/no
List price/Targeted bed size or daily volume	\$385,000/200 samples per day	\$60,000/>10-200 samples	\$85,000/30-500 tests per day
Annual service contract cost (24 hours/7 days)	—	\$6,300	inquire
Training provided with purchase/Advanced operator training	5 days at Bio-Rad/no	2 days on site/no	5 days in Redmond, WA/no
Distinguishing features (supplied by vendor)	full random access automation; three internal quality control beads run simultaneously with each sample; innovative multiplex chemistry	accurate pipetting at 1 µL; connection of one to 10 pipetting stations together through an ethernet hub, graphical user interface; added module for IFA slide processing	fully automated microplate system that meets a high level of safety (positive identification of samples, reagents, microplates, clot detection, no contamination), flexibility (reagents and microplates) and productivity (four to six plates, up to 180 specimens, four to eight different assays can be processed simultaneously)

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Automated immunoassay analyzers

Part 8 of 21	Diamedix Corp., a subsidiary of IVAX Diagnostics Amanda Schrandt amanda_schrandt@ivaxdiagnostics.com 2140 North Miami Avenue, Miami, FL 33127 305-324-2300 www.diamedix.com	Diamedix Corp., a subsidiary of IVAX Diagnostics Amanda Schrandt amanda_schrandt@ivaxdiagnostics.com 2140 North Miami Avenue, Miami, FL 33127 305-324-2300 www.diamedix.com	DiaSorin Inc. Brian Lauber brian.lauber@diasorin.com 1951 Northwestern Ave., Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	MAGO 4S/2011/Italy Italy/U.S. — batch, random access/benchtop/rack	Mago Plus Automated EIA Processor/1997/Italy Italy/U.S. 250/— batch, random access/benchtop/rack	LIAISON XL/2010/Italy Germany/Italy, Germany, U.S. — batch, random access, continuous random access/floor standing/rack
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	28 × 48 × 26/8.7	28 × 48 × 26/8.7	59 × 59 × 36/2,100 square inches
Tests available on instrument in U.S.	>50 Diamedix and 22 additional ELISA analytes plus 67 IFA kits	autoimmune: ANA ELISA screen, ENA-6 screen, SSA, SSB, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, β2 glycoprotein IgG/IgM, cardiolipin screen/IgA/IgG/IgM, gliadin IgA/IgG, MPO, PR3, TPO, TG, RF; infectious disease: toxoplasma IgG/IgM, rubella IgG/IgM, CMV IgG/IgM, B burgdorferi IgG/IgM, EBV VCA IgG/IgM, EBNA IgG/IgM, EBV-EA IgG/IgM, HSV 1&2 IgG/IgM, H. pylori IgG, measles IgG, mumps IgG, others	25 hydroxyvitamin D TOTAL, treponema IgG/IgM, anti-HAV total, measles IgG, mumps IgG
Tests not available in U.S. but submitted for clearance	—	—	—
Tests not available in U.S. but available in other countries	—	—	N_TACT II, PTH 1-84, HCV, HIV, HBsAg, Ca 125, Ca 15-3, Ca19-9, TPA-M, AFP, CEA, PSA, fPSA, S100, NSE, fT4, fT3, TSH, many others
Tests in development	—	—	toxo-Av, HGH, testosterone
Tests not available on other manufacturers' analyzers	process ELISA and IFA slide preparation simultaneously	—	B. borrelia
Fully automated microplate system	yes	yes	no
Number of each analyte performed in separate disposable unit	one analyte per well (or multiple, test dependent)	1 analyte per well	—
Number of wells in microplate	4 × 96 wells, up to 16 slides per run (minimum strip: 8; full plate: 12 strips)	minimum 1 × 8 wells; maximum 96 wells; can run four plates at a time	—
Methods supported/Separation methods	enzyme immunoassay, sample titrations and slides simultaneously with ELISA processing/coated microwell, coated tissue, cell slide	EIA/coated microwell	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	unlimited	up to 9 (analyte dependent)	25
No. of different assays programmed, calibrated at once	up to 20 (analyte dependent)	~50 preprogrammed assays	25
No. of user-definable (open) channels	20 active at a time, unlimited saved on hard drive	20 per diskette, unlimited diskette capability	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	20 (analyte dependent)/96	9/96	25/25–200 (mostly 100)
Shortest/Median onboard reagent stability/Refrigerated onboard	8 hours/1 day/no	—/—/no	168 hours/28 days/yes (12°)
Multiple reagent configurations supported	yes	yes	no
Reagent container placed directly on system for use	yes	yes	yes
Reagents bar coded/Information in bar code	yes/lot number, expiration date	yes/lot number, expiration date	yes/quantity, stability, lot number, and more
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/no, with Diamedix reagents	no/not susceptible, continuous cleaning	no/<20 ppm
Walkaway capacity in minutes/Specimens/Tests—assays	2.5 hours (analyte dependent)/120/384 (ca.12)	up to 2.5 hours—assay dependent/120/384	360/120/3,000
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	yes/liquid	no/liquid
Uses disposable cuvettes/Maximum number stored	yes/120	yes/120	yes/1,000
Uses washable cuvettes/Replacement frequency	no/—	no/—	no/—
Minimum specimen volume required	50 µL (pediatric)	50 µL (pediatric)	assay dependent
Minimum sample vol. aspirated precisely at once/Minimum dead volume	4 µL/35 µL	4 µL/25 µL (pediatric)	5 µL/150 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/—
Requires dedicated water system/Water consumption	no/—	no/—	no/—
Noise generated	—	not significant	—
Has dedicated pediatric sample cup/Dead volume	yes/35 µL	yes/35 µL	yes/50 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/11–15 mm × 75–100 mm/no	yes/11–15 mm × 75–100 mm/no	yes/10–16 mm diameter/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/no	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per CLSI standard Auto2A	no	—	yes
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	no/no	no/no	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no	yes/yes
Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	no/no	no/no
Time between initial result and reaspiration of sample for rerun	—	—	2 minutes
Autocalibration or autocalibration alert	yes	reader calibrated every run	no
Number of calibrators required for each analyte	1–6 (analyte dependent)	assay dependent, 2–6	2
Calibrants can be stored onboard/Average calibration frequency	yes/per run	no/per run	yes/1–4 weeks
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/no	yes/yes
How often QC required	each run	per run	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/—	yes/no	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/5 minutes	yes/yes/<5 minutes	yes/no/8 minutes
Stat time to completion of β-hCG test	—	—	17
Time delay from ordering stat test to aspiration of sample	—	—	2 minutes
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	120/360 (2.5 hours)	120/360 (2.5 hours—assay dependent)	57/171 (21 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes	onboard/yes (included in price)	onboard/no
LIS interfaces up and running in active user sites	Cerner, Misys, others	Cerner, Misys, others	—
LIS interface operates simultaneously with running assays	yes	yes	yes
Bidirectional interface capability	yes (host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	no	no	yes (Inpeco)
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/no/no	no/no/no	yes/yes/yes
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	normal business hours within 24–48 hours	24 hours	24 hours
Mean time between failures/To repair failures	5 months/3–6 hours	5 months/<1 day	—
Average time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 10 minutes	daily: <5 minutes; weekly: <10 minutes	weekly: 10 minutes; monthly: 10 minutes
Onboard maintenance records/Maintenance training demo module	no/no	no/no	yes/no
List price/Targeted bed size or daily volume	\$72,000 (includes first-year warranty)/30–300	\$62,000/all bed sizes, all test volumes	\$250,000/>400 beds
Annual service contract cost (24 hours/7 days)	included in rental agreement (otherwise \$8,500 per year)	service during normal business hours included in reagent rental agreement	—
Training provided with purchase/Advanced operator training	2–3 days on site/yes	1–2 days on site/yes	yes/yes
Distinguishing features (supplied by vendor)	simultaneous ELISA/IFA processing; performs serial two-fold dilutions onboard; pre-assay, full-strip, plate/reagent/sample volume check; automated system maintenance before and after each run; Ivax Diagnostics controls the manufacture of raw materials, ELISA reagents, and instrumentation	FDA-cleared (instruments and reagents); moderate complexity; strip-by-strip timing, accommodates primary reagent packaging; safeguards against insufficient reagent/sample volume; functions dependably (mean time between failures greater than five months)	secure traceability of all processes, status of reagents, and consumables; disposable pipette tips prevent sample carryover; clot detection, aspiration, and dispensation verification; single-cavity reaction cuvettes; no daily maintenance; instrument monitors maintenance needs; flash chemiluminescence technology with paramagnetic microparticle solid phase

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

Automated immunoassay analyzers

Part 9 of 21	DiaSorin Inc. Lance Schlenker lance.schlenker@diasorin.com 1951 Northwestern Avenue, Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com	DiaSorin Inc. Brian Lauber brian.lauber@diasorin.com 1951 Northwestern Avenue, Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com	Dynex Technologies, Inc. Michael Rashed mrashed@dynextechnologies.com 14340 Sullyfield Circle, Chantilly, VA 20151 703-631-7800 www.dynextechnologies.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	ETI-MAX 3000/2002/Germany Germany/U.S., Italy 160/972 batch, random access/benchttop/rack	LIAISON/1997/Germany Germany/U.S., Italy >500/>4,000 batch, continuous random access/benchttop/rack	Agility/2012/U.S., U.K. U.S./various — batch/benchttop/rack
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	40 × 45 × 30/10	45 × 96 × 34/10	48 × 48 × 36/8.6
Tests available on instrument in U.S.	EBNA-IgG, VCA-IgG, VCA-IgM reverse capture, measles IgG, varicella zoster IgG, mumps IgG, H. pylori IgG, HSV I/II IgG, Trep-Sure syphilis, CMV IgG & IgM capture, rubella IgG, toxoplasma IgG & IgM capture, ANA screen, ENA 6 screen, anti-dsDNA, anti-Sm, anti-Sm/RNP, anti-SS-A, anti-SS-B, anti-Jo-1, anti-Scl-70, anti-MPO, anti-PR3 (cANCA), anti-TPO, anti-cardiolipin, IgG, IgM, others	25 hydroxyvitamin D total, intact PTH, EBV IgM, EBNA IgG, VCA IgG, EA IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM, treponema IgG/IgM, VZV IgG, hGH, Borrelia burgdorferi, HAV IgM, HAV total antibodies, rubella IgG, HSV-1 type specific IgG, HSV-2 type specific IgG, insulin, measles IgG, mumps IgG	open system, tests provided by various manufacturers
Tests not available in U.S. but submitted for clearance	—	—	—
Tests not available in U.S. but available in other countries	—	avidity, HSV I/II IgM, HSV I/II IgG, HCG, β-2-microglobulin, prolactin, LH, FSH, S-100, AFP, HCG, ferritin, TSH, FT ₃ , FT ₄ , T ₃ , T ₄ , anti-TG, TG, anti-TPO, rubella IgM, many others	—
Tests in development	—	—	—
Tests not available on other manufacturers' analyzers	—	Borrelia burgdorferi	—
Fully automated microplate system	yes	no	yes
Number of each analyte performed in separate disposable unit	—	—	1 per well
Number of wells in microplate	minimum strip: 1, 8 wells; maximum full plate: 96 wells, can accommodate up to 7 plates at a time	—	96, 1 minimum strip
Methods supported/Separation methods	EIA/coated microplate	chemiluminescence/magnetic particle	enzyme immunoassay/coated microplate wells
No. of different measured assays onboard simultaneously	open	15	15
No. of different assays programmed, calibrated at once	open	15	12
No. of user-definable (open) channels	0	0	unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	volume dependent/—	15/100	15/96
Shortest/Median onboard reagent stability/Refrigerated onboard	no/no/no	7/28 days/yes (12°C)	—/—/no
Multiple reagent configurations supported	yes	no	yes
Reagent container placed directly on system for use	yes	yes	yes
Reagents bar coded/Information in bar code	yes/—	yes/all lot information	yes/lot information
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/no	no/no	yes/disposable tip
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/180/variable	360/144/1,500	assay dependent/200+ continuous load/12+ continuous load
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid	yes/liquid
Uses disposable cuvettes/Maximum number stored	no/—	yes/720	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—	no/—
Minimum specimen volume required	10 µL	assay dependent	10 µL
Minimum sample vol. aspirated precisely at once/Minimum dead volume	10 µL/200 µL	5 µL/150 µL	10 µL/150 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/no
Requires dedicated water system/Water consumption	no/no	no/—	no/—
Noise generated	—	—	—
Has dedicated pediatric sample cup/Dead volume	no/—	no/75 µL	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/multiple/no	yes/—/no	yes/10–17 mm diameter, 45–100 mm depth/no
Sample bar-code reading capability/Autodiscrimination	yes/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per CLSI standard Auto2A	yes	yes	—
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	yes/no	yes/yes	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/yes	yes/no
Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	no/no	no/no
Time between initial result and reaspiration of sample for rerun	—	2 minutes	—
Autocalibration or autocalibration alert	no	no	no
Number of calibrators required for each analyte	varies per kit	2	test kit dependent
Calibrants can be stored onboard/Average calibration frequency	no/each run	yes/28 days	no/per plate
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/no	no/no
How often QC required	per run	24 hours	per plate
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	no/yes	no/no
Automatic shutdown/Startup is programmable/Startup time	no/yes/5 minutes	no/no/15 minutes	no/no/3–5 minutes
Stat time to completion of β-hCG test	—	—	—
Time delay from ordering stat test to aspiration of sample	—	2 minutes	—
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	assay dependent/—	—	microplate batch process/microplate batch process
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	yes/yes	yes/yes (additional)	onboard/yes
LIS interfaces up and running in active user sites	yes	Cerner, Soft, others	—
LIS interface operates simultaneously with running assays	yes	yes	yes
Bidirectional interface capability	yes	yes (host query)	yes (host query and broadcast download)
Interface available (or will be) to auto specimen handling system	no	no	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/no/no	no/no/no	yes/yes/yes
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	24 hours	24 hours	24 hours
Mean time between failures/To repair failures	—	—	—
Average time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 30 minutes	daily: 10 minutes; weekly: 20 minutes; monthly: 30 minutes	daily: <15 minutes; weekly: <30 minutes; monthly: <1 hour
Onboard maintenance records/Maintenance training demo module	yes/no	no/no	yes/no
List price/Targeted bed size or daily volume	\$91,500 (includes first year of service)/all bed sizes, all test volumes	\$176,000 (includes first year of service)/all bed sizes, all volumes	—/various
Annual service contract cost (24 hours/7 days)	\$10,500	—	varies, multiple types available
Training provided with purchase/Advanced operator training	3 days/yes	3 days on site/yes	—/yes
Distinguishing features (supplied by vendor)	multiple assays on a plate; Windows 2000 software; continuous loading of samples, reagents, and microplates; primary tube sampling; bi-directional interface	fully automated benchtop analyzer with high throughput; unique menu; up to 15 assays onboard with ready-to-use, reagent-integral, random-access, batch and stat operation	reduces hands-on time by more than 60 percent for ELISA testing; tracks all assays, test kits, consumables, reagents, and waste so test menu can run without interruption

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

Automated immunoassay analyzers

Part 10 of 21	Dynex Technologies Michael Rashed mrasheed@dynextechnologies.com 14340 Sullyfield Circle, Chantilly, VA 20151 703-631-7800 www.dynextechnologies.com	Dynex Technologies Michael Rashed mrasheed@dynextechnologies.com 14340 Sullyfield Circle, Chantilly, VA 20151 703-631-7800 www.dynextechnologies.com	Grifols USA, LLC Timothy Wigginton tim.wigginton@grifols.com 2410 Lillyvale Avenue, Los Angeles, CA 90032 323-227-7037 www.grifols.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed	DS2/2005/US	DSX/2001/US	Triturus/1999/Spain
Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	US/worldwide 500/600 batch/benchtop/rack	US/worldwide 1,100/1,500 batch/—/—	Spain/Spain, U.S., Italy >200/>1,700 batch, random access and continuous random access/ benchtop/universal carousel
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	27 × 21 × 26/3.79	32 × 42 × 36/7	28.3 × 41.3 × 34.3/10
Tests available on instrument in U.S.	any ELISA test	ELISA plate tests	system is completely open; any U.S. clinically cleared and research-use-only EIA procedure can be programmed; infectious diseases, autoimmune diseases, bone markers, endocrinology, hemostasis, oncology markers, hepatitis, and HIV profiles
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	open system open system	open system open system	— —
Tests in development	open system	open system	—
Tests not available on other manufacturers' analyzers	none (open system)	none (open system)	—
Fully automated microplate system	yes	yes	yes
Number of each analyte performed in separate disposable unit	1 per well	1 per well	8
Number of wells in microplate	96 (minimum: 1 strip; maximum: 2 full plates)	96 (minimum: 1 strip; maximum: 4 full plates)	96, 1 minimum strip, 4 maximum full plate
Methods supported/Separation methods	enzyme immunoassay/coated microwell	enzyme immunoassay/coated microwell	EIA, EIA-coated microwell plates, onboard shaker, four individually temperature-controlled microplate positions/coated microwell
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum specimen volume required Minimum sample vol. aspirated precisely at once/Minimum dead volume Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead volume Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result and reaspiration of sample for rerun Autocalibration or autocalibration alert Number of calibrators required for each analyte Calibrants can be stored onboard/Average calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	assay dependent (24 control positions) assay dependent (24 control positions) unlimited assay dependent (18 reagent positions)/96 —/—/no yes yes, 2 mL control vials (other reagents are pour off) no/— yes/none (uses disposable tips) assay dependent/100/assay dependent open/liquid no/— no/— — 10 µL/— no/no no/— — no/— yes/10–16 mm diameter; 40–100 mm height/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/— — yes yes/yes yes yes/no — yes/no no/no — no assay dependent no/— — — — — no/no/—	assay dependent (33 control positions) assay dependent (33 control positions) unlimited assay dependent (24 reagent positions)/96 —/—/no yes yes (when using custom racks) yes/lot information when used with custom racks yes/none (uses disposable tips) assay dependent/assay dependent/4+ open/liquid no/— no/— — 10 µL/— no/no no/— — no/— yes/12–16 mm diameter; 55–100 mm height/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/— — yes yes/yes yes yes/— — yes/no no/no — no — — — no/no no/no/—	1–8 tests on 1–4 plates 8 — 8/48 —/—/no yes minimal operator preparation, handling no yes/no 180/92/8 yes/liquid no/— no/— 300 µL 2 µL/200 µL yes/no no/— has external waste port to drain into sink or floor drain no/— yes/12, 13, 16 mm/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes no/no yes/no no/no — yes 1–14 no/check every month yes/yes each run yes/no yes/yes/1–2 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspiration of sample Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface LIS interfaces up and running in active user sites LIS interface operates simultaneously with running assays Bidirectional interface capability Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) without operator On-site response time of service engineer Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	— — — yes/yes onboard/yes (additional cost) — — yes (host query and broadcast download) — no/yes/yes no 24 hours — daily: 5 minutes; weekly: 5 minutes; monthly: 15 minutes no/no	— — — yes/yes onboard/yes (additional cost) — — yes (host query and broadcast download) — no/—/— — 24 hours — daily: 5 minutes; weekly: 5 minutes; monthly: 15 minutes —	system is open, depends on reagent methodology — dependent on reagent methodology/— yes/yes yes, onboard/no CHCS, Softmax, Sunquest yes yes (host query and broadcast download) no yes/yes/yes no within 24 hours — daily: 5–20 minutes yes (includes audit trail of who replaced parts)/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided with purchase/Advanced operator training	— varies, multiple types available —/yes	— varies, multiple types available —/yes	\$79,000/300+ varies, multiple types available —/yes
Distinguishing features (supplied by vendor)	washer synchronization, eliminates plate drift; disposable tips; small footprint	washer synchronization, eliminates plate drift; modular design; disposable tips	multi-batch or continuous throughput EIA analyzer; user-defined menu, completely open system; easy color-coded worksheet and setup for operator; two probes for high-speed processing; unique cross-well washing; can use fixed probes or disposable tips

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

Automated immunoassay analyzers

Part 11 of 21	Hycor Biomedical Inc. Rich Connors rconnors@hycorbiomedical.com 3021 East 98th Street, Suite 220, Indianapolis, IN 46280 317-454-8285 www.hycorbiomedical.com	Immunodiagnostic Systems Inc. (IDS Inc.) Peter Bambic peter.bambic@idsplc.com 8425 N. 90th Street, Suite 8, Scottsdale, AZ 85258 480-278-8333 www.idsplc.com	Inova Diagnostics David Moore dmoore@inovadx.com 9900 Old Grove Road, San Diego, CA 92131 800-545-9495 www.inovadx.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed	HYTEC 288 PLUS/outside U.S. 1998, U.S. 1999/ Netherlands	IDS-iSYS/2009/France	BIO-FLASH/2011/Spain
Country where manufactured/Where reagents manufactured	Netherlands/U.S., Scotland	France/Belgium	U.S./U.S.
No. of units in clinical use in U.S./Outside U.S.	85/200	>200 worldwide	0/15
Operational type/Model type/Sample handling system	random batches/benchtop/rack-robotics	continuous random access/benchtop/sample loading rack	continuous random access/benchtop/racks
Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	29.5 x 42.5 x 27.5/8	28 x 42 x 30/~6	21 x 34 x 24/6
Tests available on instrument in U.S.	total/specific IgE, ANA scr, TG, TPO, dsDNA, RF IgG, RF IgM, RF IgA, PR-3 (c-ANCA), MPO (p-ANCA), anti-mitochondrial, ENA-6 Scr., SS-A, SS-B, Sm, Sm/RNP, Scl-70, Jo-1, gliadin IgA & IgG, GBM, GPC, anti-cardiolipin IgG & IgM, anti-cardiolipin scr., β -2 BPI IgG, IgA & IgM, user-defined channels	25-hydroxy vitamin D, IGF-I, hGH, IGFBP-3, CTX-I, intact PTH, PTH (1-34)*	tTG IgA, tTG IgG, aCL IgG, aCL IgM, DGP screen
Tests not available in U.S. but submitted for clearance	—	intact PINP	DGP IgA, DGP IgG, MPO, PR3, GBM, B2GP1 IgA, aCL IgA
Tests not available in U.S. but available in other countries	specific IgG, ssDNA, total RF, anti-tissue transglutaminase IgA and IgG, circulating immune complex -C1q and -C3d; infectious diseases: H. pylori, EBV, HSV, VZ, C. albicans, adenovirus, RSV, b. Pertussis, Flu A/B, parainfluenza, M. pneumoniae, MTB, many others	N-MID osteocalcin, BAP, 1,25-dihydroxy vitamin D, direct renin, aldosterone	SS-B, Jo-1, Scl -70, Sm, RNP, Ro52, Ro60, ENA7, centromere
Tests in development	ANCA profile, centromere, CCP, eosinophil cationic protein, trypsinase	bone trap (TRAcP 5b), ACTH	CCP3.1, ANA Screen, dsDNA, Ribo P, B2Gp1-Domain 1, DFS70
Tests not available on other manufacturers' analyzers	—	—	—
Fully automated microplate system	yes	no	no
Number of each analyte performed in separate disposable unit	8 (1 analyte per well; multiple analytes per well/screens; up to 8 analytes per run)	—	—
Number of wells in microplate	96—minimum strip: 1 strip/8 wells; maximum full plate: 12 strips/96 wells	—	—
Methods supported/Separation methods	EIA, tube-based and microplate-based assays/activated cellulose and coated well	chemiluminescent and spectrophotometric/magnetic particles	chemiluminescence/magnetic particle, bead
No. of different measured assays onboard simultaneously	varies by assay, up to 288 allergens or 8 autoimmune	15	20
No. of different assays programmed, calibrated at once	multiple	15	50
No. of user-definable (open) channels	3	0	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	varies by assay/up to 288 allergens or 8 autoimmune	15/100	20/50 test kits
Shortest/Median onboard reagent stability/Refrigerated onboard	8 hours/12 hours/no	48 hours/7 days/yes (8°–10°C)	480 hours/40 days/yes (6°–8°C)
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	yes	yes, assay dependent	yes
Reagents bar coded/Information in bar code	no/—	yes/lot key, No. within lot	yes/type, No. of tests, lot number, expiration date, master calibration curve
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/<1 part in 10,000	no/—	no/—
Walkaway capacity in minutes/Specimens/Tests-assays	yes dependent/100/288	assay dependent/120/—	—/30/20
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	closed/liquid	closed/liquid
Uses disposable cuvettes/Maximum number stored	no/—	yes/960	yes/280
Uses washable cuvettes/Replacement frequency	no/—	no/—	no/—
Minimum specimen volume required	10 μ L, 110 μ L with dead volume	6 μ L (assay dependent)	10 μ L
Minimum sample vol. aspirated precisely at once/Minimum dead volume	10 μ L–50 μ L, assay dependent/100 μ L	4 μ L/tube dependent ~80 μ L	10 μ L/50 μ L
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/no
Requires dedicated water system/Water consumption	no/—	no/no	no/—
Noise generated	—	—	—
Has dedicated pediatric sample cup/Dead volume	no/—	yes/80 μ L	yes/50 μ L
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/—/no	yes/all up to 16 x 100 mm/no	yes/12–16 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/—	yes (2 of 5 interleaved, codes 39 and 128)/yes	yes (2 of 5 interleaved, codes 39 and 128)/yes
Bar-code placement per CLSI standard Auto2A	no	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	no/no	yes/no	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	assay dependent/no	yes/yes
Sample volume can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	no/no	no/yes
Time between initial result and reaspiration of sample for rerun	—	—	30 minutes
Autocalibration or autocalibration alert	yes	yes	yes
Number of calibrators required for each analyte	1–6	2	2
Calibrants can be stored onboard/Average calibration frequency	no/monthly	no/test dependent ~7 days	no/lot change or failure of controls
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes	yes/yes
How often QC required	every assay	daily	daily
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/no/2–3 minutes	yes/yes/10 minutes	yes/yes/<10 minutes
Stat time to completion of β -hCG test	—	—	—
Time delay from ordering stat test to aspiration of sample	—	<1 minute (assay dependent)	less than 5 minutes
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	—	—	20/60 (30 minutes)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/optional	onboard/no, additional cost	onboard/yes, included
LIS interfaces up and running in active user sites	25	yes	—
LIS interface operates simultaneously with running assays	no	yes	yes
Bidirectional interface capability	yes	yes (host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	no	yes	yes
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/no	yes/yes/no	yes/yes/no
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	48 hours	24–48 hours	24 hours
Mean time between failures/To repair failures	7 months/4 hours	264 days/—	—
Average time to complete maintenance by lab personnel	daily: 10–15 minutes; weekly: 20–25 minutes; monthly: 20–25 minutes	daily: 5 minutes; weekly: 10 minutes; monthly: 10 minutes	weekly: 5 minutes; monthly: 15 minutes
Onboard maintenance records/Maintenance training demo module	yes (includes audit trail of who replaced parts)/yes	yes, includes audit trail/no	no/no
List price/Targeted bed size or daily volume	\$55,000/all sites, variable test volumes	—	—/100–500
Annual service contract cost (24 hours/7 days)	various based on package chosen	—	—
Training provided with purchase/Advanced operator training	3 days on site/yes	yes/yes	—/yes
Distinguishing features (supplied by vendor)	fully automated allergy and autoimmune testing; user-defined software channels for microtiter plate and tube-based assays	full, walkaway automation; compact, benchtop design; continuous loading with batch, random, and stat flexibility; auto start-up and shut-down; onboard refrigeration of ready-to-use reagent cartridges	random access, continuous load, chemiluminescent; benchtop footprint completing up to 450 results per shift; onboard reagents with stable calibration curves to eliminate batching and improve turnaround time

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

Automated immunoassay analyzers

Part 12 of 21 <i>See captodayonline.com/productguides for an interactive version of guide</i>	Inova Diagnostics David Moore dmoore@inovadx.com 9900 Old Grove Road, San Diego, CA 92131 800-545-9495 www.inovadx.com	Inova Diagnostics David Moore dmoore@inovadx.com 9900 Old Grove Road, San Diego, CA 92131 800-545-9495 www.inovadx.com	Inova Diagnostics Ed Bass ebass@inovadx.com 9900 Old Grove Road, San Diego, CA 92131 800-545-9495 www.inovadx.com
Name of instrument/First year sold/Where designed	DS2/2006/U.S.	DSX/2000/Guernsey, U.K.	Quanta Lyser 240/2008/Switzerland, Italy
Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	U.S./U.S., U.K. —/— batch, with continuous load/benchtop/rack	U.S./U.K. 300/>500 batch/benchtop/rack	Switzerland/U.S. 135/171 batch/benchtop/racks
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	30 × 17 × 26/3.07	32 × 42 × 36/7	36 × 47 × 32/10.5
Tests available on instrument in U.S.	autoimmune, infectious disease	autoimmune, infectious disease	open system, autoimmune, infectious disease
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	— open system—ELISA	— open system—any ELISA	— —
Tests in development	—	—	—
Tests not available on other manufacturers' analyzers	open system	open system	open system
Fully automated microplate system Number of each analyte performed in separate disposable unit	yes —	yes —	yes —
Number of wells in microplate	minimum strip 1 × 8; maximum full plate: 96 wells × 2 plates	minimum strip: 1 × 8; maximum full plate: 96 × 4 plates	96
Methods supported/Separation methods	EIA/coated microwell	EIA/coated microwell	enzyme EIA/coated microwell, IFA slides
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code	12 assays per plate unlimited unlimited 8/96 24 hours/—/no yes yes yes/yes	12 assays per plate unlimited unlimited 25/96 per 4 plates 24 hours/—/no yes requires operator prehandling/preparation yes/yes	12–22 — open system EIA/IFA —/—/no yes requires prehandling —
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum specimen volume required Minimum sample vol. aspirated precisely at once/Minimum dead volume Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead volume Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result and reaspiration of sample for rerun Autocalibration or autocalibration alert Number of calibrators required for each analyte Calibrants can be stored onboard/Average calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	—/0 with disposable tips assay dependent/98/assay dependent yes/liquid no/— no/— 200 µL 5 µL/200 µL (50 µL with microtubes) yes/— no — yes/50 µL yes/—/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes no no/yes yes yes/no no/no yes/no no/no — no varies yes/each assay yes/no each assay yes/no no/yes/1–2 minutes	yes/0 assay dependent/92/assay dependent yes/liquid no/— no/— 200 µL 5 µL/200 µL (50 µL with microtubes) yes/no no — yes/50 µL yes/various/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/— yes no no/yes yes yes/no no/no yes/no no/no — no assay specific yes/once per analyte per plate yes/yes per plate yes/no yes/—/1–2 minutes	—/<10 assay dependent/up to 240/9 quantitative, 21 qualitative yes/liquid no/— no/— 200 µL 5 µL/200 µL yes/no no/— — no/— yes/10 to 16 mm/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes — no no/yes no yes/no — yes/no — no assay dependent no/per run yes/no per run no/yes no/no/2 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspiration of sample Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface LIS interfaces up and running in active user sites	— — assay dependent/— —/yes onboard/yes (additional cost) —	— — assay dependent/— yes/yes onboard/yes (additional) Cerner Classic and Millennium, Misys, SoftComp, Live Link, Triple G, FCC, ACA, LCW, LabLink	— — — yes/yes onboard/yes (additional cost) Cerner Classic and Millennium, Misys, SoftComp
LIS interface operates simultaneously with running assays Bidirectional interface capability Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) without operator On-site response time of service engineer Mean time between failures/To repair failures Average time to complete maintenance by lab personnel	yes yes (host query) no no/no/no no — —/ <24 hours daily: 5 minutes	yes yes (host query) no no/yes/yes no within 24 hours —/ <24 hours daily: 5 minutes	yes yes (host query) no no/no/no no 24 hours 8-9 months/less than 2 hours daily: 5 minutes; weekly: 10 minutes monthly: 10 minutes
Onboard maintenance records/Maintenance training demo module	yes/no	no/no	no/—
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided with purchase/Advanced operator training	— — 8 days on site/yes	—/200+ beds — 8 days on site, 2 days at vendor offices/yes	—/500 tests/day — yes (2 days on site)/yes
Distinguishing features (supplied by vendor)	graphical interface with drag-and-drop icons; large sample throughput, with 98 samples and continuous load feature; consumable status window shows location and volume requirements during loading	fully open, true four-plate system; modular design of reader, washer, incubators; bar-code reader and ambient drawer enables easy upgrades and express shipping of replacement modules, reducing downtime; software can be configured for learned error recovery	fast processing time; low operating costs due to elimination of disposable tips; completely open high-throughput batch analyzer; reads IFA barcodes
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Automated immunoassay analyzers

<p>Part 13 of 21</p> <p><i>See captodayonline.com/productguides for an interactive version of guide</i></p>	<p>Inova Diagnostics Ed Bass ebass@inovadx.com 9900 Old Grove Road, San Diego, CA 92131 800-545-9495 www.inovadx.com</p>	<p>Ortho Clinical Diagnostics, Inc. Mark Steelman msteelma@its.jnj.com 100 Indigo Creek Drive, Rochester, NY 14626 585-453-3420 www.orthoclinical.com</p>	<p>Ortho Clinical Diagnostics, Inc. Mark Steelman msteelma@its.jnj.com 100 Indigo Creek Drive, Rochester, NY 14626 585-453-3420 www.orthoclinical.com</p>
<p>Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system</p>	<p>Quanta Lyser 2/2008/— Switzerland/U.S. 5/72 batch/benchttop/racks</p>	<p>VITROS Eci Immunodiagnostic System/1997/U.S. U.S./U.K. >3,100 worldwide cont. random access/floor-standing/universal sample trays (circular) accommodate primary and secondary containers without need for adapters 51 × 44 × 29/8.9</p>	<p>VITROS 3600 Immunodiagnostic System/2009/U.S. U.S./UK >400 worldwide continuous random access/floor-standing/universal sample trays (circular) accommodate primary and secondary containers without need for adapters 68 × 83.5 × 34.9/20.2</p>
<p>Dimensions in inches (H × W × D)/Instrument footprint in sq. feet</p>	<p>29.5 × 25.6 × 27.6/—</p>		
<p>Tests available on instrument in U.S.</p>	<p>open system, autoimmune, infectious disease</p>	<p>3rd-gen. TSH, TT3, TT4, FT3, FT4, T3-uptake, total β-hCG, estradiol, progesterone, LH, FSH, prolactin, NTx, CEA, AFP, CA 125 II, CA 15-3, ferritin, cortisol (serum and urine), CK-MB, troponin I, aHBs, B12, folate, RBC folate, equimolar PSA, HBsAg, aHCV, HBsAg (conf.), myoglobin, aHBc, aHBc IgM, aHBs, testosterone, NT-proBNP, CA 19-9, aHAV total, aHAV IgM, rubella IgG, aHIV 1+2, iPTH, HBeAg aHBe</p>	<p>3rd-gen. TSH, TT3, TT4, FT3, FT4, T3-uptake, total β-hCG, estradiol, progesterone, LH, FSH, prolactin, NTx, CEA, AFP, CA 125 II, CA 15-3, ferritin, cortisol (serum and urine), CK-MB, troponin I, aHBs, B12, folate, RBC folate, equimolar PSA, HBsAg, aHCV, HBsAg (conf.), myoglobin, aHBc, aHBc IgM, aHBs, testosterone, NT-proBNP, CA 19-9, aHAV total, aHAV IgM, rubella IgG, aHIV 1+2, iPTH</p>
<p>Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries</p>	<p>— —</p>	<p>toxog IgG, rubella IgM, toxo IgM, CMV IgG, CMV IgM, syphilis HIV Combo, vitamin D, total PSA II NTx</p>	<p>aHBe, HBeAg, rubella IgM, toxo IgG, toxo IgM, CMV IgG, CMV IgM, syphilis HIV combo, syphilis (Ex-U.S.), vitamin D, total PSA II NTx</p>
<p>Tests in development Tests not available on other manufacturers' analyzers</p>	<p>— —</p>		
<p>Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate</p>	<p>yes — 96</p>	<p>no — —</p>	<p>no — —</p>
<p>Methods supported/Separation methods</p>	<p>enzyme immunoassay, IFA slides/coated microwell</p>	<p>chemiluminescence (enhanced)/individually coated microwell</p>	<p>chemiluminescence, enhanced chemiluminescence/coated microwell</p>
<p>No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum specimen volume required Minimum sample vol. aspirated precisely at once/Minimum dead volume Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead volume Primary tube sampling/Tube sizes/Pierces caps on primary tubes</p>	<p>7 — open system EIA/IFA —/—/no yes requires prehandling yes/— no/<10⁻⁶ 64 IFA, 96 EIA yes/liquid no/— no/— 100 μL 5 μL/150 μL yes/no no/— — no/— yes/10 to 16 mm/no</p>	<p>20 20, up to 25 lots calibrated per assay 0 20/100 56 days/56 days/yes (2°–8°C) yes yes yes/test ID, expir., lot No., pack ID —/zero carryover 720/60/800 (with enhanced productivity module) no/liquid no/— no/— 10 μL 10 μL/80 μL no, but it is available/no no/— 60 decibels no/— yes/multiple ped., microtainers and cups, 5 mL, 7 mL, 10 mL on same universal sample tray/no yes (2 of 5 interl. Codabar, codes 39 & 128, & ISBT 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no assay dependent yes 1–3 no/28 days yes/yes once per 24 hours yes/yes —/—/0</p>	<p>31 31, up to 25 lots calibrated per assay — 31/100 1,008 hours/56 days/yes (2°–8°C) yes yes yes/test ID, expiration date, lot No., pack ID no/zero carryover varies/90/3,100 no/liquid no/— no/— 10 μL 10 μL/35 μL no, but it is available/no no/— — no/— yes/1.5 mL micro-collection containers; 0.5- & 2.0-mL cups; 5, 7, & 10 mL on same universal sample tray—no adapters/no yes (2 of 5 interl., Codabar, codes 39 & 128 & ISBT 128)/yes yes yes yes/yes yes yes/yes yes/yes no/no assay dependent yes 1–3 depending on assay no/28 days yes/yes once per 24 hours yes/yes —/—/0</p>
<p>Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results Time between initial result and reaspiration of sample for rerun Autocalibration or autocalibration alert Number of calibrators required for each analyte Calibrants can be stored onboard/Average calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time</p>	<p>yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes — no no/yes — yes/no no/no yes/no — — no varies —/per run yes/no per run no/— no/no/2 minutes</p>	<p>yes (2 of 5 interl. Codabar, codes 39 & 128, & ISBT 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no assay dependent yes 1–3 no/28 days yes/yes once per 24 hours yes/yes —/—/0</p>	<p>yes (2 of 5 interl., Codabar, codes 39 & 128 & ISBT 128)/yes yes yes yes/yes yes yes/yes yes/yes no/no assay dependent yes 1–3 depending on assay no/28 days yes/yes once per 24 hours yes/yes —/—/0</p>
<p>Stat time to completion of β-hCG test Time delay from ordering stat test to aspiration of sample Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface</p>	<p>— — — yes/yes onboard/yes (additional cost)</p>	<p>24 minutes immediate upon completion of last sample metering assay dependent/assay dependent (40 seconds) yes/yes yes, onboard and optional add-on/no</p>	<p>24 minutes immediate upon completion of last sample metering assay dependent/assay dependent (19 seconds) yes/yes yes, onboard and optional add-on (Data Innovations)/yes, additional cost</p>
<p>LIS interfaces up and running in active user sites</p>	<p>—</p>	<p>Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, others</p>	<p>Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, others</p>
<p>LIS interface operates simultaneously with running assays Bidirectional interface capability Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) without operator On-site response time of service engineer Mean time between failures/To repair failures</p>	<p>yes yes (broadcast download, host query) no no/—/— — 24 hours 6–8 months/—</p>	<p>yes yes (broadcast download) no yes/yes/yes no <4 hours (contract dependent) dependent on corrective action/dependent on corrective action</p>	<p>yes yes (broadcast download and host query) yes, enGen yes/yes/yes no <4 hours (contract dependent) dependent on corrective action/dependent on corrective action</p>
<p>Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module</p>	<p>daily: 5 minutes; weekly: 10 minutes; monthly: 10 minutes no/—</p>	<p>daily: <5 minutes; weekly: <30 min.; monthly: <10 minutes no/yes</p>	<p>daily: 10 minutes; weekly: 25 minutes; monthly: 15 minutes yes, includes audit trail/yes</p>
<p>List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided with purchase/Advanced operator training</p>	<p>— — yes (2 days on site)/—</p>	<p>\$109,000/various varies with service-level choices yes/yes, as needed</p>	<p>\$220,000/various varies with service-level choices yes/yes, as needed</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>processes IFA slides and ELISA assays simultaneously, LIS interface, large menu, and open-assay capability; reads IFA bar codes</p>	<p>uses Intellicheck technology to perform, monitor, document, and verify diagnostic checks throughout sample and assay processing to reduce potential of misreported results; IntelliReport provides real-time status and traceability on quality of reported results; uses enhanced chemiluminescence, MicroWell technology; provides routine and specialty immunodiagnostic testing</p>	<p>diagnostic checks throughout sample and assay processing reduces misreported results; real-time status and traceability on quality of reported results; fully automated, true random access stat testing for routine and specialty immunodiagnostic testing; single-use tips for sample and reagent metering; measures and flags results, if hemolysis, icterus, turbidity levels might affect results</p>
<p><i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i></p>			

Automated immunoassay analyzers

Part 14 of 21	Radiometer Medical ApS info@radiometeramerica.com 810 Sharon Drive, Westlake, OH 44145 +1 (440) 871-8900 www.radiometeramerica.com	Randox Laboratories Ltd. Gareth Soye evidence.support@randox.com 55 Diamond Road, Crumlin, County Antrim, BT29 40Y 0044 28 9442 2413 www.randox.com	Roche Diagnostics Sheila Brewer sheila.brewer@roche.com 9115 Hague Road, Indianapolis, IN 46250 800-428-5074 www.mylabonline.com
Name of instrument/First year sold/Where designed	AQT90/2008/Denmark	Evidence/2002/Northern Ireland	cobas 8000 modular analyzer series (cobas c 702, cobas c 701, cobas c 502, cobas e 602)/2010/Japan, Switzerland
Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	Denmark/Finland —/— random access/benchtop/inlet	Northern Ireland/Northern Ireland 8/27 batch/floor-standing/carousel	Japan/Germany >109/>1,570 random access, continuous random access/floor-standing/rack-based
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	17.7 × 18.1 × 18.9/2.4	68 × 78 × 39/22.75	52.8 × 58.8 × 45.6/—
Tests available on instrument in U.S.	myoglobin	cocaine, methamphetamine, PCP, opiates, cannabinoids, barbiturates, benzodiazepine, progesterone, prolactin, LH, FSH, estradiol, amphetamine, methadone	ACTH, AFP, anti-CCP, anti-HAV IgM, anti-HAV total, anti-Tg, anti-TPO, anti-TSHR, beta-crosslaps, CA 125, CA 15-3, CA 19-9, CEA, CK-MB, CK-MB stat, cortisol, C-peptide, DHEA-S, digoxin, estradiol, folate, FSH, FT3, FT4, HCG II stat, HCG+ beta, hGH, IgE, insulin, LH, myoglobin, myoglobin stat, N-MID osteocalcin, proBNP, proBNP stat, progesterone, prolactin, PTH, PTH stat, rubella IgG, total and free PSA; HBsAg, and anti-HCV HE4, Anti-HBs; HSV-1, HSV-2
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	CK-MB troponin T, troponin I, CK-MB, NTproBNP, bHCG, CRP, D-dimer	— CK-MB, h-FABP, myoglobin, troponin, testosterone, estradiol, prolactin, FSH, CEA, tPSA, TSH, FT4, FT3, TT4, TT3; drugs of abuse; buprenorphine, fentanyl, generic opioids, ketamine, LSD, methaqualone, 3,4MDMA, oxycodone 1, oxycodone 2, propoxyphene, TCAs generic; adhesion biomarkers, cytokines, endocrine hormones, metabolic syndrome, biomarkers	free β-HCG, PAPP-A, PTH (1-84), anti-HBc, anti-HBc IgM, HBeAg, anti-HBe, HIV Ag, HIV Ag confirmatory test, HIV Combi, HSV type 1, HSV type 2, toxo IgM, CMV IgG, others
Tests in development	troponin I, troponin T, BNP, D-Dimer, bHCG, CRP, PT-INR, APTT	—	anti HBc, anti HBc IgM, vitamin D2/D3 total, IGF-1 tacrolimus, sirolimus, cyclosporine, HIV combi, toxo IgM, CMV IgG, CMV IgM, troponin T high sensitive, HBsAg (quant); anti-HBc; anti-HBcIgM; PCT; cyfra 21-1; toxo IgM; syphilis others TnT
Tests not available on other manufacturers' analyzers	—	h-FABP, GPBB, IL-5, IL-15	—
Fully automated microplate system	no	—	no
Number of each analyte performed in separate disposable unit	—	—	—
Number of wells in microplate	—	—	—
Methods supported/Separation methods	time-resolve fluorescence/coated microwell	chemiluminescence/—	electrochemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	6	8	25 per module, maximum of 60
No. of different assays programmed, calibrated at once	6	12	25 per module
No. of user-definable (open) channels	0	0	—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	15/16	96/360	25/100–200 tests per kit
Shortest/Median onboard reagent stability/Refrigerated onboard	96 hours/7 days/no	assay dependent/1–14 days/yes (2°–8°C)	2 weeks/6 weeks/yes (20° C)
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	yes	yes	yes
Reagents bar coded/Information in bar code	yes/lot No., expiration, checksum, parameter code, cartridge ID	yes/product component, size, lot No., expiration date	yes/calibration curve, application parameters, lot number, expiration, reagent name
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/<100 ppm	no/—	—/zero, uses disposable sample tips
Walkaway capacity in minutes/Specimens/Tests-assays	—/2/10 tests	100/180/540–1,080	360/300/5,000
System is open (home-brew methods can be used)/Liquid or dry system	yes (homebrew methods can be used)/dry	no/liquid	no/liquid
Uses disposable cuvettes/Maximum number stored	no/—	no/—	yes/1,006 per module
Uses washable cuvettes/Replacement frequency	no/—	no/—	no/—
Minimum specimen volume required	2 µL	7 µL	10 µL
Minimum sample vol. aspirated precisely at once/Minimum dead volume	2.5 µL/53.5 µL	7 µL/7–350 µL (varies with cup type)	10 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	no/no	yes/yes
Requires dedicated water system/Water consumption	no/—	no/—	yes/average 12 L per hour in full operation
Noise generated	—	60 decibels	<65 decibels
Has dedicated pediatric sample cup/Dead volume	no/—	yes/100 µL	yes/100 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/11 × 66 to 13 × 78 mm/yes	yes/12 mm, 16 mm/no	yes/13 × 75, 16 × 100, false bottom/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per CLSI standard Auto2A	—	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes, autodetection of adequate specimen	yes	yes
Clot detection/Reflex testing capability	—/no	no/yes	yes/yes (data manager)
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	yes/yes, semi-quantitative with integrated system
Dilution of patient samples onboard/Automatic rerun capability	no/no	no/no	yes/yes
Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	—	no/no	no/no
Time between initial result and reaspiration of sample for rerun	—	12 minutes	—
Autocalibration or autocalibration alert	—	no	yes
Number of calibrators required for each analyte	2-level adjuster, supplied in kit	9 (multi-analyte calibrators)	2
Calibrants can be stored onboard/Average calibration frequency	yes/once per lot	yes/weekly (dependent on panel)	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	—	yes/yes	yes/yes
How often QC required	customer determined (longest interval: 1 per month)	user defined	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	—	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	—/—/30 minutes	yes/no/13 minutes	yes/yes/11 minutes
Stat time to completion of β-hCG test	18 minutes	—	9-min. incubation for hCG and 18-min. incubation for B-hCG
Time delay from ordering stat test to aspiration of sample	30 seconds	—	<1 minute
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	10/30	108/324 (5 minutes)	56/176 (21 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/no	onboard/Randox, included in price	onboard/—
LIS interfaces up and running in active user sites	—	yes	all major LISs
LIS interface operates simultaneously with running assays	yes	yes	yes
Bidirectional interface capability	yes (broadcast download and host query)	yes (host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	no	no	yes (Roche MPA systems, task targeted automation)
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	per negotiated contract	<24 hours (contract dependent)	<24 hours
Mean time between failures/To repair failures	—	—	—
Average time to complete maintenance by lab personnel	—	daily: 5 minutes; weekly: 10 minutes; monthly: 30 minutes	4–5 minutes hands-on daily maintenance
Onboard maintenance records/Maintenance training demo module	yes, includes audit trail/no	no/—	yes (includes audit trail)/yes (online help)
List price/Targeted bed size or daily volume	—	contract dependent/500+	contract dependent/large to very large
Annual service contract cost (24 hours/7 days)	flexible options available	contract dependent	included with reagent rental
Training provided with purchase/Advanced operator training	—	—/yes	5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	point-of-care instrument measures whole blood with lab quality; broad menu and parameter flexibility; closed tube and closed waste system	biochip enables simultaneous analysis of multiple parameters in single sample; maximum throughput of 1,188 tests per hour; unreported tests retrieved retrospectively; arrays contain multiple tests applicable to clinical and research applications	ECL technology-based assays provide wide measuring ranges and excellent low-end sensitivity (e.g., TropT); ready-to-use and bar-coded reagents compatible with other Elecsys Systems; range of stat assays with 9-minute assay time, integral part of c8000 platform, connects with Modular Pre-Analytics for total lab automation

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

Automated immunoassay analyzers

Part 15 of 21	Roche Diagnostics Adam Sterle adam.sterle@roche.com 9115 Hague Road, Indianapolis, IN 46250 800-428-5074 www.mylabonline.com	Roche Diagnostics Adam Sterle adam.sterle@roche.com 9115 Hague Road, Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us	Roche Diagnostics Adam Sterle adam.sterle@roche.com 9115 Hague Road, Indianapolis, IN 46250 800-428-5074 www.mylabonline.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed	Elecsys 2010/1996/—	cobas e411/2006/Japan	cobas 6000 analyzer series (cobas c 501, e 601)/2006/Japan, Switzerland
Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	Japan/Germany >800/>6,000 cont. random access/benchtop/rack or disk 22.1 × 47.2 × 28.7/9.4	Japan/Germany >350/>4,300 continuous random access/benchtop/rack, disk disk: 31.4 × 47.2 × 28.7/94; rack: 31.4 × 67 × 37.4/17.4	Japan/Germany >625/>4,800 continuous random access/floor-standing/rack 46.1 × 71.8 × 40/19.73
Tests available on instrument in U.S.	ferritin, folate II, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, free PSA, total PSA, ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone, prolactin, SHBG, testosterone, total and βHCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, HBsAg, HBeAg confirmatory, anti-HBs, IgE, PTH, others	ferritin, folate, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, free PSA, total PSA, beta crosslaps (sCTX), osteocalcin, PTH, CK-MB, HCG, HCG+b, myoglobin, troponin I, troponin T, ACTH, cortisol, DHEA-S, estradiol II, FSH, LH, progesterone, II, prolactin II, SHBG, testosterone II, anti-Tg, anti-TPO, anti-TSHR, FT3, FT4, T3, T4, TSH, t-uptake, anti-HAV, anti-HBs, many others	ferritin, folate, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, total PSA (monitoring), ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone, prolactin, SHBG, testosterone, total and β-hCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps, osteocalcin, carbamazepine, anti-HCV; anti-HBcIgM; anti-HAV IgM; anti-HAV
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	anti-HBc IgM, anti-HCV, anti-HAV IgM TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV IgM, anti-HBc, anti-Hbe, HBeAg, HIV antigen, HIV antigen confirmatory, P1NP, 25-OH vitamin D3	TG; HE4; HSV-1; HSV-2 —	TG; HE4; HSV-1; HSV-2, PCT —
Tests in development	interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, NSE, cyfra 21-1, anti-HBc, HbC IgM, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM, HIV combi, He4, vitamin D 25-OH toxo IgM, rubella IgM	total P1NP, vitamin D 25-OH, troponin T hs, hGH, IGF-1, thyroglobulin (Tg), CMV IgG, CMV IgM, HIV combi, toxo IgM, IL-6, procalcitonin (PCT), anti-HBc IgM, HBsAg (Quant); anti-HBc; anti-HBcIgM; PCT; cyfra 21-1; Toxo IgM; syphilis	interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, NSE, cyfra 21-1, anti-HBc, HbC IgM, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM, 9-minute (STAT) applications for TnT, HBsAg (Quant); Anti-HBc; Anti-HBcIgM; PCT; Cyfra 21-1; Toxo IgM; syphilis
Tests not available on other manufacturers' analyzers	9-minute PTH, Tnt	9-minute PTH and cardiac assays, 9-minute PTH, TnT	TnT
Fully automated microplate system	no	no	no
Number of each analyte performed in separate disposable unit	—	—	—
Number of wells in microplate	—	—	—
Methods supported/Separation methods	electrochemiluminescence/magnetic particle	electrochemiluminescence/magnetic particle	electrochemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	15	18	25 per module, maximum of 60
No. of different assays programmed, calibrated at once	60	18	25 per module
No. of user-definable (open) channels	0	0	—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	15/100–200 tests per kit	18/100–200 tests per kit	25/100–200 tests per kit
Shortest/Median onboard reagent stability/Refrigerated onboard	56 days/56 days/yes (20°C)	14 days/56 days/yes	2 weeks/6 weeks/yes (20°C)
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	yes	yes	yes
Reagents bar coded/Information in bar code	yes/calibration curve, application parameters, lot No., expiration, reagent name	yes/calibration curve, application parameters, lot No., expiration, reagent name	yes/calibration curve, application parameters., lot No., expiration, reagent name
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover (disposable sample tips)	no/zero carryover (disposable sample tips)	—/zero, uses disposable sample tips
Walkaway capacity in minutes/Specimens/Tests-assays	120/disk: 30, rack: 100/180	disk: 120/30/180; rack: 120/100/180	360/150/5,000
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid	no/liquid
Uses disposable cuvettes/Maximum number stored	yes/180	yes/360 assay tips; 180 assay cups	yes/1,006 per module
Uses washable cuvettes/Replacement frequency	no	no/—	no/—
Minimum specimen volume required	10 µL	10 µL	10 µL
Minimum sample vol. aspirated precisely at once/Minimum dead volume	10 µL/100 µL	10 µL/100 µL	10 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/yes
Requires dedicated water system/Water consumption	no/3 L for 250 tests	no/3 L for 250 tests	yes/average 12 L per hour in full operation
Noise generated	<70 decibels	<70 decibels	<65 decibels
Has dedicated pediatric sample cup/Dead volume	no/—	no/—	yes/100 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13–16 mm diameter/no	yes/13–16 mm diameter/no	yes/13 × 75, 16 × 100, false bottom/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per NCCLS standard Auto2A	yes	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	yes/yes (with middleware)	yes/yes (with middleware)	yes/yes (with Roche Middleware Solutions)
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	yes/yes, semi-quantitative with integrated system
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no	yes/yes
Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	yes/yes	yes/yes	no/no
Time between initial result and reaspiration of sample for rerun	—	—	—
Autocalibration or autocalibration alert	yes	yes	yes
Number of calibrators required for each analyte	2	2	2
Calibrants can be stored onboard/Average calibration frequency	no/monthly	no/monthly for lot; weekly for rack	no/every 28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes	yes/yes
How often QC required	once per 24 hours	once per day	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/4 minutes	yes/no/4 minutes	yes/yes/11 minutes
Stat time to completion of β-hCG test	9 minutes (hCG intact)	9 minutes	9-min. incubation for hCG and 18-min. incubation for B-hCG
Time delay from ordering stat test to aspiration of sample	42 seconds	42 seconds	<1 minute
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	30/88 (42 seconds)	30/86 (42 seconds)	56/176 (21 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	onboard/yes (additional cost)	onboard/yes (additional cost)
LIS interfaces up and running in active user sites	all major LISs	—	all major LIS vendors
LIS interface operates simultaneously with running assays	yes	yes	yes
Bidirectional interface capability	yes (broadcast download and host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	yes (CLAS and Roche task targeted automation)	yes	yes (Roche MPA systems and task targeted automation)
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/no	yes/yes/yes	yes/yes/no
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	<24 hours	<24 hours	<24 hours
Mean time between failures/To repair failures	—	215 days/varies	—
Average time to complete maintenance by lab personnel	daily: 1 minute; weekly: 5 minutes; biweekly: 25 minutes	daily: 5 minutes; weekly: 6 minutes; monthly: 10–15 minutes	3–5 minutes of hands-on daily maintenance
Onboard maintenance records/Maintenance training demo module	no/no (training CD-ROM)	no/no	yes (includes audit trail)/yes (online help)
List price/Targeted bed size or daily volume	varies based on contract	varies based on contract/varies; primary immunoassay system or back-up unit	varies, based on contract/—
Annual service contract cost (24 hours/7 days)	included with reagent rental	included with reagent rental	—
Training provided with purchase/Advanced operator training	3 days at Indianapolis offices/yes	4 days on site/yes	5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	liquid ready-to-use reagents; autocalibration, autodilution; ECL technology for broad dynamic ranges, and fast turnaround time, stat interrupt; onboard reagent storage; minimal maintenance	ECL technology-based assays provide wide measuring ranges and excellent low-end sensitivity (e.g., TropT); ready-to-use and bar-coded reagents fully compatible with other Elecsys systems; range of stat assays with 9-minute assay time	ECL technology-based assays provide wide measuring ranges and excellent low-end sensitivity (e.g., TropT); ready-to-use and bar-coded reagents compatible with other Elecsys systems; range of stat assays with 9-minute assay time, integral part of c8000 platform, connectable to Modular Pre-Analytics for total lab automation

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

Automated immunoassay analyzers

Part 16 of 21	Siemens Healthcare Diagnostics Christina Tassone christina.tassone@siemens.com 511 Benedict Avenue, Tarrytown, NY 10591 800-242-3233 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Mathew Fitzgerald 511 Benedict Avenue, Tarrytown, NY 10591 847-236-7404 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Maria Reda Fiorino 511 Benedict Avenue, Tarrytown, NY 10591 www.usa.siemens.com/diagnostics
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	Dimension EXL 200/2011/U.S. U.S./U.S. — batch, random access/floor-standing/segmented sample wheel/floor-standing 56 × 49 × 41/16	Dimension Vista 500 Intelligent Lab System/2009/U.S. U.S./U.S., Germany >400/>100 continuous random access/floor-standing/rack and aliquot plate system, batch 55.5 × 84.75 × 43.8/26	ADVIA Centaur CP Immunoassay System/2005/U.S. Switzerland/U.S. >535/>1,800 continuous random access/benchtop/7 × 12 position racks 43 × 29/8.7
Tests available on instrument in U.S.	tacrolimus, MPA, LOCI troponin, LOCI NT-proBNP, LOCI TSH, LOCI free T4, LOCI free T3, sirolimus, total PSA, free PSA, CardioPhase hsCRP, ferritin, HCG, LV HCG, mass CK-MB, LV mass CK-MB, myoglobin, ammonia, urine/CSF protein, lactic acid, microalbumin, prealbumin, carbamazepine, cyclosporine, cyclosporine extended range, digoxin, digitoxin, gentamicin, lidocaine, lithium, N-acetylprocainamide, many others	>130 (includes vendor-supported applications), 35 general chemistry, 14 TDMs, 17 DATs, 3 anemia, 40 plasma proteins, 20 immunoassays, including cyclosporine, LH, FSH, prolactin, and CA19-9	>64, total IgE, ferritin, folate, vit B-12, CK-MB, HCY, MYO, Tnl-Ultra, BNP, C-peptide, insulin, cortisol, HAV IgM, HAV total, HBsAg, HBeAg confirmatory, anti-HBs, anti-HBc IgM, anti-HBc total, HCV, syphilis toxo IgG, rubella IgG, rubella IgM, AFP, estradiol-6 III, FSH, total hCG, LH, progesterone, prolactin, testosterone, carbamazepine, digitoxin, digoxin, gentamicin, phenobarbital, phenytoin, eHIV
Tests not available in U.S. but submitted for clearance	—	—	cyclosporine, DHEAs, SHBG, digitoxin, aTG, aTPO, TSH3 ultra, HER2/neu
Tests not available in U.S. but available in other countries	—	PSA, fPSA, CA 15-3, CA 125	—
Tests in development	LOCI B12, LOCI folate, LOCI BNP	CA 125, CA 15-3, CA 19-9, additional cancer markers fertility panel, plasma proteins, hormones, infectious disease	toxo IgM, D-dimer, fPSA, HBeAg, anti-HBe, HIV combo
Tests not available on other manufacturers' analyzers	—	LOCI immunoassay, nephelometric assays, gen. chemistry	cPSA, HER2/neu
Fully automated microplate system	no	no	no
Number of each analyte performed in separate disposable unit	—	—	—
Number of wells in microplate	—	—	—
Methods supported/Separation methods	chemiluminescence, enzyme immunoassay, LOCI, ACMA, EMIT, PETINIA, photometry, potentiometry/magnetic particle, all LOCI and EMIT methods are homogenous	chemiluminescence, LOCI advanced chemiluminescence, EMIT, PETINIA, nephelometry/magnetic particle, homogeneous immunoassay	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	47	>100	15
No. of different assays programmed, calibrated at once	47	>100	31 (65 planned for 2008)
No. of user-definable (open) channels	10	10	—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	47/15–240	>100/20–1,200	15/50 to 200
Shortest/Median onboard reagent stability/Refrigerated onboard	72 hours/30 days/yes (2°–8°C)	72 hours/30 days/yes (2°–8°C)	4 days/42 days/yes (2°–8°C)
Multiple reagent configurations supported	yes	no	yes
Reagent container placed directly on system for use	yes	yes	yes
Reagents bar coded/Information in bar code	yes/lot #., unique flex ID, stability, expiration date	yes/test method, lot number, expiration date, number of tests	yes/reagent ID, lot No., expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/none (due to probe washing)	yes/<1 ppm	no/zero carryover
Walkaway capacity in minutes/Specimens/Tests-assays	can be hours/60/>2,000	>45/150/61,404	210/72/400
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid, reconstitutes onboard (no reagent prep required)	yes/liquid	no/liquid
Uses disposable cuvettes/Maximum number stored	yes/12,000	yes/>1,600	yes/400
Uses washable cuvettes/Replacement frequency	no/—	yes/automatic as needed	no/—
Minimum specimen volume required	2 uL	50 uL	10 uL, assay dependent
Minimum sample vol. aspirated precisely at once/Minimum dead volume	2 uL/—	50 uL/10 uL	10 uL/50 uL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/yes	yes/no
Requires dedicated water system/Water consumption	yes/5 L	no/20 L per hour	no/none
Noise generated	<75 decibels	<65 decibels	up to 65 decibels
Has dedicated pediatric sample cup/Dead volume	yes/30 uL	yes/10	no/can use microtainers
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5 mL, 7 mL, 10 mL, 1.5 mL, and 1.0 mL sample cups/ no	yes/10 × 50, 10 × 65, 13 × 65, 13 × 75, 13 × 100, 15 × 92, 16 × 100, 13 × 90/no	yes/2 mL, 5 mL, 7 mL, 10 mL/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per NCCLS standard Auto2A	yes	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	yes/yes	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes	yes/yes
Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	yes/no	can decrease/cannot increase sample volume	can decrease/cannot increase sample volume
Time between initial result and reaspiration of sample for rerun	<20 seconds	<2 minutes	varies
Autocalibration or autocalibration alert	yes	yes	yes
Number of calibrators required for each analyte	varies (3 levels for most assays)	varies 2–6	2
Calibrants can be stored onboard/Average calibration frequency	yes (NA, K, Cl)/most 90 days	yes/30 to 90 days	no/varies, average of 21 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes	yes/yes
How often QC required	24 hours or with lot change	once per 24 hours	user defined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/8 minutes	no/no/always ready	no/always ready/<5 minutes
Stat time to completion of β-hCG test	16 minutes	10 minutes	15 minutes
Time delay from ordering stat test to aspiration of sample	24 seconds	<2 minutes	<2 minutes
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	up to 146/437 (7.2 seconds)	>150/450 for immunoassay methods	60/180 (20 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard, optional add-on/yes (additional cost)	onboard/—	onboard/no
LIS interfaces up and running in active user sites	all major LIS vendors	Misys, Soft, Mediatech, Cerner, others	all major LIS vendors
LIS interface operates simultaneously with running assays	yes	yes	yes
Bidirectional interface capability	yes (broadcast download and host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	yes, Siemens VersaCell, Siemens StreamLAB	yes, StreamLAB, Advia LabCell, and Advia WorkCell	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	2–8 hours	2–8 hours	2–8 hours
Mean time between failures/To repair failures	—	—	—
Average time to complete maintenance by lab personnel	daily: <5 minutes; weekly: 10 minutes; monthly: 23 minutes	daily: <10 minutes; monthly: 10 to 20 minutes	daily: 15 minutes; weekly: 20 minutes; monthly: 30 minutes
Onboard maintenance records/Maintenance training demo module	no/yes	no/yes	yes/yes
List price/Targeted bed size or daily volume	—	—/1,500 tests per day per system	—/80,000 tests per year
Annual service contract cost (24 hours/7 days)	—	—	—
Training provided with purchase/Advanced operator training	5 days on site, 4 days at vendor offices/yes	2 days on site and/or 4 days at vendor offices/yes	3 days at vendor sites plus online training/yes
Distinguishing features (supplied by vendor)	integrates general chemistry with homogeneous LOCI and heterogeneous immunoassays onboard; allows a single platform for more than 95 percent of most requested tests; eliminates sample splitting between general chemistry tests and immunoassays; fully automated onboard ISD assays, QCC PowerPak onboard	autocalibration and QC with onboard products; homogeneous LOCI technology for high-sensitivity immunoassay testing, fast analytical time, 10-minute cardiac markers; unique integration of four technologies, including nephelometry, eliminates sample sharing/splitting to streamline workflow; can be configured as a twin system; proactive service and support through Intelligent Device Management service	automates routine operations, including ability to access/change solutions, waste, disposables, and reagents without pausing sampling or processing; onboard automatic dilutions, repeats, stats, and cascade reflex testing; disposable tips; uses same reagents/consumables as Advia Centaur/Advia Centaur XP with concordant results; throughput 180 tests/hour; average time to first result ~15 minutes

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

Automated immunoassay analyzers

Part 17 of 21	Siemens Healthcare Diagnostics Maria Reda Fiorino 511 Benedict Avenue, Tarrytown, NY 10591 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Matthew Fitzgerald 511 Benedict Avenue, Tarrytown, NY 10591 847-236-7404 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Christina Tassone christina.tassone@siemens.com 511 Benedict Avenue, Tarrytown, NY 10591 800-242-3233 www.usa.siemens.com/diagnostics
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed	ADVIA Centaur XP/2006/U.S.	Dimension Vista 1500 Intelligent Lab System/2006/U.S.	Dimension EXL with LM Integrated Chemistry System/2009/U.S.
Country where manufactured/Where reagents manufactured	Ireland/U.S.	U.S./U.S. and Germany	U.S./U.S.
No. of units in clinical use in U.S./Outside U.S.	>1,330/>2,670	>500/>200	—/—
Operational type/Model type/Sample handling system	continuous random access/floor-standing/5-position multiple size rack or puck via ADVIA LabCell and WorkCell, StreamLab, VersaCell	batch, random access continuous random access/floor-standing/sample rack and aliquot plate system	batch, random access, continuous random access/floor-standing/racks
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	51.5 × 76.5 × 41/20.6	55% × 84% × 43% /26	49 × 82 × 44 (without monitor)/25.1
Tests available on instrument in U.S.	total IgE, ferritin, folate, Vit B-12, CK-MB, HCY, MYO, Tnl-Ultra, BNP, C-peptide, insulin, cortisol, HAV IgM, HAV total, HBsAg, HBsAg confirmatory, anti-HBs, anti-HBc IgM, anti-HBc total, HCV, eHIV, vitamin D, syphilis, HBeHg, toxo IgG, toxo IgM, rubella IgG, rubella IgM, AFP, estradiol-6, estradiol-6 III, FSH, total hCG, LH, progesterone, prolactin, testosterone, DHEAs, carbamazepine, digitoxin, digoxin, gentamicin	>130 (includes vendor-supported applications), 35 general chemistry, 14 TDMs, 17 DATs, 3 anemia, 40 plasma proteins, 20 immunoassays, including PSA, FPSA, cyclosporine, LH, FSH, prolactin, and CA19-9	tacrolimus, MPA, LOCI troponin, LOCI NT-proBNP, LOCI TSH, LOCI free T4, LOCI free T3, sirolimus, total PSA, free PSA, CardioPhase hsCRP, ferritin, HCG, LV HCG, mass CK-MB, LV mass CK-MB, myoglobin, ammonia, urine/CSF protein, lactic acid, microalbumin, prealbumin, carbamazepine, cyclosporine, cyclosporine extended range, digoxin, digitoxin, gentamicin, lidocaine, lithium, N-acetylprocainamide, many others
Tests not available in U.S. but submitted for clearance	—	—	—
Tests not available in U.S. but available in other countries	—	cancer markers CA 125, CA 15-3	—
Tests in development	HIV combo, procalcitonin, anti-HBe, fPSA, D-dimer	CA 125, CA 15-3, CA 19-9, fertility panel, cancer markers, plasma proteins, hormones, cardiac, infectious disease	LOCI B12, LOCI folate, LOCI BNP
Tests not available on other manufacturers' analyzers	cPSA, HER2/neu	LOCI technology, nephelometry, general chemistry	—
Fully automated microplate system	no	no	no
Number of each analyte performed in separate disposable unit	—	—	—
Number of wells in microplate	—	—	—
Methods supported/Separation methods	acridinium ester, chemiluminescence/magnetic particle	chemiluminescence, enzyme immunoassay, ACMA, EMIT, LOCI, PETINIA, NEPH/none	chemiluminescence, enzyme immunoassay, LOCI, ACMA, EMIT, PETINIA, photometry, potentiometry/magnetic particle, all LOCI and EMIT methods are homogenous
No. of different measured assays onboard simultaneously	30 primary reagents	>100	91
No. of different assays programmed, calibrated at once	65	>100	190
No. of user-definable (open) channels	—	10	10
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	30/50, 100, 200 tests per pack	>100/20–1,200	91/15–360
Shortest/Median onboard reagent stability/Refrigerated onboard	4 days/42 days/yes (4°C)	72 hours/30 days/yes (2°–8°C)	72 hours/30 days/yes (2°–8°C)
Multiple reagent configurations supported	yes	no	yes
Reagent container placed directly on system for use	yes	yes	yes
Reagents bar coded/Information in bar code	yes/assay name, lot No., expir. date, pack ID, No. of tests	yes/test ID, lot No., individual-sequence No., exp. date	yes/lot No., unique flex ID, stability, expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	—/none—uses zero carryover	yes/<1 ppm	yes/none (due to probe washing)
Walkaway capacity in minutes/Specimens/Tests-assays	280/180/840	>45/150/61,404	can be hours/60/>2,000
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes/liquid	yes/liquid, reconstitutes on board (no reagent prep required)
Uses disposable cuvettes/Maximum number stored	yes/1,000	yes/>2,000	yes/12,000
Uses washable cuvettes/Replacement frequency	no/—	yes/automatic, as needed	no/—
Minimum specimen volume required	10 µL, assay dependent	2 µL analytical, 50 µL aliquot	2 µL
Minimum sample vol. aspirated precisely at once/Minimum dead volume	10 µL/50 µL	2 µL (GLU=1.2)/20 µL	2 µL/primary tube capable
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/no
Requires dedicated water system/Water consumption	no/2.5 L per hour	no/20 L per hour	yes/up to 5 L
Noise generated	61.3 decibels	67 decibels	<75 decibels
Has dedicated pediatric sample cup/Dead volume	no/—	yes/10 mL	yes/30 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5 mL, 10 mL, 7 mL microcup/no	yes/10 × 50, 10 × 65, 13 × 65, 13 × 75, 13 × 100, 15 × 92, 16 × 100, 13 × 90/no	yes/5 mL, 7 mL, 10 mL, 1.5 mL, and 1.0 mL sample cups/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per CLSI standard Auto2A	yes	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	yes/yes	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes	yes/yes
Sample volume can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no (does have autodilution)/no (does have autodilution)	no/no (does have autodilution)	yes/no
Time between initial result and reaspiration of sample for rerun	15 seconds	<2 minutes	<20 seconds
Autocalibration or autocalibration alert	yes	yes	yes
Number of calibrators required for each analyte	2	varies, 2–6	varies (3 levels for most assays)
Calibrants can be stored onboard/Average calibration frequency	no/average 28 days	yes/30–90 days	yes (NA, K, Cl)/most 90 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes	yes/yes
How often QC required	user defined	shortest interval: 24 hours	24 hours or with lot change
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes	no/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/none, always ready	no/no/always ready	no/no/not required
Stat time to completion of β-hCG test	18 minutes	10 minutes	16 minutes
Time delay from ordering stat test to aspiration of sample	15 seconds	<2 minutes	24 seconds
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	80/240/15 seconds	150/450 for immunoassay methods	up to 146/437 (7.2 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	yes/yes	yes/yes	onboard, optional add-on/yes (additional cost)
LIS interfaces up and running in active user sites	all major LIS vendors	Misys, Soft, Meditech, Cerner, others	all major LIS vendors
LIS interface operates simultaneously with running assays	Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others	yes	yes
Bidirectional interface capability	yes (broadcast download and host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	yes/Advia WorkCell, Advia LabCell, VersaCell, StreamLab	yes, StreamLab, Advia LabCell, and Advia WorkCell	yes, Siemens VersaCell, Siemens StreamLab
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	2–8 hours	2–8 hours	2–8 hours
Mean time between failures/To repair failures	—	—	—
Average time to complete maintenance by lab personnel	daily: 3 minutes; weekly: 20 minutes; monthly: 30 minutes	daily: <10 minutes; weekly: 10–15 minutes; monthly: 10–20 minutes	daily: <5 minutes; weekly: 10 minutes; monthly: 23 minutes
Onboard maintenance records/Maintenance training demo module	yes/yes	no/no/yes	no/yes
List price/Targeted bed size or daily volume	—/300+ beds or 400 tests per day	\$552,240/>4,000 tests per day	—
Annual service contract cost (24 hours/7 days)	multiple options	—	multiple types
Training provided with purchase/Advanced operator training	yes/4.5 days on site/yes	4 days on site, 4 days at vendor offices/yes	yes (5 days on site, 4 days at vendor offices)/no
Distinguishing features (supplied by vendor)	automates routine operations, e.g., ability to access/change solutions, waste, disposables, and reagents without pausing sampling or processing, no-pause loading of disease menu, reagents, high-throughput consumables; onboard automatic dilutions, repeats, stats, and cascade reflex testing; disposable tips; no start-up procedures; always ready; uses same reagents/consumables as Centaur CP with concordant results; processes 240 tests per hour; avg. first result in ~18 minutes	autocalibration and QC with onboard products; homogenous LOCI technology for high-sensitivity immunoassay testing, fast analytical time, 10-minute cardiac markers; unique integration of four technologies, including nephelometry, eliminates sample sharing/splitting to streamline workflow; can be configured as a twin system; proactive service and support	integrates homogeneous LOCI and heterogeneous immunoassays onboard with other chemistries; allows single platform for >95 percent of most tests; eliminates sample splitting between general chemistry tests and immunoassays; fully automated onboard ISD assays; QCC PowerPak onboard; Reagent Management standard

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

Automated immunoassay analyzers

Part 18 of 21	Siemens Healthcare Diagnostics Martu Richards martu.richards@siemens.com 511 Benedict Avenue, Tarrytown, NY 10591 914-631-8000 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Martu Richards martu.richards@siemens.com 511 Benedict Avenue, Tarrytown, NY 10591 914-631-8000 www.usa.siemens.com/diagnostics	ThermoFisher Scientific Joanne Yanco joanne.m.yanco@thermofisher.com 4169 Commercial Avenue, Portage, MI 49002 800-346-4364 www.thermoscientific.com/phadia
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	IMMULITE 1000/2002/U.S. U.S./U.S., U.K. 640/7,000 continuous random access/benchtop/loading platform	IMMULITE 2000 XPI Immunoassay System*/2009/U.S. U.S./Wales, UK 47/1,100 random access/floor-standing/rack	Phadia Laboratory System 100 ^F /1995/Sweden Sweden/Sweden — batch/benchtop/carousel
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	19 × 46 × 26/7.98	47 × 60 × 30/12.5	18 × 28 × 24 + computer/—
Tests available on instrument in U.S.	3gAllergy specific IgE, ACTH, AFP, androstenedione, anti-HBc IgM, anti-HBc total, anti-HBs, anti-TG Ab, anti-TPO Ab, beta-2 microglobulin, BR-MA (CA 15-3), calcitonin, canine TLI, canine total T4, canine TSH, carbamazepine, CEA, CK-MB, CMV IgG, cortisol, C-peptide, DHEA-SO4, digoxin, EPO, estradiol, ferritin, folic acid, free PSA, free T3, free T4, FSH, gastrin, growth hormone (hGH), H. pylori IgG, many others	3gAllergy specific IgE, ACTH, AFP, androstenedione, anti-HBc IgM, anti-HBc total, anti-HBs, anti-TG Ab, anti-TPO Ab, beta-2 microglobulin, BR-MA (CA 15-3), calcitonin, canine TLI, canine total T4, canine TSH, carbamazepine, CEA, CK-MB, cortisol, C-peptide, DHEA-SO4, digitoxin, digoxin, EPO, estradiol, ferritin, folic acid, free PSA, free T3, free T4, FSH, gastrin, growth hormone (hGH), H. pylori IgG, many others	hundreds of ImmunoCAP, specific IgE allergens, immunoCAP total IgE, tryptase and immunoCAP TG and TPO, ELIA autoimmune products currently include: CCP, dsDNA, symphony ANA Screen, 7 individual ENAs, Celikey (tissue transglutaminase) IgA/IgG, gliadin (deamidated and native) IgA/IgG, RF IgM/IgA, cardiolipin IgM/IgG, β2-glycoprotein I IgM/IgG/IgA cardiolipin IgA
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	GI-MA (CA 19-9), nicotine metabolite, free β-hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, osteocalcin, NT-proBNP, CMV IgM, ECP, cannabinoids (THC), D-dimer	GI-MA (CA 19-9), nicotine metabolite, free β-hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, osteocalcin, NT-proBNP, CMV IgM, allergen-specific IgG4, ECP, cannabinoids (THC), D-dimer	EiA PR3S, GMB, MPO, EiA CTD screen (14 ENAs), Pm/Sci, EiA Anti IgA, EiA calprotectin, others
Tests in development	D-dimer, turbo D-dimer, CMV IgM	D-dimer, EBV-EBNA IgG, EBV-VCA IgG, EBV VCA IgM, anti-CCP IgG	—
Tests not available on other manufacturers' analyzers	IGF-I, IGFBP-3, androstenedione, 3rd-gen PSA, gastrin, canine TLI, canine TSH	3gPSA, IGF-I, IGFBP-3, H. pylori IgG, androst., gastrin, canine TLI, canine TSH, veterinary free T4	ImmunoCAP specific IgE blood tests and EiA autoimmune tests
Fully automated microplate system	no	no	no
Number of each analyte performed in separate disposable unit	—	—	—
Number of wells in microplate	—	—	—
Methods supported/Separation methods	chemiluminescence/bead, centrifugation	chemiluminescence/—	fluoroenzyme immunoassay/ImmunoCAP cellulose polymer matrix reaction wells
No. of different measured assays onboard simultaneously	12	24	4
No. of different assays programmed, calibrated at once	unlimited	unlimited	7
No. of user-definable (open) channels	0	—	0, closed system
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	12; 5 for Turbo/100; 50 for Turbo i-PTH	24/200	48–96 depending on the conjugate type
Shortest/Median onboard reagent stability/Refrigerated onboard	—/30 days/yes (15°C)	—/90 days/yes (4°C)	—
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	yes	yes	yes (wash solution requires preparation)
Reagents bar coded/Information in bar code	yes/test, lot No., expiration	yes/test, lot No., expiration	yes/product name, lot No., expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/<10 ppm	no/<3 ppm	no/—
Walkaway capacity in minutes/Specimens/Tests-assays	100/—/70	300/90/1,300	180 minutes/varies with analyte/48
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid	no/liquid
Uses disposable cuvettes/Maximum number stored	yes/—	no/1,300	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—	—/—
Minimum specimen volume required	5 µL	5 µL to 100 µL	40 µL for ImmunoCAP tests and 20 µL for EiA tests
Minimum sample vol. aspirated precisely at once/Minimum dead volume	5 µL/100 µL	5 µL/50 µL	ImmunoCAP: 40 µL/40–200 µL; EiA: 50 µL/20–200 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/no
Requires dedicated water system/Water consumption	no/0.5 L per hour	no/—	no/1 L per run
Noise generated	55-68 decibels	52 decibels	—
Has dedicated pediatric sample cup/Dead volume	no/—	yes/50 µL	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/—/—	yes/75–100 mm/no	yes/10–16 mm × 50–105 mm/no
Sample bar-code reading capability/Autodiscrimination	yes	yes (2 or 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per CLSI standard Auto2A	—	yes	no
Onboard test auto inventory (determines volume in container)	yes	yes	no
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	no/yes
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	no/no	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/yes	yes/yes
Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	no/no	no/no
Time between initial result and reaspiration of sample for rerun	—	minimum 18 seconds	2.5 hours—batch run
Autocalibration or autocalibration alert	yes	yes	yes
Number of calibrators required for each analyte	2-level adjusters, supplied in kit	2-level adjusters, supplied in kit	6 per analyte for calibration run, and 2 when using stored curve
Calibrants can be stored onboard/Average calibration frequency	no/1–4 weeks (assay dependent); 2 weeks for Turbo	no/1–4 weeks (assay dependent)	yes/28 days or sooner if conjugate lots change
Multipoint calib. supported/Multiple calibs. stored for same assay	no/yes	yes/yes	yes/yes
How often QC required	customer determined	customer determined	once per work shift (user defined)
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/5 minutes	yes/yes/4 minutes	yes/yes/20 min. including request entry or downloading
Stat time to completion of β-hCG test	42 minutes; 15 minutes for Turbo (total hCG)	35 minutes	—
Time delay from ordering stat test to aspiration of sample	2.5 minutes	18 seconds	—
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	120/120 (—)	200/200 (18 seconds)	batch analyzer/48 (180 minutes processing time for batch to finish)
Can auto transfer QC results to LIS/Onboard capability to review QC	no/yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	onboard (\$2,000 QC software only, Siemens)/yes	onboard/yes, instrument side only (included)
LIS interfaces up and running in active user sites	CIS, CPSI, CCA, Misys, McKesson, Cerner, Antek, CSS, others	Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Misys, SCC, others	Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others
LIS interface operates simultaneously with running assays	yes	yes	yes
Bidirectional interface capability	yes (broadcast download and host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	no	yes, universal interface	yes
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/no	yes/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	4 hours	4 hours	—
Mean time between failures/To repair failures	10 months/4 hours	3 months/5 hours	—
Average time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 10 minutes; monthly: 20 minutes	daily: 5 to 10 minutes; weekly: 20 minutes; monthly: 20–30 minutes	daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes
Onboard maintenance records/Maintenance training demo module	—/yes	no/yes	yes/no
List price/Targeted bed size or daily volume	\$75,000; Turbo: \$77,500/>1,000 tests per month	\$130,000/>6,000 per months	\$22,000/>7,000–20,000 tests per year
Annual service contract cost (24 hours/7 days)	\$8,000	\$16,800	—
Training provided with purchase/Advanced operator training	3.5 days at vendor offices/yes	—	3.5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	large immunoassay test menu, proven reliable system	high-throughput immunoassay system; large menus combining routine, specialty, and allergy testing on one platform; no-pause sampling, automatic daily maintenance	provides accepted technology for serologic, specific IgE testing with the ImmunoCAP family of products and autoimmune markers with the EiA family of products; comprehensive clinical and technical research and extensive medical information and education; measures and reports specific IgE quantitative results across clinical range

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

Automated immunoassay analyzers

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See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	Phadia Laboratory System 250/2004/Japan, Sweden Japan, Sweden/Sweden — continuous random access/floor-standing/racks 73 x 50 x 30 + 26-in. wide computer stand/—	Phadia Laboratory System 1000/2003/Japan, Sweden Japan, Sweden/Sweden — continuous random access/floor-standing/racks 83 x 71 x 40 + 26-in. wide computer stand/—	Phadia Laboratory System 2500/2004/Sweden Japan/Sweden — continuous random access/floor-standing/racks 71 x 158 x 47 + 26-in. wide computer stand/51
Tests available on instrument in U.S.	hundreds of ImmunoCAP, specific IgE allergens, ImmunoCAP total IgE, Tryptase and ImmunoCAP TG and TPO, ELiA autoimmune products currently include: CCP, dsDNA, Symphony ANA Screen, 7 individual ENAs, celikey (tissue transglutaminase) IgA/IgG, gliadin (deamidated and native)IgA/IgG, RF IgM/IgA, Cardiolipin IgM/IgG, β 2- Glycoprotein I IgM/IgG/IgA	hundreds of ImmunoCAP, specific IgE tests, ImmunoCAP total IgE, ImmunoCAP ECP, and ImmunoCAP tryptase	hundreds of ImmunoCAP, specific IgE allergens, ImmunoCAP total IgE, Tryptase and ImmunoCAP TG and TPO tests; ELiA autoimmune products currently include: CCP, dsDNA, Symphony ANA screen, 7 individual ENAs, Celikey (tissue transglutaminase) IgA/IgG, gliadin (deamidated and native)IgA/ IgG, RF IgM/IgA, cardiolipin IgM/IgG, β 2- glycoprotein I IgM/IgG/IgA
Tests not available in U.S. but submitted for clearance	ELiA cardiolipin IgG, ELiA cardiolipin IgM, ELiA β 2-glycoprotein I IgG and ELiA β 2-glycoprotein I IgM, others	—	cardiolipin IgA
Tests not available in U.S. but available in other countries	—	—	ELiA PR3S, GMB, MPO, ELiA CTD screen (14 ENAs), Pm/Sci, ELiA anti IgA, ELiA calprotectin, others
Tests in development	—	—	—
Tests not available on other manufacturers' analyzers	ImmunoCAP specific IgE blood tests and ELiA autoimmune tests	ImmunoCAP specific IgE blood tests	ImmunoCAP specific IgE blood tests and ELiA autoimmune assays
Fully automated microplate system	no	no	no
Number of each analyte performed in separate disposable unit	—	—	—
Number of wells in microplate	—	—	—
Methods supported/Separation methods	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells	fluorescence/coated microwell, fluoroenzyme immunoassay, ImmunoCAP cellulose polymer matrix reaction wells
No. of different measured assays onboard simultaneously	4	3	up to 8
No. of different assays programmed, calibrated at once	not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory	not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory	not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory
No. of user-definable (open) channels	0, closed system	0, closed system	0, closed system
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	3/400 or 100 depending on the conjugate type	3/400 or 100 depending on the conjugate type	8/400, 100, or 50 depending on the conjugate type
Shortest/Median onboard reagent stability/Refrigerated onboard	5 days/1 year/yes (2°–8°C)	5 days/1 year/yes (2°–8°C)	5 days/1 year/yes (2°–8°C)
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	yes (wash solution requires preparation)	yes (wash solution requires preparation)	yes
Reagents bar coded/Information in bar code	yes/product name, lot No., expiration date	yes/product name, lot No., expiration date	yes/product name, lot number, expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/—	no/zero carryover (disposable sample tips)	no/0 (disposable sample tips)
Walkaway capacity in minutes/Specimens/Tests-assays	470/50 simultaneously/370 tests	460/200 simultaneously/2,400 tests	470/800 simultaneously (370 tests)/6,400 tests
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid	no/liquid
Uses disposable cuvettes/Maximum number stored	no/—	no/—	no/—
Uses washable cuvettes/Replacement frequency	—	—	—
Minimum specimen volume required	40 μ L for ImmunoCAP tests and 20 μ L for ELiA tests	40 μ L per test	40 μ L for ImmunoCAP tests and 20 μ L for ELiA tests
Minimum sample vol. aspirated precisely at once/Minimum dead volume	40 μ L/40–200 μ L for ImmunoCAP tests and 50 μ L/50–200 μ L for ELiA tests (varies with tube type)	40 μ L/40–200 μ L (varies with tube type)	40 μ L/40–200 μ L for ImmunoCAP tests and 50 μ L/50–200 μ L for ELiA tests (varies with tube type)
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/yes
Requires dedicated water system/Water consumption	no/10 L	no/10 L	yes/121 L
Noise generated	65 decibels	68 decibels	64 decibels
Has dedicated pediatric sample cup/Dead volume	no/—	no/—	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10–17 mm x 50–105 mm/no	yes/10–17 mm x 50–105 mm/no	yes/10–17 mm x 50–105 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per CLSI standard Auto2A	no	no	no
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	yes/yes	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	no/yes	yes/yes
Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	no/no	no/no
Time between initial result and reaspiration of sample for rerun	100 minutes	100 minutes	100 minutes
Autocalibration or autocalibration alert	yes	yes	yes
Number of calibrators required for each analyte	6 per analyte for calibration run, and 2 per analyte when using stored curve	6 per analyte for calibration run, and 2 per analyte when using stored curve	5 or 6 per analyte for calibration run (assay dependent), and 2 per analyte when using stored curve
Calibrants can be stored onboard/Average calibration frequency	yes/28 days or sooner if conjugate lots change	yes/28 days or sooner if conjugate lots change	yes/28 days or sooner if conjugate lots change
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes	yes/yes
How often QC required	once per work shift (user defined)	once per work shift (user defined)	once per work shift (user defined)
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/30 minutes unattended	yes/yes/30 minutes unattended	yes/yes/30 minutes unattended
Stat time to completion of β -hCG test	—	—	—
Time delay from ordering stat test to aspiration of sample	6 minutes	6 minutes	—
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	20 specimens/60 (100 minutes to first result, then 1 result per 60 seconds)	80 specimens/240 (100 minutes to first result, then 1 result per 15 seconds)	160 specimens/480 (100 minutes to first result, then 8 results per 15 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (instrument side only)	onboard/yes (instrument side only)	onboard/—
LIS interfaces up and running in active user sites	Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others	Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others	Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, HL7, others
LIS interface operates simultaneously with running assays	yes	yes	yes
Bidirectional interface capability	yes (broadcast download and host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	yes	yes	yes
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	<24 hours	<24 hours	<24 hours
Mean time between failures/To repair failures	—	—	—
Average time to complete maintenance by lab personnel	daily: 1 minute; weekly: 10 minutes; monthly: 15 minutes	daily: 1 minute; weekly: 10 minutes; monthly: 15 minutes	daily: 1 minute; weekly: 10 minutes; monthly: 15 minutes
Onboard maintenance records/Maintenance training demo module	yes/—	yes/—	yes/—
List price/Targeted bed size or daily volume	\$75,000/>20,000–95,000 tests per year	\$235,000/>95,000 tests per year	—/>200,000 tests per year
Annual service contract cost (24 hours/7 days)	—	—	—
Training provided with purchase/Advanced operator training	3.5 days at vendor offices/yes	4.5 days at vendor offices/yes	—/yes
Distinguishing features (supplied by vendor)	provides accepted technology for serologic, specific IgE testing with the ImmunoCAP family of products and autoimmune markers with the ELiA family of products; comprehensive clinical and technical research and extensive medical information and education	provides accepted technology for serologic, specific IgE testing with the ImmunoCAP family of products; comprehensive clinical and technical research and extensive medical information and education; measures and reports specific IgE quantitative results across the clinical range	continuous random access analyzer provides more than 6,000 tests in one run; high-throughput instrument optimized for cost-conscious laboratories; efficient and flexible to meet allergy and autoimmune assay testing needs

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Automated immunoassay analyzers

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See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	Phadia Laboratory System 5000/2004/Sweden Japan/Sweden — continuous random access/floor-standing/racks 71 x 236 x 47 + 26-inch wide computer stand/77	AIA-2000/2008/Japan Japan/Japan 50/400 continuous random access/floor-standing/rack, sorter drawer 49.6 x 59.1 x 35.7/14.66	AIA-900/2011/Japan Japan/Japan 30/300 continuous random access/floor-standing/rack 35.04, 50.79, or 58.64 x 26.18 x 49.09/6-10
Tests available on instrument in U.S. Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Tests in development Tests not available on other manufacturers' analyzers	hundreds of ImmunoCAP specific IgE allergens, immunoCAP total IgE, tryptase and immunoCAP TG and TPO, ELiA autoimmune products currently include: CCP, dsDNA, symphony ANA Screen, 7 individual ENAs, celikey (tissue transglutaminase) IgA/IgG, gliadin (deamidated and native) IgA/IgG, RF IgM/IgA, cardiolipin IgM/IgG, β -2-glycoprotein I IgM/IgG/IgA cardiolipin IgA EEliA PR3S, GMB, MPO, EliA CTD screen (14 ENAs), Pm/Sci, EliA Anti IgA, EliA calprotectin, others	TSH 3rd-Gen, TSH, FT4, FT3, T4, T3, T-uptake, TPOAb, TgAb, bHCG, estradiol, FSH, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, beta 2 microglobulin, C-peptide, cortisol, hGH, IgEII, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen, ferritin, folate, B12, testosterone, CA 19-9, intact PTH, RBC folate, cystatin C, ACTH, DHEA-S, homocysteine — BNP, HBsAg, HBsAb, HbCag, HbCAb, HBeAg, cTnl third generation, PSA II, TrAb, HCVAb, HCG, free PSA	TSH, TSH3rdGen, T4, TT3, TU, FT4, FT3, TPOAb, TgAb, BHCG, estradiol, FSH, LHII, progesterone, prolactin, testosterone, AFP, CEA, PSA, CA125, CA19-9, 27.29, B2 microglobulin, C-peptide, insulin, IgEII, PAP, cortisol, HGH, B12, folate, RBC folate, ferritin, intact PTH, CK-MB, myoglobin, cTnl2ndGen, HbA1c, cystatin C, ACTH, DHEA-S, homocysteine — BNP, HBsAg; HBsAb, HbCAb, HBeAb, cTnl third generation, PSAII, TrAb, HCVAb, HCG, free PSA
Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate	no — —	no — —	no — —
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum specimen volume required Minimum sample vol. aspirated precisely at once/Minimum dead volume Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead volume Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result and reaspiration of sample for rerun Autocalibration or autocalibration alert Number of calibrators required for each analyte Calibrants can be stored onboard/Average calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	fluorescence/coated microwell, fluoroenzyme immunoassay, ImmunoCAP cellulose polymer matrix reaction wells up to 8 not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory 0, closed system 8/400, 100, or 50 depending on the conjugate type 5 days/1 year/yes (2°-8°C) yes yes yes/product name, lot number, expiration date no/0 (disposable sample tips) 470/800 simultaneously (370 tests)/9,200 tests no/liquid no/— — 40 μ L for ImmunoCAP tests and 50 μ L for EliA tests 40 μ L/40-200 μ L for ImmunoCAP tests and 50 μ L/50-200 μ L for EliA tests (varies with tube type) yes/yes yes/215 L 64 decibels no/— yes/10-17 mm x 50-105 mm/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes no yes yes/yes yes yes/yes no/no yes/yes no/no 100 minutes yes 5 or 6 per analyte for calibration run (assay dependent), and 2 per analyte when using stored curve yes/28 days or sooner if conjugate lots change yes/yes once per work shift (user defined) yes/yes yes/yes/30 minutes unattended	fluorescence/bead 48 48 0 48/— (this is a unitized test cup) 72 hours/72 hours/no yes yes yes/lot No., test code no/zero 172/200/960 no/dry no/— no/— 500 μ L tube, 100 μ L cup 10 μ L/500 μ L tube, 100 μ L cup yes/no no/— — no/— yes/7mL and 10 mL or 15 x 75 and 100, 13 x 75 and 100/no yes (2 or 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no varies no 2 or 6 (analyte dependent) no/90 days yes/yes 24 hours yes/yes no/no/5 minutes	fluorescence, enzyme immunoassay/bead 45 entire menu — unitized test cup/unitized test cup 72 hours/3 days/no no yes yes/test, lot no/zero, disposable tips 30/45/45 no/dry no/— no/— 10 μ L 10 μ L/100 μ L yes/no no/— — no/— yes/13 x 75, 100; 16 x 75, 100/no yes (2 or 5 interleaved, Codabar, codes 39 and 128)/yes — yes yes/yes yes yes/no no/no yes/yes yes/no 20 minutes no 2 or 6 no/90 days yes/yes 24 hours no/yes no/no/10 minutes
Stat time to completion of β -hCG test Time delay from ordering stat test to aspiration of sample Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface LIS interfaces up and running in active user sites LIS interface operates simultaneously with running assays Bidirectional interface capability Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component Can order (via modem) malfunctioning part(s) without operator On-site response time of service engineer Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	— — 320 specimens/960 (100 minutes to first result, then 8 results per 15 seconds) yes/yes onboard/— Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, HL7, others yes yes (broadcast download and host query) yes yes/yes/yes no <24 hours — daily: 1 minute; weekly: 10 minutes; monthly: 15 minutes yes/—	~18 minutes 40 seconds 66/200 (18 seconds) yes/yes —/no — yes yes (broadcast download and host query) yes (Hitachi, A&T, Bayer, Thermo, iLAS) no/no/no no 24 hours 5 months/24 hours daily: 5 minutes; weekly: 5 minutes yes, includes audit trail/no	~18 minutes 1 minute 30/90 (0.67 minute sample cycle) yes/no no/no all major LIS suppliers yes yes (broadcast download and host query) no no/no/no no 24 hours — daily: 5 minutes; weekly: 15 minutes; monthly: 20 minutes no/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided with purchase/Advanced operator training	—/>>400,000 tests per year — —/yes	\$185,000/65+ beds, 1,500-2,000 tests depends on acquisition option 4 days at vendor office/no	\$60,000 base model/500+ monthly \$6,000 base model —/no
Distinguishing features (supplied by vendor)	continuous random access analyzer provides more than 9,000 tests in one run; high throughput; efficient and flexible to meet allergy and autoimmune assay testing needs	available in two models: standard and LA; unitized test cups similar to all AIA systems; three separate incubators to minimize processing time; no reagent preparation; dual clot detection, automated sample dilution, and pretreatment; appropriate for stat and routine use	three models available (base model, base model plus nine-tray sorter, base model plus 19-tray sorter) offer increasing automation and capacity; connections and software built in for all three models; unitized test cups, no reagent preparation; automated sample dilution, pretreatment, automated reschedule, retest

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

Automated immunoassay analyzers

Part 21 of 21	TOSOH Bioscience Inc. Shanti Narayanan shanti.narayanan@tosoh.com 6000 Shoreline Court, Suite 101 South San Francisco, CA 94080 800-248-6764 www.tosoh.com	TOSOH Bioscience Inc. Susan Kolarik susan.kolarik@tosoh.com 6000 Shoreline Court, Suite 101 South San Francisco, CA 94080 800-248-6764 www.tosoh.com	TOSOH Bioscience Inc. Susan Kolarik susan.kolarik@tosoh.com 6000 Shoreline Court, Suite 101 South San Francisco, CA 94080 800-248-6764 www.tosoh.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	AIA-360/2004/Japan Japan/Japan 1,500/4,000 continuous random access/benchtop/carousel	AIA-1800/2003/Japan Japan/Japan 80/550 continuous random access/floor-standing/rack, sort drawer, standard and LA	AIA-600 II/2000/Japan Japan/Japan 680/1,600 continuous random access/benchtop/chain
Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	21 x 19 x 16/2.1	65 x 50 x 37/12.8	19.8 x 31.6 x 29.1/6.4
Tests available on instrument in U.S.	10 minutes short time (ST) assays: TSH, FT4, T3, T4, T-uptake, FT3, β -hCG, estradiol, FSH, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, β -2-microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I second generation, ferritin, testosterone, CA 19-9, intact PTH, cystatin C, HbA1c, ACTH, DHEA-S, homocysteine	TSH, 3rd-gen. TSH, FT4, T3, T4, T-uptake, FT3, TPO Ab, Tg Ab, β hCG, estradiol, FSH, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, β -2-microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I second generation, ferritin, folate, B12, testosterone, CA 19-9, RBC folate, intact PTH, cystatin C, ACTH, DHEA-S, homocysteine	TSH, 3rd-gen. TSH, FT4, T3, T4, T-uptake, FT3, TPO Ab, Tg Ab, β -hCG, estradiol, FSH, hCG, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, β -2-microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I second generation, ferritin, folate, B12, testosterone, CA 19-9, intact PTH, RBC folate, cystatin C, HbA1c, ACTH, DHEA-S, homocysteine
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	— BNP, HBsAg, HBsAb, HbCag, HbCAb, HBeAg, cTnI third generation, PSA II, TrAb, HCVAb, HCG, free PSA	— BNP, HBsAg, HBsAb, HbCag, HbCAb, HBeAg, cTnI third generation, PSA II, TrAb, HCVAb, HCG, free PSA	— HBsAg, HBsAb, HBeAg, HbcAb, HbeAb, BNP, cTnI third generation, PSA II, TrAb, HCVAb, HCG, free PSA
Tests in development Tests not available on other manufacturers' analyzers	— D-dimer, Tg	— vitamin D, D-dimer, Tg	—
Fully automated microplate system	—	—	no
Number of each analyte performed in separate disposable unit	—	—	—
Number of wells in microplate	—	—	—
Methods supported/Separation methods	fluorescence, EIA/bead	fluorescence, EIA/bead	fluorescence, EIA/bead
No. of different measured assays onboard simultaneously	25	31 trays	26
No. of different assays programmed, calibrated at once	entire menu	entire menu	entire menu
No. of user-definable (open) channels	0	0	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	—/unitized test cup	—/unitized test cup	—/unitized test cup
Shortest/Median onboard reagent stability/Refrigerated onboard	72 hours/72 hours/—	72 hours/72 hours/—	72 hours/72 hours/—
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	yes	yes	yes
Reagents bar coded/Information in bar code	yes/lot No., test code	yes/lot No., test code	yes/lot No., test code
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover	no/zero carryover	no/zero carryover
Walkaway capacity in minutes/Specimens/Tests-assays	58/25/25	58/170/640	52/26/26
System is open (home-brew methods can be used)/Liquid or dry system	no/dry	no/dry	no/dry
Uses disposable cuvettes/Maximum number stored	no	—/unitized test cup	—/unitized test cup
Uses washable cuvettes/Replacement frequency	—	—	—
Minimum specimen volume required	500 μ L tube, 100 μ L cup	500 μ L tube, 100 μ L cup	500 μ L tube, 100 μ L cup
Minimum sample vol. aspirated precisely at once/Minimum dead volume	10 μ L/500 μ L tube, 100 μ L cup	10 μ L/500 μ L tube, 100 μ L cup	10 μ L/500 μ L tube, 100 μ L cup
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/no	yes/no
Requires dedicated water system/Water consumption	no/—	no/—	no/—
Noise generated	—	—	—
Has dedicated pediatric sample cup/Dead volume	no/—	no/—	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/primary draw tubes: 13 x 75 and 100; 16 x 75 and 100/no	yes/primary draw tubes: 7 mL and 10 mL or 15 x 75 and 100; 13 x 75 and 100/no	yes/primary draw tubes: 7 mL and 10 mL or 15 x 75 and 100, 13 x 75 and 100/no
Sample bar-code reading capability/Autodiscrimination	yes/yes	yes/yes	yes/yes
Bar-code placement per CLSI standard Auto2A	yes	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	yes/no	yes/yes	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	no/no	yes/yes	yes/no
Sample volume can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	no/no	no/yes
Time between initial result and reaspiration of sample for rerun	—	varies	—
Autocalibration or autocalibration alert	no	no	no
Number of calibrators required for each analyte	2 or 6 (analyte dependent)	2 or 6 (analyte dependent)	2 or 6 (analyte dependent)
Calibrants can be stored onboard/Average calibration frequency	no/90 days	no/90 days	no/90 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes	yes/yes
How often QC required	24 hours	24 hours	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/no	yes/yes	no/no
Automatic shutdown/Startup is programmable/Startup time	no/no/5 minutes	no/no/5 to 8 minutes	no/no/5 minutes
Stat time to completion of β -hCG test	~18 minutes	~18 minutes	~18 minutes
Time delay from ordering stat test to aspiration of sample	60 seconds	40 seconds	60 seconds
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	12/36 (1 minute)	60/180 (20 seconds)	20/60 (1 minute)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/no	yes/yes	yes/no
Data-management capability/Instrument vendor supplies LIS interface	Antek, Schuyler House, more	yes/no	optional add-on (all major LIS vendors—Schuyler House, Misys, LabForce, McKesson, Antrim, Data Innovations)/yes (additional cost)
LIS interfaces up and running in active user sites	—	yes	Schuyler House, Fletcher Flora
LIS interface operates simultaneously with running assays	—	yes	yes
Bidirectional interface capability	no	yes (broadcast download and host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	no	yes (Hitachi, Siemens, Thermo, iLAS)	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/no/no	no/no/no	no/no/no
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	—	24 hours	24 hours
Mean time between failures/To repair failures	>6 months/24 hours	5 months/24 hours	98 percent uptime/—
Average time to complete maintenance by lab personnel	daily: 5 minutes	daily: 5 to 8 minutes; weekly: 5 minutes; monthly: none	daily: 5 minutes; weekly: 5 minutes; monthly: none
Onboard maintenance records/Maintenance training demo module	no/no	yes (includes audit trail of who replaced parts)/no	no/no
List price/Targeted bed size or daily volume	\$25,000/200 to 1,000 tests per month	\$175,000/65+ beds, 1,500 to 2,000 tests	\$70,000/500–2,500 tests per month
Annual service contract cost (24 hours/7 days)	\$2,050–\$3,500	\$11,458	\$5,941
Training provided with purchase/Advanced operator training	training DVD; on-site install	4 days at vendor offices/no	3 days at vendor offices/no
Distinguishing features (supplied by vendor)	unitized test cups; primary tube sampling; no reagent preparation, room-temperature stability for five days; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use; compact size; four tests per sample; random access	two models: standard and LA; unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room-temperature stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use	unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room-temperature stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use

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