

Automated immunoassay analyzers

Part 1 of 24	Abbott Diagnostics Pamela Sunderman pamelasunderman@abbott.com 100 Abbott Park Rd, CP1-4, Abbott Park IL, 60064 847-937-4689 www.abbottdiagnostics.com	Abbott Diagnostics Pamela Sunderman pamelasunderman@abbott.com 100 Abbott Park Rd, CP1-4, Abbott Park IL, 60064 847-937-4689 www.abbottdiagnostics.com
<i>See accompanying article on page 14</i>		
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.	AxSYM/AxSYM Plus/1993 worldwide, 1994 U.S./U.S. U.S./U.S. 946/7,554	ARCHITECT i2000/1998, i2000SR/2003, i4000SR/2007/U.S. U.S., Japan/U.S., Europe 475/5,625
Operational type/Model type/Sample handling system	continuous random access/stat, batch floor-standing/segment	batch, random access, continuous random access/floor-standing/track and LAS
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	60.5 × 63 × 33.5/14.6	48 × 61 × 49/20.3, i2000, 48 × 68 × 44/22.7 per module
Tests available on instrument in U.S.	AFP, CA 125, CA 15-3, CEA, free PSA, total PSA, BNP, CK-MB, myoglobin, troponin-I, CMV IgG, rubella IgG, rubella IgM, Toxo IgG, Toxo IgM, acetaminophen, amphetamine/methamphetamine, barbiturates II U, benzodiazepines, cannabinoids, cocaine metabolite, methadone, opiates, phencyclidine (PCP), REA ethanol, salicylate, tricyclic antidepressants, many others	folate, HIV Ag/Ab Combo, 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
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	— CA 19-9, D-dimer, CMV IgG, HBe, beta2 microglobulin, insulin, digitoxin, third generation TSH, cyclosporine, others	B12, vitamin D AFP, anti-HAV IgG, vitamin B12, NGAL, proGRP, MPO, SCC, anti-HAV IgG, anti-HBe, HBeAg, CMV IgG, CMV IgG avidity, others
Tests in development	—	carbamazepine, gentamicin, methotrexate, Tg, vitamin D
Tests not available on other manufacturers' analyzers	—	—
Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate	no — —	no — —
Methods supported/Separation methods	FPIA, MEIA, ion capture, REA/heterogen., bead (microparticle), fiber matrix filter	CHEMIFLEX (enhanced chemiluminescence) with 5 flexible protocols/magnetic microparticle
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	20 20 0 20/100	25 25 — 25/100-test and 500-test per kit
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	onboard reagent stability: 112, 224, 336/no no yes yes/assay name, reagent lot No., expiration date, pack No. ID	—/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
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	no/<0.1 ppm 60/90/90 no/liquid yes/90 reaction vessels	no/<0.1ppm 300/135/12,500 no/liquid yes/1,200
Uses washable cuvettes/Replacement frequency Minimum specimen volume required Minimum sample vol. aspirated precisely at once/Minimum dead volume	no/— 83 µL/150 µL 10 µL/73 µL for sample cup, 450 µL for aliquot, 4.5 mL for primary	no/— 50 µL 150 µL/50 µL for all tube types
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	yes (soft close of files only)/optional no/— 52-68 decibels no yes/100 and 75 mm/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 seconds no 6 pt. or 2 pt. w/ master calib., 6 pt., index calib. no/4 weeks yes/yes (up to 4 curves/analyte) shortest interval: 8 hours, longest: 24 hours	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 no/no yes/yes no/no <20 seconds yes 2-6 pt. curve no/cal required with new lot yes/yes (up to 4 curves/analyte) 3 levels every 24 hours for quantitative, 2 levels for qualitative
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes/yes no/no/1 minute	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	10 minutes 30 seconds from standby 68-120 tests/flexible platform—load list dependent (assay dependent) yes/yes onboard/no all major LIS vendors yes yes (broadcast download and host query) yes no/yes/yes yes, AbbottLink per negotiated contract 13 weeks /per negotiated contract daily: 14 minutes; weekly: 65 minutes; monthly: 11 minutes	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 10.4 weeks/per negotiated contract daily: 16 minutes; weekly: <10 minutes; monthly: none (for both manual and auto procedures) yes/yes
Onboard maintenance records/Maintenance training demo module	no/no	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	\$124,000/up to 200 immunoassays tests per day flexible options available yes/yes	\$169,500/>200 immunoassays per day flexible options available yes/yes
Distinguishing features (supplied by vendor)	menu, reliability, online exception help, pressure monitoring, foam avoidance, ratio calculation, stat turnaround time; refer to operations manual for operational precautions, limitations, and hazards	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
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>		

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Part 2 of 24	Abbott Diagnostics Pamela Sunderman pamelasunderman@abbott.com 100 Abbott Park Rd, CP1-4, Abbott Park IL, 60064 847-937-4689 www.abbottdiagnostics.com	Abbott Diagnostics Pamela Sunderman pamelasunderman@abbott.com 100 Abbott Park Rd, CP1-4, Abbott Park IL, 60064 847-937-4689 www.abbottdiagnostics.com
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.	ARCHITECT ci4100 (2009), ci8200 (2003), ci16200 (2007)/U.S. U.S., Japan/U.S., Europe 164/396 (c4000), 394/1809 (c8000), 19/355 (c16000)	ARCHITECT i1000SR/2008/U.S. U.S., Japan/U.S., Europe 370/2,380
Operational type/Model type/Sample handling system	batch, random access, continuous random access/floor-standing/robotic sample handler uses multi-dimensional sample handling	continuous random access/floor-standing/robotic sample handler allows batch, random access, continuous access and reagent loading and unloading
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	48 × 127 × 49/43.2	49 × 59 × 30/14.7
Tests available on instrument in U.S.	folate, HIV Ag/Ab Combo, 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	folate, HIV Ag/Ab combo, 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
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	B12, vitamin D AFP, HE-4, proGRP, NGAL, B12, vitamin D, anti-HAV IgG, anti-HBc, anti-HBs, HBsAg, HBsAg confirmatory, many others	B12, vitamin D AFP, ProGRP, NGAL, vitamin B12, vitamin D, anti-HAV IgG, anti-HBc, anti-HBs, HBsAg, HBsAg confirmatory, others
Tests in development	AFP, anti-HAV IgG, anti-HBc, NGAL, carbamazepine, gentamicin, methotrexate, Tg	AFP, anti-HAV IgG, anti-HBc, NGAL, carbamazepine, fentamicin, methotrexate, Tg
Tests not available on other manufacturers' analyzers	—	—
Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate	— — —	— — —
Methods supported/Separation methods	photometric, potentiometric, and CHEMIFLEX (enhanced chemiluminescence)/—	chemiluminescence/magnetic particle
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	80–93, based on analyzer 80–93, based on analyzer 220 93/50–1,700	25 25 none 25/25–100
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	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	—/30 days tracked in hours/yes yes yes yes/assay No., reagent serial No., lot No., test per kit, exp. onboard stability time, others
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	open system/SmartWash technology 300/367/>75,000 yes/liquid both disposable and semi-permanent glass/1,200 or 165/330	no/<0.1 ppm 3 hrs/65/25 no/liquid yes/360
Uses washable cuvettes/Replacement frequency Minimum specimen volume required Minimum sample vol. aspirated precisely at once/Minimum dead volume	yes/as needed, 1-year minimum 2 µL 50 µL	no/— 60 µL 60 µL/50 µL
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	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 pt. no/IA: calibration with new lot, CC: 28 days yes/yes from 2 levels after calibration, to 3 per 24 hours	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 pt. curve no/calibration required with new lot yes/yes from 2 levels for qualitative to 3 levels every 24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	yes/yes —/no/10 minutes	yes/yes no/no/6.5 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) 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 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 21 (c4000), 17 (c8000), 13 (c16000)/per negotiated contract daily: <15 minutes; weekly: <35 minutes; monthly: 15 minutes (for manual and automated procedures) yes/yes	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 per negotiated contract 26 weeks/per negotiated contract daily: 10 minutes; weekly: 17 minutes; monthly: 90 minutes 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	\$375,000/200–500 immunoassay tests per day flexible options available yes/yes	\$125,000/40–250 tests per day flexible options available yes/yes
Distinguishing features (supplied by vendor)	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	streamlined workload mgmt., contin. access to reagents, samples, and supplies, 65 samples load cap., 13 universal bay, up to 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; refer to operations manual for operational precautions, limitations, and hazards
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>		

Automated immunoassay analyzers

Part 3 of 24	Alere Jon Rutherford jon.rutherford@alere.com 2 Research Way, Princeton, NJ 08540 877-441-7440 www.alere.com	Alere Jon Rutherford jon.rutherford@alere.com 2 Research Way, Princeton, NJ 08540 877-441-7440 www.alere.com	Alere Jon Rutherford jon.rutherford@alere.com 2 Research Way, Princeton, NJ 08540 877-441-7440 www.alere.com
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	AtheNA/2002/U.S. U.S./U.S. 150/— batch/benchtop/multichannel pipetting or automated with front end	AIMS/2007/Switzerland Switzerland/U.S. 15/— batch/benchtop/rack	DS2/2007/U.S. U.S./U.S. — batch/benchtop/rack
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	9.5 × 17 × 20/—	40 × 67 × 35/—	27 × 21 × 26/4
Tests available on instrument in U.S.	AtheNA Multi-Lyte multiplexing assays, including: ANA (ANA, dsDNA, SS, SSB, Sm, RNP, Scl-70, Jo-1, centromere B, histones), autoimmune vasculitis (MPO, PR3, GBM), TPO/Tg (thyroid peroxidase, thyroglobulin), RF IgM (rheumatoid factor), EBV IgG (viral capsid antigen, EBNA-1, EA), EBV IgM (VCA), MMRV IgG (measles, mumps, rubella, varicella-zoster), MMV IgG (measles, mumps, many others ToRCH IgG, borrelia VisE-1/pepC10	AtheNA Multi-Lyte multiplexing assays, including: ANA (ANA, dsDNA, SS, SSB, Sm, RNP, Scl-70, Jo-1, centromere B, histones), autoimmune vasculitis (MPO, PR3, GBM), TPO/Tg (thyroid peroxidase, thyroglobulin), RF IgM (rheumatoid factor), EBV IgG (viral capsid antigen, EBNA-1, EA), EBV IgM (VCA), MMRV IgG (measles, mumps, rubella, varicella-zoster), MMV IgG (measles, mumps, many others ToRCH IgG, borrelia VisE-1/pepC10	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. leuko
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	—	—	—
Tests in development	HIV-1, cardiolipin IgG, syphilis	HIV-1, cardiolipin IgG, syphilis	—
Tests not available on other manufacturers' analyzers	—	—	enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leukocyte
Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate	no 1-10 minimum strip: 1; maximum full plate: 96-well plate	yes assay dependent minimum strip: 8; maximum full plate: 96-well plate	yes 1 analyte per well, multiple analytes per well 96 (minimum: 1; maximum: 96)
Methods supported/Separation methods	fluorescence/bead	enzyme immunoassay, multiflexing/bead, coated microwell	enzyme immunoassay/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	10 10 0 —/96 —/—/no	4 multiple unlimited 4/96 —/—/no	24 24 unlimited 18/24 8 hours/1 day/no
Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code	no no, requires operator prehandling/preparation no/—	yes yes no/—	yes placed directly on system no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays	no/<0.9% 30 ±10/—/—	yes/3% assay dependent/240/4	no/0 120 minutes/98/24
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	open/liquid no/— no/— 10 µL — yes/no no/— —	open/liquid no/— no/— 210 µL based on 16-mm tube 10 µL/200 µL based on 16-mm tube yes/no no/— —	yes/liquid no/— no/— 10 µL 10 µL/50 µL no/no no/— —
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	no/— no/—/— yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes no — — — no/no — — yes 5 per well no/calibration in every well yes/no 1 per month no/— no/no/30 minutes	no/— yes/10 × 16 mm outer dimensions/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/— — yes no/yes yes yes/no no/no yes/no — — 5 per well no/calibration in every well yes/no every assay —/yes yes/yes/10 minutes	no/— yes/primary, pouroff/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes no/yes yes yes/no no/no yes/no no/no no analyte dependent no/within each run no/no with every assay no/yes yes/yes/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) 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	— — 48/84 no/yes yes, onboard/yes (additional cost) Cerner, Sunquest no no yes, AIMS no/—/— — 24-48 hours 6 months/<1 day daily: 15 minutes; weekly: 30 minutes; monthly: 5 minutes no/—	— — assay dependent/—/— —/yes yes, onboard/yes (additional cost) — no — — no/—/— — 24-48 hours — daily: 15 minutes; weekly: 20 minutes; monthly: 20 minutes no/—	— — —/— yes/yes onboard/yes (additional cost) Cerner, Millenium, Sunquest, Soft, Mysis, etc. yes yes (host query) no no/yes/no no 24 hrs — (recently launched)/— daily: 5 minutes; weekly: 20 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	\$60,000/8 tests per day \$8,000 yes/—	\$149,900/>150 beds \$19,500 5 days on site/—	\$48,200/<350 beds \$9,000 3 days on site/yes
Distinguishing features (supplied by vendor)	large FDA-cleared menu on the Luminex platform; every sample has a unique calibration curve generated at the time the beads are read; at least 50 discrete readings for every analyte in every test system	fully automated integrated open system that allows processing of Athena Multi-Lyte multiplexing assays and ELISA on one platform	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

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

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Part 4 of 24	Alere Jon Rutherford jon.rutherford@alere.com 2 Research Way, Princeton, NJ 08540 877-441-7440 www.alere.com	Awareness Technology Inc. Robert Guerin info@awaretech.com 1935 SW Martin Hwy., Palm City, FL 34990 772-283-6540 www.awaretech.com	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Blvd, Brea, CA 92821 714-961-3140 www.beckmancoulter.com
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	DSX/2004/U.S. U.S./U.S. approx. 500/— batch/benchtop/rack	ChemWell/1998/U.S. U.S./open system 50+/2,500+ batch, random access/benchtop/rack	Access/Access 2 Immunoassay System/2001/U.S. U.S./U.S, France, Ireland >2,400/>4,000 continuous random access/benchtop/rack
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	32 × 42 × 36/7	16 × 34 × 20/4	18.5 × 39 × 24/6.5
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, ds-DNA, 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	cortisol, total IgE, EPO, ferritin, folate, intrinsic factor Ab, sTR, 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	—	unlimited—open system	HAV Ab, HAV IgM, Hbc Ab, Hbc IgM, HBs Ab, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM
Tests in development	—	—	vitamin D, PIGF, sFit-1
Tests not available on other manufacturers' analyzers	enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko	—	—
Fully automated microplate system	yes	yes	no
Number of each analyte performed in separate disposable unit	1 analyte per well, multiple analytes per well	up to 12	—
Number of wells in microplate	96 (minimum: 1; maximum: 96)	minimum strip, 8; maximum full plate, 96	—
Methods supported/Separation methods	enzyme immunoassay/coated microwell	EIA/coated microwell	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	48	up to 12	24
No. of different assays programmed, calibrated at once	48	unlimited	24
No. of user-definable (open) channels	unlimited	unlimited	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	24/48	27/assay dependent	24/100 tests per kit; 50 tests per cartridge
Shortest/Median onboard reagent stability/Refrigerated onboard	8 hours/1 day/no	assay dependent/assay dependent/yes (10°C below ambient)	336 hours/28 days/yes (3°–10°C)
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	placed directly on system	yes	yes
Reagents bar coded/Information in bar code	no/—	no	yes/specific cartridge ID, expiration date, lot No., unique reagent pack ID No.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/0	no/none	no/<10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	120 minutes/98/48	assay dependent/96/12	up to 180 based on consumable capacity/60/assay dependent
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	no/—	yes/96	yes/294
Uses washable cuvettes/Replacement frequency	no/—	yes/assay dependent	no/—
Minimum specimen volume required	10 µL	2 µL	specimen container dependent
Minimum sample vol. aspirated precisely at once/Minimum dead volume	5 µL/50 µL	2 µL/—	5 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no	no/no
Requires dedicated water system/Water consumption	no/—	no/—	no/—
Noise generated	—	—	<70 decibels
Has dedicated pediatric sample cup/Dead volume	no/—	no/—	yes/100 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/primary, pouroff/no	yes/12 × 100 mm/no	yes/12 × 75, 13 × 75 and 100, 16 × 75 and 100/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	no/—	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	no
Measures No. of tests remaining/Short sample detection	no/yes	no/no	yes/yes
Auto detection of adequate reagent or specimen	yes	yes	yes
Clot detection/Reflex testing capability	yes/no	no/yes	yes/yes (Access 2 only)
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no	no/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	yes/yes	no/no
Time between initial result and reaspiration of sample for rerun	—	assay dependent	36 seconds
Autocalibration or autocalibration alert	no	no	no
Number of calibrators required for each analyte	analyte dependent	assay dependent	assay dependent
Calibrants can be stored onboard/Average calibration frequency	no/within each run	yes/assay dependent	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	no/no	yes/yes	yes/yes
How often QC required	with every assay	shortest interval: each run; longest: daily	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/5 minutes	yes/yes/2 minutes	no/no/remains in ready mode
Stat time to completion of β-hCG test	—	assay dependent	15 minutes
Time delay from ordering stat test to aspiration of sample	—	30 seconds	≥36 seconds
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	—	assay dependent/—	33/100 (36 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 (included)	onboard/yes (included or additional cost—negotiable)
LIS interfaces up and running in active user sites	Cerner, Millenium, Sunquest, Soft, Mysis, etc.	—	all major LIS vendors
LIS interface operates simultaneously with running assays	yes	no	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	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/no	yes/yes/yes	no/no/no
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	24 hours	within 48 hours	per negotiated service contract
Mean time between failures/To repair failures	4 months/2 hours	—	—
Average time to complete maintenance by lab personnel	daily: 10 minutes; weekly: 20 minutes; monthly: 20 minutes	daily: <10 minutes; weekly: <10 minutes; monthly: <10 minutes	daily: 15 minutes; weekly: 30 minutes
Onboard maintenance records/Maintenance training demo module	no/no	no/no	yes (Access 2 only)/online help with maintenance instructions
List price/Targeted bed size or daily volume	\$76,660/>350 beds	\$25,000/up to 500 tests per day	\$149,800/all volumes and hospital sizes
Annual service contract cost (24 hours/7 days)	\$10,000	\$4,000	\$15,800
Training provided with purchase/Advanced operator training	3 days on site/no	3 days on site/no	yes/yes (Access 2 only)
Distinguishing features (supplied by vendor)	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	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

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 24	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Blvd, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Blvd, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Blvd, Brea, CA 92821 714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold/Where designed	UniCel DxI 600 Access Immunoassay System/2007/U.S.	UniCel DxI 800 Access Immunoassay System/2003/U.S.	UniCel DxC 600i Synchron Access Clinical System/2006/U.S.
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., France, Ireland >200/>100 continuous random access/floor standing/rack, direct track sampling	U.S./U.S., France, Ireland >500/>500 continuous random access/floor standing/rack, direct track sampling	U.S./U.S., France, Ireland >400/100 continuous random access/floor standing/rack-closed tube
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	67 × 61.5 × 37.5/16.02	67 × 67.5 × 37.5/17.6	62 × 128 × 48/42.7
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, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM	— HAV Ab, HAV IgM, HbC Ab, HbC IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM	— HAV Ab, HAV IgM, HbC Ab, HbC IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, others
Tests in development Tests not available on other manufacturers' analyzers	vitamin D, PIGF, sFit-1 —	vitamin D, PIGF, sFit-1 —	vitamin D, PIGF, sFit-1 —
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	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)	chemiluminescence, enzyme immunoassay/magnetic particle 89 89 100 89/100 tests per kit (immunoassay); 300 tests per container (general chemistry) 336 hours/28 days/yes (3°–10°C)/yes
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, 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	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	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	yes/<10 ppm 60/76/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	no/liquid yes/1,000 no/— specimen container dependent 5 μL/80 μL no/no no/— <65 decibels	no/liquid yes/>1,000 no/— specimen container dependent 5 μL/160 μL no/no no/— <60 decibels	no/liquid yes/125 yes/— container dependent 3 μL/20 μL (general chemistry) yes/yes yes/16 L per hour —
Has dedicated pediatric sample cup/Dead volume Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/100 μL yes/12 × 75, 13 × 75 and 100, 16 × 75 and 85 and 100 mm/no	yes/100 μL yes/12 × 75, 13 × 75 and 100, 16 × 75, 85, and 100 mm/no	yes/— yes/13 × 75 and 100, 15 × 75 and 92, 16 × 100 mm/yes
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 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	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes yes/yes (general chemistry) yes/yes yes/yes chemistry dependent dependent 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 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)	15 minutes 1 minute (general chemistry) 90/720 (40 seconds) (general chemistry) yes/yes optional add-on/yes (additional cost)
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	all major LIS vendors yes yes (broadcast download and host query) yes, Beckman Coulter automation systems yes/yes/yes no per negotiated contract — daily: <10 minutes yes/online help with maintenance instructions	all major LIS vendors yes yes (broadcast download and host query) yes (Beckman Coulter automation systems) yes/yes/yes no per negotiated contract — daily: <10 minutes yes/online help with maintenance instructions	all major LIS vendors yes yes (broadcast download and host query) yes (Beckman Coulter automation systems) yes/yes/validate for the DxC 600i no per negotiated service contract — — 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	\$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	\$325,000/moderate volume, <300 samples per day per negotiated contract yes/yes
Distinguishing features (supplied by vendor)	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	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

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Automated immunoassay analyzers

Part 6 of 24	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Blvd Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Blvd Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Blvd Brea, CA 92821 714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold/Where designed	UniCel Dxl 660i Synchron Access Clinical System/2009/ U.S.	UniCel DxC 680i Synchron Access Clinical System/2009/ U.S.	UniCel Dxl 860i 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.	>75/>50	4/2	8/0
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 x W x D)/Instrument footprint in sq. feet	68 x 147 x 48/49	68 x 153 x 48/51	68 x 155 x 48/51.7
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 β hCG, 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 β hCG, 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 β hCG, 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, rubella IgM	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	115	115	120
No. of different assays programmed, calibrated at once	115	115	120
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	115/100 tests per kit (immunoassay); 300 tests per container (general chemistry)	115/100 tests per kit (immunoassay); 300 tests per container (general chemistry)	120/100 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)	336 hours/28 days/yes (2°–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	60/112/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system	closed/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 μ L/20 μ L (general chemistry)	3 μ L/20 μ L (general chemistry)	3 μ L/20 μ L (general chemistry)
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes	yes/yes
Requires dedicated water system/Water consumption	yes/up to 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 x 75 and 100, 15 x 92 and 75, 16 x 100 mm/yes	yes/13 x 75 and 100, 15 x 75 and 92, 16 x 100 mm/yes	yes/13 x 75 and 100, 15 x 75 and 92, 16 x 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
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	—/—	—/—	—
LIS interfaces up and running in active user sites	—	—	—
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/yes	yes/yes/validate for the DxC 600i	yes/yes/yes
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	\$575,000/high volume, 300–750 samples per day	\$610,000/high volume, 300–750 samples per day	\$615,000/high to very high volume, 500–1,500 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; 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	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

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 24	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Blvd 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	bioMérieux Inc. Stephane Gelin stephane.gelin@biomerieux.com 100 Rodolphe St. Durham, NC 27712 919-620-2430 www.biomerieux-usa.com
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	UniCel DxC 880i Synchron Access Clinical System/2008/U.S. U.S./U.S., France, Ireland >65/>65 continuous random access/floor standing/rack closed-tube	SPA PLUS (Specialist Protein Analyzer)/2007/Japan Japan/United Kingdom — batch, random access/two sample carousels (each holds 45 samples, 30 primary tubes, 15 non-bar-coded sample tubes/cups)	VIDAS Immunoassay Analyzer/1991/U.S. Italy/France 2,200/25,000 batch, random access/benchtop/—
Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	68 x 161 x 48/53.7	20.5 x 31.5 x 25.2/14	Vidas 30 system: 16 x 32 x 2/4.5; MiniVidas system: 21 x 21 x 17/4
Tests available on instrument in U.S.	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 β hCG, unconjugated estradiol, fast hTSH, free T3, total T4, thyroglobulin, TPOAb, PSA, free PSA, BR-GI-OV monitors and many others	freelite kappa (free kappa light chain), freelite lambda (free lambda light chain), 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	TSH, FT4, T4, T3, total PSA, HCG, LH, FSH, estradiol 2, prolactin, progesterone, testosterone, ferritin, D-dimer, procalcitonin, 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
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, rubella IgM	— CH50	— 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, PIGF, sFit-1	hevyLite IgG kappa, hevyLite IgG lambda, hevyLite IgA kappa, hevyLite IgA lambda, hevyLite IgM kappa, CSF assays, others	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	—	—	—
Methods supported/Separation methods	chemiluminescence, enzyme immunoassay/magnetic particle	turbidimetry	fluorescence, EIA/EIA coated, solid phase receptacle pipetting device
No. of different measured assays onboard simultaneously	120	24	MiniVidas: 12; Vidas: 30
No. of different assays programmed, calibrated at once	120	—	total menu
No. of user-definable (open) channels	100	—	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	120/100 tests per kit (immunoassay)/300 tests per container (general chemistry)	24/100	unit dose format 30 or 60/—
Shortest/Median onboard reagent stability/Refrigerated onboard	336 hrs/28 days/yes (2°–10°C)	672 hours/30 days/yes	—/—/no
Multiple reagent configurations supported	yes	yes	no
Reagent container placed directly on system for use	yes	yes	placed directly on system
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/—	yes/assay name, lot No., calibration, expiration
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/<10 ppm	no/—	no/zero carryover
Walkaway capacity in minutes/Specimens/Tests-assays	60/112/assay dependent	~60/45/assay dependent	assay dependent/12–30/12–30
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	closed/liquid	no/dry
Uses disposable cuvettes/Maximum number stored	no/125	no/60	no/—
Uses washable cuvettes/Replacement frequency	yes/—	yes/—	no/—
Minimum specimen volume required	container dependent	150 μ L	100–200 μ L, dependent on assay
Minimum sample vol. aspirated precisely at once/Minimum dead volume	3 μ L/20 μ L (general chemistry)	3 μ L/150 μ L	100 μ L, dependent on assay/—
Supplied with UPS (backup power)/Requires floor drain	yes/—	yes/no	yes/no
Requires dedicated water system/Water consumption	yes/up to 16 L per hour	no/3.5 L	no/—
Noise generated	—	—	—
Has dedicated pediatric sample cup/Dead volume	yes/—	no/—	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13 x 75 and 100, 15 x 75 and 92, 16 x 100 mm/yes	yes/most tube sizes, including 12 x 75 mm/no	no/—/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes (Codabar, codes 39 and 128)/—	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	no
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	no/no
Auto detection of adequate reagent or specimen	yes	yes	no
Clot detection/Reflex testing capability	yes/yes	no/no	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes (general chemistry)	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes	yes	no/no
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	chemistry dependent	<10 min	—
Autocalibration or autocalibration alert	—	yes	yes
Number of calibrators required for each analyte	assay dependent	6	—
Calibrants can be stored onboard/Average calibration frequency	no/28 days	no/—	no/14 or 28 days, assay dependent
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes	no/yes
How often QC required	24 hours	—	shortest interval: 8 hours, longest: 24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/no	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/remains in ready mode	no/no/<15 minutes	no/no/always remains ready
Stat time to completion of β -hCG test	15 minutes	—	30 minutes
Time delay from ordering stat test to aspiration of sample	1 minute (general chemistry)	—	no delay
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	90/720 (40 seconds) (general chemistry)	35/106 (10.5 minutes incubation)	—/Vidas: 20; MiniVidas: 8; Vidas: 60; MiniVidas: 24
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/no	onboard/yes (additional cost)
LIS interfaces up and running in active user sites	—	Cerner Classic, Cerner Millennium, SCC Soft Computer, Cyberlab, Sunquest, Mediatech Middleware, others	Misys, Medtech, McKesson, Advanced Lab Systems, Citation, Cerner, Dawning, Geneysis, Compulab, 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)
Interface available (or will be) to auto specimen handling system	yes, Beckman Coulter automation systems	no	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	no/no/no	no/yes/yes
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	per negotiated service contract	24 hours	within 24 hours
Mean time between failures/To repair failures	—	258 days, with 2 scheduled preventative maintenance visits/4 hrs on-site	Vidas: 350 days/MiniVidas: 1,000 days
Average time to complete maintenance by lab personnel	—	daily: <10 minutes; weekly: <10 minutes; monthly: <15 minutes	weekly: 10–15 minutes
Onboard maintenance records/Maintenance training demo module	yes/online help with maintenance instructions	no/no	yes (includes audit trail)/—
List price/Targeted bed size or daily volume	\$650,000/high to very high volume, 750–2,250 samples per day	—	—
Annual service contract cost (24 hours/7 days)	—	—	—
Training provided with purchase/Advanced operator training	—	5 days (includes installation)/yes	—
Distinguishing features (supplied by vendor)	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	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

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

Automated immunoassay analyzers

Part 8 of 24	Bio-Rad Laboratories Clinical Diagnostics Group David Tomichek david_tomichek@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-741-5119 www.bio-rad.com	Bio-Rad Laboratories Clinical Diagnostics Group Greg Stewart greg_stewart@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-724-7000 www.bio-rad.com	Bio-Rad Laboratories Clinical Diagnostics Group Mary Borick mary_borick@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-741-4791 www.bio-rad.com
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	PR 3100TSC Photometer/2006/Austria Austria/U.S. 45/— batch/benchtop/rack 7 x 13 x 13/2	PhD System/2000/Belgium France/U.S. 200/300 batch/benchtop/rack 35 x 66 x 35/16
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	—	—
Tests not available in U.S. but submitted for clearance	anti-CCP IgG, toxoplasma IgM, rubella IgM, CMV IgM	none	—
Tests not available in U.S. but available in other countries	syphilis IgM, toxoplasma IgM, rubella IgM, CMV IgM	ANA screen, ENA Plus screen, anti-dsDNA, anti-Jo-1, anti-SS-A, anti-SS-B, anti-Scl-70, anti-Sm, anti-Sm/RNA, anti-centromere, antiphospholipid tests, toxo IgG, others	—
Tests in development	gastrointestinal disease, vitamin D, lyme, HIV, hepatitis	—	—
Tests not available on other manufacturers' analyzers	heterophile antibodies	none	—
Fully automated microplate system	no	no	no
Number of each analyte performed in separate disposable unit	—	—	1
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/coated microwell	EIA and IFA/coated microwell or slide
No. of different measured assays onboard simultaneously	440	1	8 EIA or 4 IFA
No. of different assays programmed, calibrated at once	440	1	8 EIA or 4 IFA
No. of user-definable (open) channels	—	none	no limit
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	440/100	0/—	8/192
Shortest/Median onboard reagent stability/Refrigerated onboard	720 hours/30 days/yes (2°–8°C)	—/—/no	4 hours/—/no
Multiple reagent configurations supported	no	no	yes
Reagent container placed directly on system for use	yes	no	requires operator prehandling/preparation
Reagents bar coded/Information in bar code	yes/kit type, lot number, kit serial number	no/—	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/2 ppm	no/—	yes/—
Walkaway capacity in minutes/Specimens/Tests-assays	480 minutes/280/17,600	1/up to 96/1	—/192/—
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	no/liquid	yes/liquid
Uses disposable cuvettes/Maximum number stored	yes/800	no/—	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—	no/—
Minimum specimen volume required	5 µL	10 µL	1 µL specimen
Minimum sample vol. aspirated precisely at once/Minimum dead volume	5 µL/70 µL	—	1 µL/200 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no	yes/no
Requires dedicated water system/Water consumption	no/0.5 L per hour	no/—	no/—
Noise generated	<67 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	no/—/no	yes/micro–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)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/no
Bar-code placement per CLSI standard Auto2A	yes	no	yes
Onboard test auto inventory (determines volume in container)	yes	no	no
Measures No. of tests remaining/Short sample detection	yes/yes	no/no	no/yes
Auto detection of adequate reagent or specimen	yes	no	yes
Clot detection/Reflex testing capability	yes/yes	no/no	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	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	no
Number of calibrators required for each analyte	assay dependent	assay dependent	1–5
Calibrants can be stored onboard/Average calibration frequency	no/30 days	no/weekly	no/each run
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	no/no	yes/no
How often QC required	24 hours/24 hours	shortest interval: weekly; longest interval: monthly	each run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	—/no	no/no
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	—	—
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	no/no	no/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/no	no/no	onboard/no
LIS interfaces up and running in active user sites	Misys/Sunquest, CSI, Data Innovations, Meditech, Cerner Classic/Millennium, Rubicon, Soft	—	—
LIS interface operates simultaneously with running assays	yes	no	yes
Bidirectional interface capability	yes	no	yes
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/yes/yes	no/no/no
Can order (via modem) malfunctioning part(s) without operator	no	no	no
On-site response time of service engineer	—	units returned for service	<24 hours
Mean time between failures/To repair failures	—	—	6 months/4 hours
Average time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 30 minutes	weekly: 5 minutes; monthly: 5 minutes	daily: 5 minutes; weekly: 15 minutes; monthly: 30 minutes
Onboard maintenance records/Maintenance training demo module	yes/no	no/—	no/no
List price/Targeted bed size or daily volume	\$385,000/200 samples per day	\$9,500/5-500 tests per day	\$44,100/>50 tests per day
Annual service contract cost (24 hours/7 days)	—	inquire	inquire
Training provided with purchase/Advanced operator training	5 days at Bio-Rad/no	1 day on site	2 days on site/no
Distinguishing features (supplied by vendor)	full random access automation; three internal quality control beads run simultaneously with each sample; innovative multiplex chemistry	compact, stand-alone microplate photometer; onboard computer allowing user control of instrument and data reduction; colored touchscreen with wizard interface provides streamlined operation of all assays	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

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 24	Bio-Rad Laboratories Clinical Diagnostics Group Greg Stewart greg.stewart@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-724-7000 www.bio-rad.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	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
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	EVOLIS/2001/Germany Germany/U.S. 275/1,350 batch/benchtop/rack 37 × 44 × 30/10	MAGO 4S/2011/Italy Italy/U.S. — batch, random access/benchtop/rack 28 × 48 × 26/8.7	Mago Plus Automated EIA Processor/1997/Italy Italy/U.S. 250/— batch, random access/benchtop/rack 28 × 48 × 26/8.7
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, β 2 glycoprotein IgG/IgM, cardiolipin screen/IgA/IgG/IgM, gliadin IgA/IgG, MPPO, 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, <i>H. pylori</i> IgG, measles IgG, mumps IgG, others
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, HBc 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	infectious disease and autoimmune panels	—	—
Tests not available on other manufacturers' analyzers	—	process ELISA and IFA slide preparation simultaneously	—
Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate	yes — minimum strip, 1; maximum full plate, 96	yes one analyte per well (or multiple, test dependent) 4 × 96 wells, up to 16 slides per run (minimum strip: 8; full plate: 12 strips)	yes 1 analyte per well minimum 1 × 8 wells; maximum 96 wells; can run four plates at a time
Methods supported/Separation methods	EIA/coated microwell	enzyme immunoassay, sample titrations and slides simultaneously with ELISA processing/coated microwell, coated tissue, cell slide	EIA/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	4-8 4-8 contact Bio-Rad representative 4/96 30 minutes/assay dependent/— yes yes yes/— no/no (disposable tips) varies by assay/180/4 no/liquid microplates/— microplates/— 0.2 μ L 10 μ L/200 μ L yes/no no/— 60 decibels no/— yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/no no yes no/no no yes/no no/no yes/no no/no — no assay dependent no/with each run yes/no user determined yes/yes (through Unity QC program) no/no/5 minutes	unlimited up to 20 (analyte dependent) 20 active at a time, unlimited saved on hard drive 20 (analyte dependent)/96 8 hours/1 day/no yes yes yes/lot number, expiration date no/no, with Diamedix reagents 2.5 hours (analyte dependent)/120/384 (ca.12) yes/liquid yes/120 no/— 50 μ L (pediatric) 4 μ L/35 μ L yes/no no/— — yes/35 μ L yes/11-15 mm × 75-100 mm/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/no no yes yes/yes yes no/no no/no yes/no no/no — yes 1-6 (analyte dependent) yes/per run yes/no each run yes/— yes/yes/5 minutes	up to 9 (analyte dependent) ~50 preprogrammed assays 20 per diskette, unlimited diskette capability 9/96 —/—/no yes yes yes/lot number, expiration date no/not susceptible, continuous cleaning up to 2.5 hours—assay dependent/120/384 yes/liquid yes/120 no/— 50 μ L (pediatric) 4 μ L/25 μ L (pediatric) yes/no no/— not significant yes/35 μ L yes/11-15 mm × 75-100 mm/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes — yes yes/yes yes no/no no/no yes/no no/no — reader calibrated every run assay dependent, 2-6 no/per run yes/no per run yes/no yes/yes/<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) 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/yes onboard/yes in development	— — 120/360 (2.5 hours) yes/yes onboard/yes Cerner, Misys, others	— — 120/360 (2.5 hours—assay dependent) yes/yes onboard/yes (included in price) Cerner, Misys, others
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 (broadcast download) no yes/no/no no 24 hours — daily: 5 minutes; monthly: 60 minutes yes/no	yes yes (host query) no no/no/no no normal business hours within 24-48 hours 5 months/3-6 hours daily: 5 minutes; weekly: 10 minutes no/no	yes yes (broadcast download and host query) no no/no/no no 24 hours 5 months/<1 day daily: <5 minutes; weekly: <10 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	\$65,000/30-500 tests per day inquire 4 days in Redmond, Wash./no	\$72,000 (includes first-year warranty)/30-300 included in rental agreement (otherwise \$8,500 per year) 2-3 days on site/yes	\$62,000/all bed sizes, all test volumes service during normal business hours included in reagent rental agreement 1-2 days on site/yes
Distinguishing features (supplied by vendor)	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)	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)

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Automated immunoassay analyzers

Part 10 of 24	DiaSorin Inc. Brian Lauber brian.lauber@diasorin.com 1951 Northwestern Ave., Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com	DiaSorin Inc. Lance Schlenker lance.schlenker@diasorin.com 1951 Northwestern Ave., Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com	DiaSorin Inc. Brian Lauber brian.lauber@diasorin.com 1951 Northwestern Ave., Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com
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	LIAISON XL/2010/Italy Germany/Italy, Germany, U.S. — batch, random access, continuous random access/floor standing/rack	ETI-MAX 3000/2002/Germany Germany/U.S., Italy 160/972 batch, random access/benchtop/rack	LIAISON/1997/Germany Germany/U.S., Italy >500/>4,000 batch, continuous random access/benchtop/rack
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	59 × 59 × 36/2,100 square inches	40 × 45 × 30/10	63 × 136 × 66 cm/10
Tests available on instrument in U.S.	—	EA(D) IgG, EBNA-IgG, VCA-IgG, VCA-IgM reverse capture, measles IgG, varicella zoster IgG, mumps IgG, <i>H. pylori</i> 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
Tests not available in U.S. but submitted for clearance	—	—	—
Tests not available in U.S. but available in other countries	250H vitamin D total, N_TACT II, PTH 1-84, HCV, HIV, HBsAg, Ca 125, Ca 15-3, Ca19-9, TPA-M, AFP, CEA, PSA, fPSA, S100, NSE, beta 2 M, TT4, TT3, TSH, T4, many others	—	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	measles, mumps, parvovirus B19, mycoplasma P, toxo-M, toxo-Av, osteo, ACTH, trep, ferritin, calc II FSH, HCG, CMV-G, CMV-M, CMV-Av, rub-M, rub-G, HSV 1/2 G, many others	—	—
Tests not available on other manufacturers' analyzers	borrelia B., parvovirus B19, mycoplasma P.	HBeAg, anti-HBe	Borrelia burgdorferi, VZV IgG, HSV-1 type specific IgG, HSV-2 type specific IgG, EBV IgM, EBNA IgG, VCA IgG, EA IgG
Fully automated microplate system	no	yes	no
Number of each analyte performed in separate disposable unit	—	—	—
Number of wells in microplate	—	minimum strip: 1, 8 wells; maximum full plate: 96 wells, can accommodate up to 7 plates at a time	—
Methods supported/Separation methods	chemiluminescence/magnetic particle	EIA/coated microplate	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	25	open	15
No. of different assays programmed, calibrated at once	25	open	15
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	25/25–200 (mostly 100)	volume dependent/—	15/100
Shortest/Median onboard reagent stability/Refrigerated onboard	168 hours/28 days/yes (12°)	no/no/no	7/28 days/yes (12°C)
Multiple reagent configurations supported	no	yes	no
Reagent container placed directly on system for use	yes	yes	yes
Reagents bar coded/Information in bar code	yes/quantity, stability, lot number, and more	yes/—	yes/all lot information
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/<20 ppm	yes/no	no/no
Walkaway capacity in minutes/Specimens/Tests-assays	360/120/3,000	assay dependent/180/variable	360/144/1,500
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/1,000	no/—	yes/720
Uses washable cuvettes/Replacement frequency	no/—	no/—	no/—
Minimum specimen volume required	assay dependent	10 μ L	assay dependent
Minimum sample vol. aspirated precisely at once/Minimum dead volume	5 μ L/150 μ L	10 μ L/200 μ L	5 μ L/150 μ L
Supplied with UPS (backup power)/Requires floor drain	yes/—	yes/no	yes/no
Requires dedicated water system/Water consumption	no/—	no/no	no/—
Noise generated	—	—	—
Has dedicated pediatric sample cup/Dead volume	yes/50	no/—	no/75 μ L
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10–16 mm diameter/no	yes (multiple)/no	yes/—/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes/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/no	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	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	—	2 minutes
Autocalibration or autocalibration alert	yes	no	no
Number of calibrators required for each analyte	1 or 2	varies per kit	2
Calibrants can be stored onboard/Average calibration frequency	yes/1–4 weeks	no/each run	yes/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/no	yes/no
How often QC required	24 hours	per run	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes	no/yes
Automatic shutdown/Startup is programmable/Startup time	yes/no/8 minutes	no/yes/5 minutes	no/no/15 minutes
Stat time to completion of β -hCG test	17	—	—
Time delay from ordering stat test to aspiration of sample	2 minutes	—	2 minutes
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	57/171 (21 seconds)	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/no	yes/yes	yes/yes (additional)
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 (broadcast download and host query)	yes	yes (host query)
Interface available (or will be) to auto specimen handling system	yes (INPECO)	no	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	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	24 hours
Mean time between failures/To repair failures	—	—	—
Average time to complete maintenance by lab personnel	weekly: 10 minutes; monthly: 10 minutes	daily: 5 minutes; weekly: 30 minutes	daily: 10 minutes; weekly: 20 minutes; monthly: 30 minutes
Onboard maintenance records/Maintenance training demo module	yes/no	yes/no	no/no
List price/Targeted bed size or daily volume	—/>400 beds	\$79,000 (includes first year of service)/all bed sizes, all test volumes	\$168,000 (includes first year of service)/all bed sizes, all volumes
Annual service contract cost (24 hours/7 days)	—	\$10,500	—
Training provided with purchase/Advanced operator training	yes/yes	3 days/yes	3 days on site/yes
Distinguishing features (supplied by vendor)	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	multiple assays on a plate; Windows 2000 software; continuous loading of samples, reagents, and microplates; primary tube sampling; bidirectional 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

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 24	Dynex Technologies Michael Rashed mrashed@magellanbio.com 14340 Sullyfield Circle, Chantilly, VA 20151 703-631-7000 www.dynextechnologies.com	Grifols USA, LLC Timothy Wigginton tim.wigginton@grifols.com 2410 Lillyvale Ave., Los Angeles, CA 90032 323-227-7415 www.grifols.com	Hycor Biomedical Inc. Carie Keller ckeller@hycorbiomedical.com 7272 Chapman Ave., Garden Grove, CA 92841 714-933-3000 www.hycorbiomedical.com
Name of instrument/First year sold/Where designed	Agility/2011/U.S., UK	Triturus/1999/Spain	HYTEC 288 PLUS/outside U.S. 1998, U.S. 1999/ Netherlands
Country where manufactured/Where reagents manufactured	U.S./various	Spain/Spain, U.S., Italy	Netherlands/U.S., Scotland
No. of units in clinical use in U.S./Outside U.S.	—	>200/>1,700	68/185
Operational type/Model type/Sample handling system	batch/benchttop/rack	batch, random access and continuous random access/ benchttop/universal carousel	random batches/benchttop/rack-robotics
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	48 × 48 × 36/8.6	28.3 × 41.3 × 34.3/10	29.5 × 42.5 × 27.5/8
Tests available on instrument in U.S.	open system, tests provided by various manufacturers	system is completely open; any U.S. clinically cleared and research-use-only EIA procedure can be pro- grammed; infectious diseases, autoimmune diseases, bone markers, endocrinology, hemostasis, oncology markers, hepatitis, and HIV profiles	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-car- diolipin scr., β-2 BPI IgG, IgA & IgM, user-defined channels
Tests not available in U.S. but submitted for clearance	—	—	—
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
Tests in development	—	—	ANCA profile, centromere, CCP, eosinophil cationic protein, tryptase
Tests not available on other manufacturers' analyzers	any ELISA test	—	—
Fully automated microplate system	yes	yes	yes
Number of each analyte performed in separate disposable unit	1 per well	8	8 (1 analyte per well; multiple analytes per well/screens; up to 8 analytes per run)
Number of wells in microplate	96, 1 minimum strip	96, 1 minimum strip, 4 maximum full plate	96—minimum strip: 1 strip/8 wells; maximum full plate: 12 strips/96 wells
Methods supported/Separation methods	chemiluminescence, enzyme immunoassay/—	EIA, EIA-coated microwell plates, onboard shaker, four individually temperature-controlled microplate positions/ coated microwell	EIA, tube-based and microplate-based assays/activated cellulose and coated well
No. of different measured assays onboard simultaneously	16	1–8 tests on 1–4 plates	varies by assay, up to 288 allergens or 8 autoimmune
No. of different assays programmed, calibrated at once	16	8	multiple
No. of user-definable (open) channels	unlimited	—	3
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	16/96	8/48	varies by assay, up to 288 allergens or 8 autoimmune
Shortest/Median onboard reagent stability/Refrigerated onboard	—/—/no	—/—/no	8 hours/12 hours/no
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	yes	minimal operator preparation, handling	yes
Reagents bar coded/Information in bar code	yes/lot information	no	no
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/disposable tip	yes/no	yes/<1 part in 10,000
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/200+ continuous load/12+ continuous load	180/92/8	assay dependent/100/288
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/—	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—	no/—
Minimum specimen volume required	10 µL	300 µL	10 µL, 110 µL with dead volume
Minimum sample vol. aspirated precisely at once/Minimum dead volume	10 µL/150 µL	2 µL/200 µL	10 µL–50 µL, assay dependent/100 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/no
Requires dedicated water system/Water consumption	no/—	no/—	no/—
Noise generated	—	has external waste port to drain into sink or floor drain	—
Has dedicated pediatric sample cup/Dead volume	no/—	no/—	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10–17 mm diameter, 45–100 mm depth/no	yes/12, 13, 16 mm/no	yes/—/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)/—
Bar-code placement per CLSI standard Auto2A	—	yes	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/no	yes/yes	no/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	no/no
Time between initial result and reaspiration of sample for rerun	—	—	—
Autocalibration or autocalibration alert	no	yes	yes
Number of calibrators required for each analyte	test kit dependent	1–14	1–6
Calibrants can be stored onboard/Average calibration frequency	no/per plate	no/check every month	no/monthly
Multipoint calib. supported/Multiple calibs. stored for same assay	no/no	yes/yes	yes/yes
How often QC required	per plate	each run	every assay
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/no	yes/no	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/3–5 minutes	yes/yes/1–2 minutes	yes/no/2–3 minutes
Stat time to completion of β-hCG test	—	system is open, depends on reagent methodology	—
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)	microplate batch process/microplate batch process	dependent on reagent methodology/—	—
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	yes, onboard/no	onboard/optional
LIS interfaces up and running in active user sites	—	CHCS, Softmax, Sunquest	25
LIS interface operates simultaneously with running assays	yes	yes	no
Bidirectional interface capability	yes (host query)	yes (host query and broadcast download)	yes
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	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	within 24 hours	48 hours
Mean time between failures/To repair failures	—	—	7 months/4 hours
Average time to complete maintenance by lab personnel	daily: <15 minutes; weekly: <30 minutes; monthly: <1 hour	daily: 5–20 minutes	daily: 10–15 minutes; weekly: 20–25 minutes; monthly: 20–25 minutes
Onboard maintenance records/Maintenance training demo module	yes/no	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
List price/Targeted bed size or daily volume	—/50+ samples per day, 250+ beds	\$79,000/300+	\$55,000/all sites, variable test volumes
Annual service contract cost (24 hours/7 days)	—	varies, multiple types available	\$5,500
Training provided with purchase/Advanced operator training	—/yes	—/yes	3 days on site/yes
Distinguishing features (supplied by vendor)	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; uses prepackaged SmartKits direct-load reagent kits	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	fully automated allergy and autoimmune testing; user-defined software channels for microtiter plate and tube-based assays

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 24	Immunodiagnostic Systems Inc. (IDS Inc.) Ken Gibbs kenneth.gibbs@idsplc.com 8425 N. 90th Street, Suite 8, Scottsdale, AZ 85258 480-278-8333 www.idsplc.com	Inova Diagnostics Ed Bass ebass@inovadx.com 9900 Old Grove Road, San Diego, CA 92131 800-545-9495 www.inova.com	Inova Diagnostics Ed Bass ebass@inovadx.com 9900 Old Grove Road, San Diego, CA 92131 800-545-9495 www.inova.com
Name of instrument/First year sold/Where designed	IDS-iSYS/2009/France	BIO-FLASH/2011/Spain	DS2/2006/U.S.
Country where manufactured/Where reagents manufactured	France/Belgium	U.S./U.S.	U.S./U.S., U.K.
No. of units in clinical use in U.S./Outside U.S.	>200 worldwide	0/15	—/—
Operational type/Model type/Sample handling system	continuous random access/benchtop/sample loading rack	continuous random access/benchtop/racks	batch, with continuous load/benchtop/rack
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	28 × 42 × 30/—	21 × 34 × 24/6	30 × 17 × 26/3.07
Tests available on instrument in U.S.	25-hydroxy vitamin D, IGF-1, hGH, IGFBP-3, CTX-I	tTG IgA, tTG IgG, aCL IgG, aCL IgM	autoimmune, infectious disease
Tests not available in U.S. but submitted for clearance	intact PTH	DPG IgA/IgG screen	—
Tests not available in U.S. but available in other countries	intact PTH, intact PINP, N-MID Osteocalcin BAP	MPO, PR3, GBM	open system—ELISA
Tests in development	bone trap (TRAcP 5b), aldosterone, renin, PTH 1-34, bioactive PTH (1-84)	—	—
Tests not available on other manufacturers' analyzers	—	CCP3.1, ANA Screen, dsDNA, PS/PT, Ribo P, centromere, B2GP1 IgA, aCL IgA, SS-A, SS-B, Jo-1, Scl-70, Sm, RNP	open system
Fully automated microplate system	no	no	yes
Number of each analyte performed in separate disposable unit	—	—	—
Number of wells in microplate	—	—	minimum strip 1 × 8; maximum full plate: 96 wells × 2 plates
Methods supported/Separation methods	chemiluminescence/magnetic particle	chemiluminescence/magnetic particle, bead	EIA/coated microwell
No. of different measured assays onboard simultaneously	15	20	12 assays per plate
No. of different assays programmed, calibrated at once	15	50	unlimited
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	15/100	20/50 and 100-test kits	8/96
Shortest/Median onboard reagent stability/Refrigerated onboard	48 hours/7 days/yes (8°–10°C)	480 hours/40 days/yes (6°–8°C)	24 hours/—/no
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	yes, assay dependent	yes	yes
Reagents bar coded/Information in bar code	yes/LOT key, No. within lot, XML	yes/type, No. of tests, lot number, expiration date, master calibration curve	yes/yes
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/—	no/—	—/0 with disposable tips
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/120/960	—/30/20	assay dependent/98/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	closed/liquid	yes/liquid
Uses disposable cuvettes/Maximum number stored	yes/960	yes/280	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—	no/—
Minimum specimen volume required	10 µL	10 µL	200 µL
Minimum sample vol. aspirated precisely at once/Minimum dead volume	5 µL/tube dependent ~80 µL	10 µL/50 µL	5 µL/200 µL (50 µL with microtubes)
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/—
Requires dedicated water system/Water consumption	no/—	no/—	no
Noise generated	—	—	—
Has dedicated pediatric sample cup/Dead volume	yes/80 µL	yes/50 µL	yes/50 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/all up to 16 × 100 mm/no	yes/12–16 mm/no	yes/—/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, codes 39 and 128)/yes	yes (2 of 5 interleaved, 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	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	yes/yes	yes/yes	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	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/yes	no/no
Time between initial result and reaspiration of sample for rerun	—	30 minutes	—
Autocalibration or autocalibration alert	yes	yes	no
Number of calibrators required for each analyte	2	2	varies
Calibrants can be stored onboard/Average calibration frequency	no/test dependent ~7 days	no/lot change or failure of controls	yes/each assay
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes	yes/no
How often QC required	—	daily	each assay
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes	yes/no
Automatic shutdown/Startup is programmable/Startup time	yes/yes/10 minutes	yes/yes/<10 minutes	no/yes/1–2 minutes
Stat time to completion of β-hCG test	—	—	—
Time delay from ordering stat test to aspiration of sample	—	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)	assay dependent/—
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	—/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/no, additional cost	onboard/yes, included	onboard/yes (additional cost)
LIS interfaces up and running in active user sites	—	—	—
LIS interface operates simultaneously with running assays	yes	yes	yes
Bidirectional interface capability	yes (host query)	yes (broadcast download and host query)	yes (host query)
Interface available (or will be) to auto specimen handling system	yes	yes	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/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	—	—	—/<24 hours
Average time to complete maintenance by lab personnel	daily: 15 minutes; weekly: 30 minutes; monthly: 15 minutes	weekly: 5 minutes; monthly: 15 minutes	daily: 5 minutes
Onboard maintenance records/Maintenance training demo module	yes, includes audit trail/no	no/no	yes/no
List price/Targeted bed size or daily volume	—	\$92,500/100–500	—
Annual service contract cost (24 hours/7 days)	—	—	—
Training provided with purchase/Advanced operator training	—/yes	—/yes	8 days on site/yes
Distinguishing features (supplied by vendor)	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	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

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

Automated immunoassay analyzers

Part 13 of 24	Inova Diagnostics Ed Bass ebass@inovadx.com 9900 Old Grove Road, San Diego, CA 92131 800-545-9495 www.inova.com	Inova Diagnostics Ed Bass ebass@inovadx.com 9900 Old Grove Road, San Diego, CA 92131 800-545-9495 www.inova.com	Inova Diagnostics Ed Bass ebass@inovadx.com 9900 Old Grove Road, San Diego, CA 92131 800-545-9495 www.inova.com
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	DSX/2000/Guernsey, U.K. U.S./U.K. 300/>500 batch/benchtop/rack 32 × 42 × 36/7	Quanta Lyser 240/2008/Switzerland, Italy Switzerland/U.K. 110/95 batch/benchtop/racks 36 × 47 × 32/10.5	Quanta Lyser 2/2008/— Switzerland/U.K. 0/50 batch/benchtop/racks 29.5 × 25.6 × 27.6/—
Tests available on instrument in U.S.	autoimmune, infectious disease	open system, 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—any ELISA	— —	— —
Tests in development Tests not available on other manufacturers' analyzers	— open system	— —	— —
Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate	yes — minimum strip: 1 × 8; maximum full plate: 96 × 4 plates	yes 1 96	yes — 96
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	EIA/coated microwell 12 assays per plate unlimited unlimited 25/96 per 4 plates 24 hours/—/no yes requires operator prehandling/preparation yes/yes 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	enzyme EIA/coated microwell, IFA slides 9 — open system 9/88 24 hours/—/no yes requires operator prehandling/preparation — —/ <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 yes/per run yes/no per run no/yes no/no/2 min	enzyme immunoassay, IFA slides/coated microwell 9 — open system —/EIA: 180; IFA: 240 —/—/no yes placed directly on system yes/— no/<10 ⁶ 240/96/192 yes/liquid no/— no/— 100 µL 5 µL/150 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 — yes/no no/no yes/no — — no varies —/varies yes/— per run no/— no/—/—
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	— — assay dependent yes/yes onboard/yes (additional) Cerner Classic and Millennium, Misys, SoftComp, Live Link, Triple G, FCC, ACA, LCW, LabLink yes yes (host query) no no/yes/yes no within 24 hours —/ <24 hours daily: 5 minutes no/no	— — — yes/yes onboard/yes (additional cost) 3 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 no/—	— — — yes/— onboard/yes (additional cost) — yes yes (broadcast download, host query) no no/—/— — 24 hours 6-8 months/— daily: 5 minutes; weekly: 10 minutes monthly: 10 minutes no/—
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided with purchase/Advanced operator training	—/200+ beds — 8 days on site, 2 days at vendor offices/yes	\$125,000/500 tests/day — yes (8 days on site)/yes	— — yes (4-8 days on site)/—
Distinguishing features (supplied by vendor)	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 trained for learned error recovery	fast processing time; low operating costs due to elimination of disposable tips; completely open high-throughput batch analyzer	processes IFA slides and ELISA assays simultaneously, LIS interface, large menu, and open-assay capability

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

Automated immunoassay analyzers

Part 14 of 24	Ortho Clinical Diagnostics, Inc. Mark Steelman msteelma@its.jnj.com 100 Indigo Creek Drive, Rochester, NY 14626 585-453-3420 www.orthoclinical.com	Ortho Clinical Diagnostics, Inc. Mark Steelman msteelma@its.jnj.com 100 Indigo Creek Drive, Rochester, NY 14626 585-453-3420 www.orthoclinical.com	Phadia Nicole Vosters nicole.vosters@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us
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	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 & secondary containers without need for adapters	VITROS 3600 Immunodiagnostic System/2009/U.S. U.S./UK >300 worldwide continuous random access/floor standing/universal sample trays (circular) accommodate primary & secondary containers without need for adapters	Phadia Laboratory System 100 ^E /1995/Sweden Sweden/Sweden — batch/benchtop/carousel
Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	51 x 44 x 29/8.9	68 x 83.5 x 34.9/20.2	18 x 28 x 24 + computer/—
Tests available on instrument in U.S.	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	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, aHBe, HBeAg	hundreds of ImmunoCAP specific IgE Allergens, ImmunoCAP total IgE, and ImmunoCAP TG and TPO tests. ELiA autoimmune products currently include: CCP, dsDNA, Symphony ANA Screen, individual ANA's, Celikey IgA and IgG (tissue transglutaminase), and gliadin IgA and IgG EliA cardiolipin IgG, EliA cardiolipin IgM, EliA β 2-glycoprotein I IgG and EliA β 2-glycoprotein I IgM, others EliA PR3S, EliA GBM, EliA MPO, EliA CTD Screen, EliA Cardiolipin IgA, EliA B2 GPI IgA, EliA PM/Sc, others — Phadia US Inc. ImmunoCAP specific IgE blood tests and ELiA autoimmune assays
Tests not available in U.S. but submitted for clearance			
Tests not available in U.S. but available in other countries	aHBe, toxo IgG, rubella IgM, toxo IgM, CMV IgG, CMV IgM	aHBe, HBeAg, rubella IgM, toxo IgG, toxo IgM, CMV IgG, CMV IgM	
Tests in development	HIV Combo, syphilis (Ex-U.S.), vitamin D, total PSA II	HIV Combo, syphilis (Ex-U.S.), vitamin D, total PSA II	
Tests not available on other manufacturers' analyzers	NTx	NTx	
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 (enhanced)/individually coated microwell	chemiluminescence, enhanced chemiluminescence/coated microwell	fluoroenzyme immunoassay/ImmunoCAP cellulose polymer matrix reaction wells
No. of different measured assays onboard simultaneously	20	31	4
No. of different assays programmed, calibrated at once	20, up to 25 lots calibrated per assay	31, up to 25 lots calibrated per assay	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	20/100	31/100	48-96 depending on the conjugate type
Shortest/Median onboard reagent stability/Refrigerated onboard	56 days/56 days/yes (2°-8°C)	1,008 hours/56 days/yes (2°-8°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 ID, expir., lot No., pack ID	yes/test ID, expiration date, lot No., pack ID	yes/product name, lot No., expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	—/zero carryover	no/zero carryover	no/—
Walkaway capacity in minutes/Specimens/Tests-assays	720/60/800 (with enhanced productivity module)	varies/90/3,100	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	no/—	no/—	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—	—/—
Minimum specimen volume required	10 μ L	10 μ L	40 μ L for ImmunoCAP tests and 50 μ L for ELiA tests
Minimum sample vol. aspirated precisely at once/Minimum dead volume	10 μ L/80 μ L	10 μ L/35 μ L	ImmunoCAP: 40 μ L/40-200 μ L; ELiA: 50 μ L/50-200 μ L
Supplied with UPS (backup power)/Requires floor drain	no, but it is available/no	no, but it is available/no	yes/no
Requires dedicated water system/Water consumption	no/—	no/—	no/1 L per run
Noise generated	60 decibels	—	—
Has dedicated pediatric sample cup/Dead volume	no	no/—	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/multiple ped., microtainers and cups, 5 mL, 7 mL, 10 mL on same universal sample tray/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/10-16 mm x 50-105 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl. Codabar, codes 39 & 128, & ISBT 128)/yes	yes (2 of 5 interl., Codabar, codes 39 & 128 & ISBT 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Bar-code placement per CLSI standard Auto2A	yes	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	yes/yes	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/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/no	no/no	no/no
Time between initial result and reaspiration of sample for rerun	assay dependent	assay dependent	2.5 hours—batch run
Autocalibration or autocalibration alert	yes	yes	yes
Number of calibrators required for each analyte	1-3	1-3 depending on assay	6 for calibration run, and 2 when using stored curve
Calibrants can be stored onboard/Average calibration frequency	no/28 days	no/28 days	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 24 hours	once per 24 hours	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	—/—/0	—/—/0	yes/yes/20 min. including request entry or downloading
Stat time to completion of β -hCG test	24 minutes	24 minutes	—
Time delay from ordering stat test to aspiration of sample	immediate upon completion of last sample metering	immediate upon completion of last sample metering	—
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	assay dependent/assay dependent (40 seconds)	assay dependent/assay dependent (19 seconds)	batch analyzer/48/180 minutes processing time for batch to finish
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, onboard and optional add-on/no	yes, onboard and optional add-on (Data Innovations)/yes, additional cost	onboard/yes, instrument side only (included)
LIS interfaces up and running in active user sites	Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, others	Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, 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)	yes (broadcast download and host query)	yes (broadcast download and host query)
Interface available (or will be) to auto specimen handling system	no	yes, enGen	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	<4 hours (contract dependent)	<4 hours (contract dependent)	—, swap
Mean time between failures/To repair failures	depend. on corrective action/depend. on corrective action	depend. on corrective action/depend. on corrective action	—
Average time to complete maintenance by lab personnel	daily: <5 minutes; weekly: <30 min.; monthly: <10 min.	daily: 10 minutes; weekly: 25 minutes; monthly: 15 min.	daily: 5 minutes; weekly: 10 minutes; monthly: 15 min.
Onboard maintenance records/Maintenance training demo module	no/yes	yes, includes audit trail/yes	yes/no
List price/Targeted bed size or daily volume	\$109,000/various	\$220,000/various	\$22,000/>7,000-20,000 tests per year
Annual service contract cost (24 hours/7 days)	varies with service level choices	varies with service level choices	—
Training provided with purchase/Advanced operator training	yes/yes, as needed	yes/yes, as needed	3.5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	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	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	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; 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

Part 15 of 24	Phadia Nicole Vosters nicole.vosters@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us	Phadia Nicole Vosters nicole.vosters@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us	Phadia Nicole Vosters nicole.vosters@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us
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	Phadia Laboratory System 250/2004/Japan, Sweden Japan, Sweden/Sweden — continuous random access/floor standing/racks 73 × 50 × 30 + 26-in. wide computer stand/—	Phadia Laboratory System 1000/2003/Japan, Sweden Japan, Sweden/Sweden — continuous random access/floor standing/racks 83 × 71 × 40 + 26-in. wide computer stand/—	Phadia Laboratory System 2500/2004/Sweden Japan/Sweden — continuous random access/floor standing/racks 71 × 158 × 47 + 26-in. wide computer stand/51
Tests available on instrument in U.S.	hundreds of ImmunoCAP specific IgE allergens, ImmunoCAP total IgE, and ImmunoCAP TG and TPO tests. ELIA autoimmune products currently include: CCP, dsDNA, Symphony ANA Screen, individual ENA's, Celikey IgA and IgG (tissue transglutaminase), and gliadin IgA and IgG	hundreds of ImmunoCAP specific IgE tests and ImmunoCAP total IgE	hundreds of ImmunoCAP specific IgE allergens, immunoCAP total IgE, and immunoCAP TG and TPO tests, ELIA autoimmune products currently include: CCP, dsDNA, Symphony ANA Screen, individual ENA's, Celikey IgA and IgG (tissue transglutaminase), and gliadin IgA and IgG, ELIA cardiolipin IgG, ELIA cardiolipin IgM, ELIA β2-glycoprotein I IgG and ELIA β2-glycoprotein I IgM, ELIA gliadin DP IgA/IgG
Tests not available in U.S. but submitted for clearance	ELIA cardiolipin IgG, ELIA cardiolipin IgM, ELIA β2-glycoprotein I IgG and ELIA β2-glycoprotein I IgM, others	—	—
Tests not available in U.S. but available in other countries	ELIA PR3S, ELIA GBM, ELIA MPO, ELIA CTD Screen, ELIA Cardiolipin IgA, ELIA β2 GPI IgA, ELIA PM/Sc, others	—	ELIA PR3S, ELIA GBM, ELIA MPO, ELIA CTD screen, ELIA cardiolipin IgA, ELIA β2 GPI IgA, ELIA PM/Sc, ELIA fibrillarlin, ELIA RNA Pol III, ELIA PCNA, ELIAAMI-2, ELIA borrelia, others
Tests in development	—	—	—
Tests not available on other manufacturers' analyzers	ImmunoCAP specific IgE blood tests and ELIA autoimmune assays	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 up to 8 methods
No. of different measured assays onboard simultaneously	3 methods	3 methods	up to 8 methods
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 µL for ImmunoCAP tests and 50 µL for ELIA tests	40 µL per test	40 µL for ImmunoCAP tests and 50 µL for ELIA tests
Minimum sample vol. aspirated precisely at once/Minimum dead volume	40 µL/40–200 µL for ImmunoCAP tests and 50 µL/50–200 µL for ELIA tests (varies with tube type)	40 µL/40–200 µL (varies with tube type)	40 µL/40–200 µL for ImmunoCAP tests and 50 µL/50–200 µL 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 × 50–105 mm/no	yes/10–17 mm × 50–105 mm/no	yes/10–17 mm × 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 NCCLS 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 to provide 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

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 24	Phadia Nicole Vosters nicole.vosters@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us	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
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	AQT90/2008/Denmark Denmark/Finland —/— random access/benchtop/inlet 17.7 x 18.1 x 18.9/2.4	Evidence/2002/Northern Ireland Northern Ireland/Northern Ireland 8/27 batch/floor standing/carousel 68 x 78 x 39/22.75
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	hundreds of ImmunoCAP specific IgE allergens, immunoCAP total IgE, and ImmunoCAP TG and TPO tests, ELIA autoimmune products currently include: CCP, dsDNA, Symphony ANA Screen, individual ENAs, Celikey IgA and IgG (tissue transglutaminase), and gliadin IgA and IgG, EiiA cardiolipin IgG, EiiA cardiolipin IgM, EiiA β -glycoprotein I IgG and EiiA β -glycoprotein I IgM, EiiA gliadin DP IgA/IgG — EiiA PR3S, EiiA GBM, EiiA MPO, EiiA CTD screen, EiiA cardiolipin IgA, EiiA β 2 GPI IgA, EiiA PM/Sc, EiiA fibrillar, EiiA RNA Pol III, EiiA PCNA, EiiAMI-2, EiiA borrelia, others	— — Tnl, CKMB, MYO, NT-proBNP, β hcG, CRP, D-dimer	cocaine, methamphetamine, PCP, opiates, cannabinoids, barbiturates, benzodiazepine, progesterone, prolactin, LH, FSH, estradiol — CK-MB, h-FABP, myoglobin, troponin I, estradiol, FSH, LH, progesterone, PRL, testosterone, FT4, FT3, TSH, TT4, TT3, CEA, fPSA, tPSA, buprenorphine, fentanyl, generic opioids, ketamine, LSD, methaqualone, 3,4 MDMA, oxycodone 1, oxycodone 2, propoxyphene, TCAs Generic Research assays available: E-selectin, L-selectin, others
Tests in development Tests not available on other manufacturers' analyzers	— ImmunoCAP specific IgE blood tests and ELIA autoimmune assays	BNP, TnT, hsCRP, APTT, PT-INR —	— CAIII, h-FABP, GPBB, IL-5, IL-15
Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate	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 NCCLS 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 methods 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 EiiA tests 40 μ L/40–200 μ L for ImmunoCAP tests and 50 μ L/50–200 μ L for EiiA 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	time-resolve fluorescence/coated microwell 6 6 0 15/16 96 hours/7 days/no yes yes yes/lot No., expiration, checksum, parameter code, cartridge ID no/<100 ppm —/2/10 tests yes (homebrew methods can be used)/dry no/— no/— 2 μ L 2.5 μ L/53.5 μ L no/no no/— — no/— yes/11 x 66 to 13 x 78 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes — yes yes/yes no —/no no/no no/no — 2-level adjuster, supplied in kit yes/once per lot — customer determined (longest interval: 1 per month) — —/—/30 minutes	chemiluminescence/— 8 12 0 96/360 assay dependent/1–14 days/yes (2°–8°C) yes yes yes/product component, size, lot No., expiration date no/— 100/180/540–1,080 no/liquid no/— no/— 7 μ L 7 μ L/7–350 μ L (varies with cup type) no/no no/— 60 decibels yes/100 μ L yes/12 mm, 16 mm/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes no/yes no/no no/no no/no 12 minutes no 9 (multi-analyte calibrators) yes/weekly (dependent on panel) yes/yes user defined yes/yes yes/no/13 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 30 seconds 10/30 yes/yes onboard/no — yes yes (broadcast download and host query) no yes/yes/yes no per negotiated contract — yes, includes audit trail/no	— — 108/324 (5 minutes) yes/yes onboard/Randox, included in price yes yes yes (host query) no yes/yes/yes no <24 hours (contract dependent) — daily: 5 minutes; weekly: 10 minutes; monthly: 30 minutes 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	— flexible options available —	contract dependent/500+ contract dependent —/yes
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	POC instrument measures whole blood with lab quality; broad menu and parameter flexibility; closed tube and closed waste system	biochip enables simul. analysis of multiple parameters in single sample; max. throughput of 1,188 tests per hour; unreported tests retrieved retrospectively; arrays contain multiple tests applicable to clinical and research applications

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

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Part 17 of 24	Roche Diagnostics Sheila Brewer sheila.brewer@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.roche.com/labsystems/us	Roche Diagnostics Adam Sterle adam.sterle@roche.com 9115 Hague Road, Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us
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	cobas e 602/2010/Japan, Switzerland Japan/Germany —/>>200 random access, continuous random access/floor standing/rack-based	Elecsys 2010/1996/— Japan/Germany >800/>6,000 cont. random access/benchtop/rack or disk	cobas e411/2006/Japan Japan/Germany >225/>3,500 continuous random access/benchtop/rack, disk
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	52.8 × 58.8 × 45.6/—	22.1 × 47.2 × 28.7/9.4	disk: 31.4 × 47.2 × 28.7/9.4; rack: 31.4 × 67 × 37.4/17.4
Tests available on instrument in U.S.	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, others TG	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, HbAg confirmatory, anti-HBs, IgE, PTH, others anti-HBc IgM, anti HCV, anti HAV IgM	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 anti-HBc
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	Anti-HCV, free PSA, total PSA, 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, CMV IgM, CA 72-4, Cyfra 21-1, NSE, HE4, digitoxin, troponin T high sensitive, troponin T high sensitive stat, Tg confirmatory test, PLGF, others free PSA, total PSA, anti-HCV, anti HBc, anti HBc IgM, vitamin D2/D3 total, HSV type 1, HSV type 2, IGF-1 tacrolimus, sirolimus, cyclosporine, HIV combi, toxo IgM, CMV IgG, CMV IgM, HE4, troponin T high sensitive, others TnT	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	HE4, total P1NP, vitamin D 25-OH, troponin T hs, PIGF, sFit-1, hGH, IGF-1, thyroglobulin (Tg), CMV IgG, CMV IgM, HIV combi, HSV type I and II, toxo IgM, IL-6, procalcitonin (PCT), anti-HBc IgM
Tests in development		9-minute PTH, Tnt	9-minute PTH and cardiac assays, 9-minute PTH, TnT
Tests not available on other manufacturers' analyzers			
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	electrochemiluminescence/magnetic particle	electrochemiluminescence/magnetic particle	electrochemiluminescence, magnetic particle/magnetic particle
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	25 per module 25 per module — 25 per module/10–200	15 60 0 15/100–200 tests per kit	18 18 0 18/100–200 tests per kit
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	1 week/56 days/yes (20°C) yes yes yes/calibration curve, application parameters, lot number, expiration, reagent name	56 days/56 days/yes (20°C) yes yes yes/calibration curve, application parameters, lot No., expiration, reagent name	14 days/56 days/yes yes yes yes/calibration curve, application parameters, lot No., expiration, reagent name
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	no/disposable tips 360/300/1,000 closed/liquid yes/1,006 per module no/— 10 µL 10 µL/100 µL yes/yes yes/~12 L per hour <65 decibels yes/100 µL yes/13 × 75, 16 × 100, false bottom/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/— —/yes — yes 2 no/28 days yes/yes 24 hours yes/yes yes/yes/12 minutes	no/zero carryover (disposable sample tips) 120/disk: 30, rack: 100/180 no/liquid yes/180 no 10 µL 10 µL/100 µL yes/no no/3 L for 250 tests <70 decibels no/— yes/13–16 mm diameter/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/no yes/yes — yes 2 no/monthly yes/yes once per 24 hours yes/yes no/no/4 minutes	no/zero carryover (disposable sample tips) disk: 120/30/180; rack: 120/100/180 no/liquid yes/360 assay tips; 180 assay cups no/— 10 µL 10 µL/100 µL yes/no no/3 L for 250 tests <70 decibels no/— yes/13–16 mm diameter/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/no yes/yes — yes 2 no/monthly for lot; weekly for rack yes/yes once per day yes/yes yes/no/4 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	18 minutes <1 minute 56/176 (21 seconds) yes/yes onboard/— all major LIS yes yes (broadcast download and host query) yes yes/yes/yes no <24 hours — daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes yes (includes audit trail)/yes	9 minutes (hCG intact) 42 seconds 30/88 (42 seconds) yes/yes onboard/yes (additional cost) all major LIS yes yes (broadcast download and host query) yes (CLAS and Roche task targeted automation) no/yes/no no <24 hours — daily: 1 minute; weekly: 5 minutes; biweekly: 25 minutes no/no (training CD-ROM)	9 minutes 42 seconds 30/86 (42 seconds) yes/yes onboard/yes (additional cost) — yes yes (broadcast download and host query) yes yes/yes/yes no <24 hours 215 days/varies daily: 5 minutes; weekly: 6 minutes; monthly: 10–15 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	contract dependent/large to very large included with reagent rental —	varies based on contract included with reagent rental 3 days at Indianapolis offices/yes	varies based on contract/varies; primary immunoassay system or back-up unit included with reagent rental 4 days on site/yes
Distinguishing features (supplied by vendor)	ECL technology provides broad measuring ranges and low-end sensitivity; troponin T and pro-BNP; cobas 8000 has 24 unique configurations to be tailored to a wide range of throughput and consolidation needs with one interface	liquid ready-to-use reagents; autocalibration, autodilution; ECL technology for broad dynamic ranges, and fast turnaround time, stat interrupt; onboard reagent storage; minimal maintenance	liquid ready-to-use reagents; ECL technology for broad dynamic ranges; fast turnaround time; stat interrupt; minimal maintenance

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

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Part 18 of 24	Roche Diagnostics Nathan Patton nathan.patton@roche.com 9115 Hague Road, Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us	Roche Diagnostics Sheila Brewer sheila.brewer@roche.com 9115 Hague Road, Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us
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.	MODULAR ANALYTICS E170/2001/Japan Japan/Germany >500/>300 (combination of E and EE systems) and >25 Integrated Modular Systems (U.S. only)	cobas e601/2006/— Japan/Germany >500/—
Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	continuous random access/floor-standing/rack 47 x 47 x 31.5 (Modular E configuration)/approximately 60 (one module system)	continuous random access/floor-standing/rack 46.1 x 71.8 x 40/19.73
Tests available on instrument in U.S.	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, 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, HBsAg, many others anti HAV IgM, PCT, anti HbC IgM	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, many others anti HAV IgM, PCT, anti HbC IgM
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-Hbe, HBeAg, HIV antigen, HIV antigen confirmatory, HIV combi, P1NP, others interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, NSE, anti-HBc, HbC IgM, HBeAg, anti-HBe, HIV combi, He4, vitamin D 25-OH, toxo IgM, rubella IgM	TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-Hbe, HBeAg, HIV antigen, HIV antigen confirmatory, HIV combi, P1NP, others 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
Tests in development		
Tests not available on other manufacturers' analyzers	TnT	TnT
Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate	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	electrochemiluminescence/magnetic particle, electrochemiluminescence 25 per module, maximum of 60 25 per module — 25/100-200 tests per kit 14 days/35 days/yes (20° C) yes yes yes/calibration curve, application parameters, lot No., expiration, reagent name —/zero, uses disposable sample tips	electrochemiluminescence/magnetic particle 25 per module 25 per module — 25 per module/100 to 200 56 days/56 days/yes (20° C) yes yes yes/calibration curve, application parameters., lot No., expiration, reagent name —/zero, uses disposable sample tips
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	—/zero, uses disposable sample tips 360/—/1,006 no/liquid yes/1,006 no/— 10 μ L —/100 μ L yes/yes yes/30 L per hour in full operation <65 decibels yes/100 μ L yes/13 x 75 to 16 x 100/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/yes yes/yes — yes 2 no/monthly yes/yes 24 hours yes/yes yes/yes/11 minutes	—/zero, uses disposable sample tips 360/300/1,000 no/liquid yes/1,006 no/— 10 μ L 10 μ L/100 μ L yes/yes yes/up to 30 L/hour in full operation <65 decibels yes/100 μ L yes/13 x 75 to 16 x 100/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/yes yes/yes — yes 2 no/every 28 days yes/yes 24 hours yes/yes yes/yes/11 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	18 minutes — 56/176 (21 seconds) yes/yes onboard/yes (additional cost) all major LISs yes yes (broadcast download and host query) yes (Roche Modular Pre-Analytcs systems and task targeted automation) yes/yes/no	18 minutes 42 seconds 56/176 (21 seconds) yes/yes onboard/yes (additional cost) all major laboratory information systems yes yes (broadcast download and host query) yes (Roche Modular Pre-Analytcs)
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	no \leq 24 hours — daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes yes/yes	no \leq 24 hours — daily: 5 minutes.; weekly: 10 minutes; monthly: 15 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, based on contract included with reagent rental 5 days at vendor offices/yes	varies, based on contract/— — 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	expandable liquid ready-to-use reagents are compatible with other Elecsys systems and with Pre-Analytic Automation; ECL technology provides broad measuring range and low-end sensitivity, troponin T, auto-rerun and dilute	ECL technology provides brand measuring ranges and low-end sensitivity; TnT; ready-to-use bar-coded reagents compatible with other Elecsys Systems; compatible with Modular Pre-Analytcs for walkaway automation

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

Tabulation does not represent an endorsement by the College of American Pathologists.

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Automated immunoassay analyzers

Part 19 of 24	Siemens Healthcare Diagnostics Jason F. Ong jason.f.ong@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 847-236-7328 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Colleen Grier colleen.m.grier@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 914-524-3824 diagnostics.siemens.com	Siemens Healthcare Diagnostics Louise Loughran louise.loughran@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 310-645-8200 x7035 www.siemens.com/diagnostics
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	Dimension EXL 200/2011/U.S. U.S./U.S. —/— batch, random access/floor standing/segmented sample wheel/floor standing 56 x 49 x 41/16	Dimension Vista 500 Intelligent Lab System/2009/U.S. U.S./U.S., Germany 250/150 continuous random access/floor standing/rack and aliquot plate system, batch 55.5 x 84.75 x 43.8/26	ADVIA Centaur CP Immunoassay System/2005/U.S. Germany/U.S. >200/>400 batch, random access, continuous random access/benchtop/7 x 12 position racks 43 x 29/8.7
Tests available on instrument in U.S.	>90	>125 (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	total IgE, ferritin, folate, vit B-12, CKMB, 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, rubella IgG, rubella IgM, AFP, estradiol-6 III, FSH, total hCG, LH, progesterone, prolactin, testosterone, DHEAS, carbamazepine, digitoxin, digoxin, gentamicin, phenobarbital, phenytoin, eHIV, many others cyclosporine, DHEAs, SHBG, digitoxin, aTG, aTPO, TSH3 ultra, Her2/neu, HBsAg/confirmatory, HBsAb, HBcTotal, HBc IgM, HCV, rubella IgG, rubella IgM, toxo IgG, others
Tests not available in U.S. but submitted for clearance	—	—	—
Tests not available in U.S. but available in other countries Tests in development	— LOCI free T3, LOCI B12, LOCI folate, mycophenolic acid	PSA, FPSA, CA 15-3, CA 125 CA 125, CA 15-3, CA 19-9, additional cancer markers fertility panel, plasma proteins, hormones, infectious disease LOCI immunoassay, nephelometric assays, gen. chemistry	SHBG, toxo IgG, toxo IgM, D-dimer, fPSA, HBeAg, anti-HBe, eHIV cPSA, HER-2/neu
Tests not available on other manufacturers' analyzers	—	—	—
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	photometry, potentiometry, others/LOCI, ACMA, EMIT, PETINIA and turbidimetric/— 47 47 10 47/15-240 24 hours/30 days/yes (2°-8°C) yes yes yes/— yes/— can be hours/60/>2,000 yes/liquid, reconstitutes on board yes/12,000 no/— 2 uL 2 uL/— yes/no yes/5 L <75 decibels yes/30 uL yes/5 mL, 7 mL, 10 mL, 1.5 mL and 1.0 mL sample cups, pediatric tubes/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes/yes yes/yes yes/yes yes/no varies yes varies yes/— yes/yes 24 hours or with lot change yes/yes no/no/8 minutes	chemiluminescence, LOCI advanced chemiluminescence, EMIT, PETINIA, nephelometry/magnetic particle, homogeneous immunoassay >100 >100 10 >100/20 to 1,200 72 hours/30 days/yes (2°-8°C) no yes yes/test method, lot number, expiration date, number of tests yes/<1 ppm >45/150/61,404 yes/liquid yes/>1,600 yes/automatic as needed 50 uL 50 uL/10 uL yes/yes no/20 L per hour <65 decibels no, can use small sample cup/10 yes/10 x 50, 10 x 65, 13 x 65, 13 x 75, 13 x 100, 15 x 92, 16 x 100, 13 x 90/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes/yes yes/yes yes/yes can decrease, but cannot increase sample volumes <2 minutes yes varies 2-6 yes/30 to 90 days yes/yes once per 24 hours yes/yes no/no/always ready	chemiluminescence/magnetic particle 15 31 (65 planned for 2008) — 15/50 to 100 96 hours/28 days/yes (2°-8°C) yes yes yes/reagent ID, lot No., expiration date no/zero carryover 210/400/400 no/liquid yes/400 no/— 10 uL, assay dependent 10 uL/50 uL yes/no no/— up to 65 decibels no/— yes/multiple/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes yes/yes 20 seconds yes 2 no/varies, average of 21 days yes/yes user defined yes/yes yes/yes/<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) 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	— 24 seconds —/— (7.2 seconds) no/yes onboard, optional add-on/yes (additional cost) all major LIS vendors yes yes (broadcast download and host query) yes, Siemens VersaCell, Siemens StreamLAB yes/yes/yes yes 2-8 hours — daily: 5 minutes; weekly: 10 min.; monthly: 23 min. no/no	10 <2 minutes >150/450 for immunoassay methods yes/yes onboard/— Misys, Soft, Mediatech, Cerner, others yes yes (broadcast download and host query) yes, StreamLAB automation system in development yes/yes/yes no 2-8 hours — daily: <10 minutes; monthly: 10 to 20 minutes no/yes	15.6 minutes <1 to 2 minutes 50 seconds 60/180 (20 seconds) yes/yes onboard/no Cerner, Misys, Mediatech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, most major vendors yes yes (broadcast download and host query) no yes/yes/— no 4 hours, 24 hours maximum — daily: 15 minutes; weekly: 20 min.; monthly: 30 min. 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	— — 5 days on site, 4 days at vendor offices/yes	—/1,500 tests per day per system — 2 days on site and/or 4 days at vendor offices/yes	depends on GPO affiliation/community hospital, satellite labs — 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; Reagent Management System standard	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; Siemens Remote Service	automates routine operations, including ability to access/change solutions, waste, disposables, and reagents w/o 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 w/concordant results; throughput 180 tests/hour; avg. time to first result ~15.6 min.

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Name of instrument/First year sold/Where designed	ADVIA Centaur XP/2006/U.S.	Dimension Vista 1500 Intelligent Lab System/2006/U.S.	Dimension Xpand Plus Integrated Chemistry System/2004/U.S.
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	Ireland/U.S. 475/425 continuous random access/floor standing/5-position multiple size rack or puck via ADVIA LabCell and WorkCell	U.S./U.S. and Germany 450/200 batch, random access continuous random access/floor standing/sample rack and aliquot plate system	U.S./U.S. —/— random access, cont. random access/floor-standing/ racks
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	51.5 × 72.4 × 41/20.6	55 3/8 × 84 7/8 × 43 3/8/26	45 × 51 × 31 (without monitor)/10.6
Tests available on instrument in U.S.	total IgE, ferritin, folate, Vit B-12, CKMB, HCV, MYO, TnI-Ultra™, BNP, C-peptide, insulin, cortisol, HAV IgM, HAV total, HBsAg, HBsAg confirmatory, anti-HBs, anti-HBc IgM, anti-HBc total, HCV, eHIV, toxo IgG, toxo IgM, rubella IgG, rubella IgM, AFP, estradiol-6, estradiol-6 III, FSH, total hCG, LH, progesterone, prolactin, testosterone, DHEAS, carbamazepine, digoxin, digoxin, gentamicin, many others	> 125 (includes vendor-supported applications), 35 general chemistry, 14 TDMs, 17 DATs, 3 anemia, 40 plasma proteins, 20 immunoassays including PSA, FPSSA, cyclosporine, LH, FSH, prolactin, and CA19-9	mycophenolic acid, sirolimus, tacrolimus, thyronine uptake, total T4/thyroxine, triiodothyronine, cardiac troponin I, ferritin, free PSA, free T4/thyroxine, human chorionic gonadotropin hormone, mass CK-MB, myoglobin, NT-pro BNP, thyroid stimulating hormone, total PSA CardioPhase hsCRP, complement C3, complement C4, C-reactive protein, C-reactive protein extended range, IgA, IgG, IgM, 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	SHBG, procalcitonin, HBeAg, anti-HBe, fPSA, D-dimer	CA 125, CA 15-3, CA 19-9, fertility panel, cancer markers, plasma proteins, hormones, cardiac, infectious disease LOCI technology, nephelometry, general chemistry	—
Tests not available on other manufacturers' analyzers	cPSA, HER2/neu	—	performs heterogeneous immunoassay and general assays on single platform—fully auto. ISD 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	chemiluminescence/magnetic particle	chemiluminescence, enzyme immunoassay, ACMA, EMIT, LOCI, PETINIA, NEPH/none	ACMA, EMIT, PETINIA, photometry, potentiometry/heterogeneous, magnetic particle
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 to 1,200	47/15–360
Shortest/Median onboard reagent stability/Refrigerated onboard	96 hours/28 days/yes (4°C)	72 hours/30 days/yes (2°–8°C)	48 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/— 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/reconstitutes onboard, no reagent preparation required by operator/liquid
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	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 2 L per hours
Noise generated	61.3 decibels	67 decibels	<70 decibels
Has dedicated pediatric sample cup/Dead volume	no/—	no (can use small sample cup)/10 µL	no (can use small sample cup)/10–20 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/—/no	yes/10 × 50, 10 × 65, 13 × 65, 13 × 75, 13 × 100, 15 × 92, 16 × 100, 13 × 90/no	yes/5, 7, 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 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	no/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/yes
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	22 hours/24 hours	shortest interval: 24 hours/—	24 hours
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	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 83/up to 250 (14.4 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	yes/yes	yes/yes	optional/yes (additional)
LIS interfaces up and running in active user sites	onboard/yes (LIS allowance)	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, others	yes (StreamLab, ADVIA LabCell in development)	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	4–24 hours max	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: 15 minutes
Onboard maintenance records/Maintenance training demo module	yes/yes	no/no/yes	yes/yes
List price/Targeted bed size or daily volume	\$225,000/300+ beds or 400 tests per day	\$552,240/>4,000 tests per day	—
Annual service contract cost (24 hours/7 days)	varies, GPO dependent	inquire	multiple types
Training provided with purchase/Advanced operator training	—/4.5 days on site/yes	4 days on site, 4 days at vendor offices/yes	5 days on site; 4 days at vendor offices/no
Distinguishing features (supplied by vendor)	automates routine operations, includ. ability to access/change solutions, waste, disposables, and reagents w/o pausing sampling or processing; onboard automatic dilutions, repeats, stats and cascade reflex testing; disposable tips; no start-up procedures; always ready; uses same reagents/consumables as Centaur CP w/concordant results; processes 240 tests/hour; avg. time first result ~18 min.	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; Siemens Remote Service	consolidated low-volume workstation integrates immunoassays onboard with other chemistries; allows single platform to meet more than 95 percent of testing needs; eliminates sample splitting, aliquotting

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Name of instrument/First year sold/Where designed	Dimension RxL Max/Max Suite Integrated Chemistry System/2003/U.S.; Dimension RxL Integrated Chemistry System/1997/U.S.	Dimension EXL with LM Integrated Chemistry System/2009/U.S.	IMMULITE 1000/2002/U.S.
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. —/— batch, random access, cont. random access/floor standing/racks	U.S./U.S. —/— batch, random access, continuous random access/floor standing/racks	U.S./U.S., U.K. >7,000 worldwide continuous random access/benchtop/loading platform
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	44 × 62.5 × 30.5/13.2	49 × 82 × 44 (without monitor)/25.1	19 × 46 × 26/7.98
Tests available on instrument in U.S.	mycophenolic acid, sirolimus, tacrolimus, thyronine uptake, total T4/thyroxine, triiodothyronine, cardiac troponin I, ferritin, free PSA, free T4/thyroxine, human chorionic gonadotropin hormone, mass CK-MB, myoglobin, NT-pro BNP, thyroid stimulating hormone, total PSA CardioPhase hsCRP, complement C3, complement C4, C-reactive protein, C-reactive protein extended range, IgA, IgG, IgM, many others	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	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
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
Tests in development	—	LOCI B12, LOCI folate, MPA, LOCI BNP	D-dimer, turbo D-dimer, CMV IgM
Tests not available on other manufacturers' analyzers	—	—	IGF-I, IGFBP-3, androst., 3rd-gen PSA, gastrin, canine TLI, canine TSH
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	ACMIA, EMIT, PETINIA, photometry, potentiometry/heterogeneous, magnetic particle	chemiluminescence, enzyme immunoassay, LOCI, ACMIA, EMIT, PETINIA, photometry, potentiometry/magnetic particle, all LOCI and EMIT methods are homogenous	chemiluminescence/bead, centrifugation
No. of different measured assays onboard simultaneously	91 (with optional reagent management system)	91	12
No. of different assays programmed, calibrated at once	190	190	unlimited
No. of user-definable (open) channels	10	10	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	Max=47, Max Suite=91/15 to 360	91/15-360	12; 5 for Turbo/100; 50 for Turbo i-PTH
Shortest/Median onboard reagent stability/Refrigerated onboard	48 hours/30 days/yes (2°-8°C)	72 hours/30 days/yes (2°-8° C)	—/30 days/yes (15°C)
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	yes	placed directly on system	yes
Reagents bar coded/Information in bar code	yes/lot No., unique flex ID, stability, expiration date	yes/lot No., unique flex ID, stability, expiration date	yes/test, lot No., expir.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/— due to probe washing	yes/none (due to probe washing)	no/<10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	can be hours/60/>2,000/>5,000	can be hours/60/>2,000	100/—/70
System is open (home-brew methods can be used)/Liquid or dry system	yes/no reagent prep required by operator for liquid	yes/liquid, reconstitutes on board (no reagent prep required by the operator)	no/liquid
Uses disposable cuvettes/Maximum number stored	yes/12,000	yes/12,000	yes/—
Uses washable cuvettes/Replacement frequency	no/—	no/—	no/—
Minimum specimen volume required	2 µL	2 µL	5 µL
Minimum sample vol. aspirated precisely at once/Minimum dead volume	2 µL/primary tube capable	2 µL/primary tube capable	5 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/no
Requires dedicated water system/Water consumption	yes/3 L per hour/up to 5 L per hour	yes/up to 5 L	no/0.5 L per hour
Noise generated	<70 decibels	<75 decibels	55-68 decibels
Has dedicated pediatric sample cup/Dead volume	yes/10-20 µL	yes/30 µL	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5, 7, 10 mL/no	yes/5, 7, 10 mL/no	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
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	no/yes	yes/no	no/no
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/no
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/no	no/no
Time between initial result and reaspiration of sample for rerun	<20 seconds	<20 seconds	—
Autocalibration or autocalibration alert	yes	yes	yes
Number of calibrators required for each analyte	varies—3 levels for most assays	varies (3 levels for most assays)	2-level adjustors, supplied in kit
Calibrants can be stored onboard/Average calibration frequency	yes (Na, K, Cl)/most 90 days	yes (NA, K, Cl)/most 90 days	no/1-4 weeks (assay dependent); 2 weeks for Turbo
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes	no/yes
How often QC required	24 hours	24 hours or with lot change	customer determined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	no/yes	no/yes
Automatic shutdown/Startup is programmable/Startup time	not required/—/—	no/no/not required	no/no/5 minutes
Stat time to completion of β-hCG test	16 minutes	16 minutes	42 minutes; 15 minutes for Turbo (total hCG)
Time delay from ordering stat test to aspiration of sample	24 seconds	24 seconds	2.5 minutes
Throughput per hour for three analytes on each specimen, in number of specimens/Number of tests (cycle time)	up to 166/up to 500 (7.2 seconds)	up to 146/437 (7.2 seconds)	120/120 (—)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes	no/yes
Data-management capability/Instrument vendor supplies LIS interface	optional/yes (additional cost)	onboard, optional add-on (EasyLink Informatics System)/yes (additional cost)	onboard/yes (additional cost)
LIS interfaces up and running in active user sites	all major LIS vendors	all major LIS vendors	CIS, CPSI, CCA, Misys, McKesson, Cerner, Antek, CSS, 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	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	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	2-8 hours	2-8 hours	4 hours
Mean time between failures/To repair failures	—	—	10 months/4 hours
Average time to complete maintenance by lab personnel	daily: 5 minutes, weekly: 10 minutes, monthly: 15 minutes	daily: <10 minutes; weekly: 10-15 minutes; monthly: 10-20 minutes	daily: 5 minutes; weekly: 10 minutes; monthly: 20 minutes
Onboard maintenance records/Maintenance training demo module	yes/yes	no/no	—/yes
List price/Targeted bed size or daily volume	—	—	\$75,000; Turbo: \$77,500/>1,000 tests per month
Annual service contract cost (24 hours/7 days)	multiple types	multiple types	\$8,000
Training provided with purchase/Advanced operator training	5 days on site, 4 days at vendor offices/yes	yes (5 days on site, 4 days at vendor offices)/no	3.5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	integrates heterogeneous immunoassays onboard with other chemistries; single platform for more than 95 percent of most requested tests; eliminates sample splitting between general tests and immunoassays	integrates homogeneous LOCI and heterogeneous immunoassays onboard with other chemistries; allows single platform for >95 percent of most tests; eliminates sample splitting between gen. chemistry tests and immunoassays; fully automated onboard ISD assays	reliability and performance; large test menu

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

Automated immunoassay analyzers

Part 22 of 24	Siemens Healthcare Diagnostics Martu Richards martu.richards@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 914-524-3828 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Martu Richards martu.richards@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 914-631-8000 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Christina Tassone christina.tassone@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics
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	IMMULITE 2000/1998/U.S. U.S./U.S., U.K. >5,500 worldwide continuous random access/floor standing/rack 47 x 60 x 30/12.5	IMMULITE 2000 XPi Immunoassay System*/2009/U.S. U.S./Wales, UK —/600 random access/floor standing/rack 47 x 60 x 30/12.5	Stratus CS Acute Care Diagnostic System/1998/U.S. U.S./U.S. —/— random access/benchtop/whole blood collection tube 18 x 27 x 22/4.1
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, CKMB, cortisol, C-peptide, DHEA-SO4, digitoxin, digoxin, EPO, estradiol, ferritin, folic acid, free PSA, free T3, free T4, FSH, gastrin, growth hormone (hGH), 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	mass CK-MB, myoglobin, β -hCG, D-dimer, NT-proBNP, high-sensitivity troponin I, CardioPhase hsCRP
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, allergen-specific IgG4, ECP, cannabinoids (THC), D-dimer anti-CCP IgG, D-dimer, HBsAb quantitative, EBV-EBNA IgG, EBV-VCA IgG, EBV-VCA IgM, Lyme screen	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 D-dimer, EBV-EBNA IgG, EBV-VCA IgG, EBV VCA IgM, Lyme screen, anti-CCP IgG	— —
Tests in development	3gPSA, IGF-1, IGFBP-3, H. pylori IgG, androst., gastrin, canine TLI, canine TSH, veterinary free T4	3gPSA, IGF-1, IGFBP-3, H. pylori IgG, androst., gastrin, canine TLI, canine TSH, veterinary free T4	—
Tests not available on other manufacturers' analyzers	—	—	—
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	chemiluminescence/bead, centrifugation	chemiluminescence/—	fluorescence, EIA, dendrimer technology/fiber matrix filter
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	24 unlimited — 24/200 —/90 days/yes (4°C) yes yes yes/test, lot No., expiration no/<3 ppm 300/90/1,300	24 unlimited — — — — — 300/90/1,300	up to 4 1 0 up to 4 TestPaks/unit dose TestPak — yes yes yes/assay ID, lot No., expiration, calibration parameter no/zero carryover 14 minutes to 1st result, subsequent results in 4 minutes intervals/1/up to 4
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	no/liquid yes/1,300 no/— 5 μ L to 100 μ L sample 5 μ L/50 μ L yes/no no/— 52 decibels yes/50 μ L yes/75–100 mm height; 12–16 mm width/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes —/— yes/yes no/no minimum 18 seconds yes 2-level adjustors, supplied in kit no/1–4 weeks (assay dependent) yes/yes customer determined	no/liquid no/— — 5 μ L to 100 μ L 5 μ L/50 μ L yes/— no/— — yes/uses specialized racks yes/75–100 mm/no yes (2 or 5 interleaved, Codabar, codes 39 and 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes no/no — yes 2 level adjustors, supplied in kit no/1–4 weeks (assay dependent) yes/yes customer determined	no/liquid no/— no/— 2.5 mL whole blood 50-90 μ L/— optional/no no/— <65 decibels no yes/4 or 5 mL/yes yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes — —/yes yes yes/no not affected yes/no no/no — yes 1 Calpak no/30–90 days same lot, new lot yes/yes shortest interval: daily electronic QC, longest: every 30 days for liquid controls yes/yes no/no/30 minutes to warm up
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	35 minutes (total HCG) 18 seconds 200/200 (18 seconds) yes/yes onboard/yes (additional cost) Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Misys, SCC, others	35 minutes 18 seconds 200/200 (18 seconds) yes/yes onboard (\$2,000 QC software only, Siemens)/yes —	14 minutes immediately 3/9 yes/yes yes/yes (additional cost) 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) yes (universal interface) yes/yes/yes no 4 hours 3 months/5 hours daily: 5 to 10 minutes; weekly: 20 minutes; monthly: 20–30 minutes no/yes	yes yes (broadcast download and host query) yes, universal interface yes/yes/yes no 4 hours 3 months/5 hours daily: 5 to 10 minutes; weekly: 20 minutes; monthly: 20–30 minutes no/yes	yes no no no/yes/yes no 2 to 8 hours >225 days/2.9 hours monthly: 10 minutes no/yes
Onboard maintenance records/Maintenance training demo module	no/yes	no/yes	no/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided with purchase/Advanced operator training	\$124,500/>6,000 tests per month \$16,500 (RealTime Solutions) varies on site, 5 days at vendor offices/yes	under development/>6,000 per months under development —	—/any size emergency department multiple types 3 days on site/no
Distinguishing features (supplied by vendor)	high-throughput system, combines specific allergens and routine esoteric testing on one platform; clot detection; sample/reagent level detection; autodilution & autoreflex testing; remote diagnostics; QM & logistics reports	—	whole blood collection tubes or precentrifuged plasma; onboard centrifugation; unit-dose test packs; color-coded calibrators packaged on Calpacks; diluent packs; self-contained system; closed container sampling; electronic QC; POCT1-A compliant when interfaced to Telcor or MAS Data Managers; also available as the Stratus CS Kiosk System, a stand-alone workstation featuring its own cart, refrigerator, & uninterruptible power supply

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

* IMMULITE 2000 XPi Immunoassay System is under development, not for sale in U.S.

Automated immunoassay analyzers

Part 23 of 24	TOSOH Bioscience Inc. Susan Kolarik susan.kolarik@tosoh.com 6000 Shoreline Court, Ste. 101 South San Francisco, CA 94080 800-248-6764 www.tosoh.com	TOSOH Bioscience Inc. Shanti Narayanan shanti.narayanan@tosoh.com 6000 Shoreline Court, Ste. 101 South San Francisco, CA 94080 800-248-6764 www.tosoh.com	TOSOH Bioscience Inc. Shanti Narayanan shanti.narayanan@tosoh.com 6000 Shoreline Court, Ste. 101 South San Francisco, CA 94080 800-248-6764 www.tosoh.com
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-900/2011/Japan Japan/Japan —/40 continuous random access/floor standing/rack	AIA-2000/2008/Japan Japan/Japan 26/200 continuous random access/floor standing/rack, sorter drawer	AIA-360/2004/Japan Japan/Japan 1,300/3,000 continuous random access/benchtop/carousel
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	35.04, 50.79, or 58.64 × 26.18 × 49.09/6–10	49.6 × 59.1 × 35.7/14.66	21 × 19 × 16/2.1
Tests available on instrument in U.S.	TSH, TSH3rdGen, T4, TT3, TU, FT4, FT3, TPOAb, TgAb, BHCG, estradiol, FSH, LH, progesterone, prolactin, Testosterone, AFP, CEA, PSA, CA125, CA19-9, 27.29, B2 microglobulin, C-peptide, insulin, IgE, PAP, cortisol, HGH, B12, folate, RBC folate, ferritin, intact PTH, CK-MB, myoglobin, cTnI2ndGen, HbA1c, cystatin C	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, IgE, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen, ferritin, folate, B12, testosterone, CA 19-9, intact PTH, RBC folate, cystatin C	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, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen., ferritin, testosterone, CA 19-9, intact PTH, cystatin C, HbA1c
Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	ACTH, DHEA-S BNP, HbSAg, HbSAb, HbCAb, HbEAb, cTnI3rdGen, PSAII, TrAb, HCVAb, HCG, free PSA vitamin D, D-dimer	ACTH, DHEA-S BNP, HbSAg, HbSAb, HbCAg, HbCAb, HbEAg, cTnI 3rd gen, PSA II, TrAb, HCVAb, HCG, free PSA vitamin D, D-dimer	ACTH, DHEA-S BNP, HbSAg, HbSAb, HbCAg, HbCAb, HbEAg, cTnI 3rd gen., PSA II, TrAb, HCVAb, HCG, free PSA vitamin D, D-dimer
Tests in development Tests not available on other manufacturers' analyzers	—	—	—
Fully automated microplate system Number of each analyte performed in separate disposable unit Number of wells in microplate	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	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 µL 10 µL/100 µL yes/no no/— — no/— yes/13 × 75, 100; 16 × 75, 100/no	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 µL tube, 100 µL cup 10 µL/500 µL tube, 100 µL cup yes/no no/— — no/— yes/7mL and 10 mL or 15 × 75 and 100, 13 × 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, EIA/bead 25 entire menu 0 —/unitized test cup 72 hours/72 hours/— yes yes yes/lot No., test code no/zero carryover 58/25/25 no/dry no no 500 µL tube, 100 µL cup 10 µL/500 µL tube, 100 µL cup no/no no/— — no yes/primary draw tubes: 13 × 75 and 100; 16 × 75 and 100/no yes/yes yes yes yes/yes yes yes/no no/no no/no no/no — no 2 or 6 (analyte dependent) no/90 days yes/yes 24 hours no/no no/no/5 minutes
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 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	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	yes/yes yes yes yes/yes yes yes/no no/no no/no no 2 or 6 (analyte dependent) no/90 days yes/yes 24 hours no/no 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) 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	~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	~18 minutes 40 seconds 66/200 (18 second) 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 60 seconds 12/36 (1 minute) yes/no Antek, Schuyler House, more — — no no no/no/no no — >6 months/24 hours daily: 5 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	\$60,000 base model/500+ monthly \$6,000 base model —/no	\$185,000/65+ beds, 1,500–2,000 tests depends on acquisition option 4 days at vendor's office/no	\$25,000/200 to 1,000 tests per month \$2,050–\$3,500 training DVD; on-site install
Distinguishing features (supplied by vendor)	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	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	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

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

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receivable systems

Laboratory-provider
links software

Bedside glucose
testing systems

Middleware systems

Anatomic pathology
computer systems

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Hematology analyzers

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Automated immunoassay analyzers

Part 24 of 24	TOSOH Bioscience Inc. Susan Kolarik susan.kolarik@tosoh.com 6000 Shoreline Court, Ste. 101 South San Francisco, CA 94080 800-248-6764 www.tosoh.com	TOSOH Bioscience Inc. Susan Kolarik susan.kolarik@tosoh.com 6000 Shoreline Court, Ste. 101 South San Francisco, CA 94080 800-248-6764 www.tosoh.com
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	AIA-1800/2003/Japan Japan/Japan 80/550 continuous random access/floor standing/rack, sort drawer, standard and LA 65 × 50 × 37/12.8	AIA-600 II/2000/Japan Japan/Japan 680/1,600 cont. random access/benchtop/chain 19.8 × 31.6 × 29.1/6.4
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	TSH, 3rd-gen. TSH, FT4, T3, T4, T-uptake, FT3, TPO Ab, Tg Ab, βhCG, 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 2nd gen., ferritin, folate, B12, testosterone, CA 19-9, RBC folate, intact PTH, cystatin C ACTH, DHEA-S BNP, HBSAg, HBSAb, HBCAg, HBCAb, HBeAg, cTnl 3rd gen., PSA II, TrAb, HCVAb, HCG, free PSA vitamin D, D-dimer —	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 2nd gen., ferritin, folate, B12, testosterone, CA 19-9, intact PTH, RBC folate, cystatin C, HbA1c ACTH, DHEA-S HBSAg, HBSAb, HBeAg, HbcAb, HbeAb, BNP, cTnl 3rd gen., PSA II, TrAb, HCVAb, HCG, free PSA vitamin D, D-dimer —
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	fluorescence, EIA/beam 31 trays entire menu 0 —/unitized test cup 72 hours/72 hours/— yes yes yes/lot No., test code no/zero carryover 58/170/640 no/dry —/unitized test cup — 500 μL tube, 100 μL cup 10 μL/500 μL tube, 100 μL cup yes/no no/— — no yes/primary draw tubes: 7 mL and 10 mL or 15 × 75 and 100; 13 × 75 and 100/no yes/yes	fluorescence, EIA/beam 26 entire menu 0 —/unitized test cup 72 hours/72 hours/— yes yes yes/lot No., test code no/zero carryover 52/26/26 no/dry —/unitized test cup — 500 μL tube, 100 μL cup 10 μL/500 μL tube, 100 μL cup yes/no no/— — no yes/primary draw tubes: 7 mL and 10 mL or 15 × 75 and 100, 13 × 75 and 100/no yes/yes
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 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 to 8 minutes	yes yes yes/yes yes yes/no no/no yes/no no/yes — no 2 or 6 (analyte dependent) no/90 days yes/yes 24 hours no/no 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) 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	~18 minutes 40 seconds 60/180 (20 seconds) yes/yes yes/no yes yes yes (broadcast download and host query) yes (Hitachi, Siemens, Thermo, iLAS) no/no/no no 24 hours 5 months/24 hours daily: 5 to 8 minutes; weekly: 5 minutes; monthly: none yes (includes audit trail of who replaced parts)/no	~18 minutes 60 seconds 20/60 (1 minute) yes/no optional add-on (all major LIS vendors—Schuyler House, Misys, LabForce, McKesson, Antrim, Data Innovations)/yes (additional cost) yes yes (broadcast download and host query) no no/no/no no 24 hours 98% uptime/— daily: 5 minutes; weekly: 5 minutes; monthly: none 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	\$175,000/65+ beds, 1,500 to 2,000 tests \$11,458 4 days at vendor offices/no	\$70,000/500–2,500 tests per month \$5,941 3 days at vendor offices/no
Distinguishing features (supplied by vendor)	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

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