

## Automated immunoassay analyzers

Part 1 of 31	Abbott Diagnostics Hamid Erfanian hamid.erfaniaan@abbott.com 100 Abbott Park Rd, Abbott Park IL, 60064 847-938-9485 www.abbottdiagnostics.com	Abbott Diagnostics Hamid Erfanian hamid.erfaniaan@abbott.com 100 Abbott Park Rd, Abbott Park IL, 60064 847-938-9485 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. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	AxSYM/AxSYM Plus/1993 worldwide, 1994 U.S./U.S. U.S./U.S. 1,275/12,937 cont. random access/stat, batch floor-standing/segment 60.5 x 63 x 33.5/14.6	ARCHITECT i2000/1998, i2000SR/2003, i4000SR/2007/U.S. U.S./U.S. 468/6,752 batch, random access, cont. random access/floor-standing/track & LAS 48 x 61 x 49/20.3, i2000, 48 x 68 x 44/22.7 per module
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	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, estradiol, FSH, hCG (Total B-hCG), LH, progesterone, prolactin, testosterone, anti-HAV, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-HBs, anti-HCV, HBsAg, HBsAg confirmatory, active-B12 (HoloTC), anti-CCP, vitamin B12, cortisol, ferritin, folate, glycated hemoglobin, homocysteine, carbamazepine, digoxin, gentamicin, N-acetyl-procainamide, phenobarbital, phenytoin, procainamide, quinidine, theophylline, tobramycin, valproic acid, vancomycin, anti-Tg, anti-TPO, free T3, free T4, T-uptake, total T3, total T4, ultrasensitive hTSH II — — CA 19-9, D-dimer, CMV IgG, HBe, beta2 microglobulin, insulin, digitoxin, 3rd gen TSH, cyclosporine, HIV Ag/Ab combo, anti-HIV-1/HIV-2 — — — —	(i2000/i2000SR) 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, valproic acid, vancomycin, anti-Tg, anti-TPO, free T3, free T4, T-uptake, total T3, total T4, TSH, cyclosporine, sirolimus, tacrolimus, anti-CCP; (i4000SR) 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, anti-CCP, C-peptide, cortisol, ferritin, homocysteine, insulin, intact PTH, digoxin, phenobarbital, phenytoin, theophylline, valproic acid, vancomycin, anti-Tg, anti-TPO, free T3, free T4, others HE-4 — AFP, HE-4, anti-HAV IgG, vitamin B12, folate, NGAL, proGRP, MPO, SCC, anti-HAV IgG, anti-HBe, HBeAg, CMV IgG, CMV IgG avidity, CMV IgM, rubella IgG, rubella IgM, Toxo IgG, Toxo IgG avidity, Toxo IgM, anti-HTLV-I/HTLV-II, HIV Ag/Ab combo, syphilis, others — vitamin D, carbamazepine, gentamicin, methotrexate, Tg — —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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	FPIA, MEIA, ion capture, REA/heterogen., bead (microparticle), fiber matrix filter 20 20 0 20/100  onboard reagent stability: 112, 224, 336/no no yes yes/assay name, reagent lot No., expir. date, pack No. ID  no/<0.1 ppm 60/90/90 no/liquid yes/90 reaction vessels no 83 µL/150 µL 10 µL/73 µL for sample cup, 450 µL for aliquot, 4.5 mL for primary yes (soft close of files only)/optional no/— 52–68 decibels no yes/100 & 75 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 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/yes no/no/1 minute	CHEMIFLEX (enhanced chemiluminescence) w/5 flexible protocols/magnetic microparticle 25 25 — 25/100-test & 500-test per kit  30 days/30 days/yes (2°–12°C) yes yes yes/assay No., reagent serial No., lot No., tests per kit, exp. date, onboard stability time, master calibration curve no/<0.1ppm 300/135/12,500 no/liquid yes/1,200 no/— 50 µL 150 µL/50 µL for all tube types yes/no no/— 48–70 decibels no yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no <20 seconds yes 2–6 pt. curve no/minimum 30 days or once per lot yes/yes 3 levels every 24 hours for quantitative, 2 levels for qualitative yes/yes —/no/10 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	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 no — yes (broadcast download & host query) yes yes no/yes/yes yes, AbbottLink 12 hours 5 months/within 12 hours per customer request yes daily: 14 min, weekly: 65 min, monthly: 11 min no/no	15.6 minutes <20 seconds 67/200 tests per hour yes/yes onboard/no all major LIS vendors yes no — yes (broadcast download & host query) yes yes yes/yes/yes yes, AbbottLink 12 business hours 10.4 weeks/— yes daily: 16 min, weekly: <10 min, monthly: none (for both manual & auto procedures) yes/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/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 TAT; see operations manual for additional information	CHEMIFLEX tech. delivers excellent sensitivities and extended linearities, RSH allows priority and routine samples to be processed simultaneously w/o compromising stats; see operations manual for additional information

## Automated immunoassay analyzers

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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	ARCHITECT ci4100, ci8200, ci16200/2003, 2007/U.S. U.S./U.S. 41 (ci4100), 281 (ci8200), 15 (ci16200)/157 (ci4100), 1,487 (ci8200), 201 (ci16200) batch, random access, cont. random access/floor-standing/robotic sample handler uses multi-dimensional sample handling 48 x 127 x 49/43.2	ARCHITECT i1000SR/2008/U.S. U.S./U.S. 162/1,438 continuous random access/floor-standing/robotic sample handler allows batch, random access, cont. access and reagent loading and unloading 49 x 59 x 30/14.7
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development  User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	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, free T3, free T4, T-uptake, total T3, total T4, TSH, cyclosporine, sirolimus, tacrolimus, acetaminophen, amphetamine/methamphetamine, barbiturates, benzodiazepines, benzodiazepines-serum, cannabinoids, cocaine, ecstasy, ethanol, methadone, opiates, phencyclidine (PCP), propoxyphene, salicylate, tricyclic antidepressants, others HE-4, anti-HBs, HBsAg, HBsAg confirmatory — AFP, HE-4, proGRP, NGAL, B12, folate, anti-HAV IgG, anti-HBc, anti-HBs, HBsAg, HBsAg confirmatory, MPO, SCC, testosterone, CMV IgG, CMV IgG avidity, CMV IgM, rubella IgG, rubella IgM, Toxo IgG, Toxo IgG avidity, Toxo IgM, syphilis, HIV Ag/Ab combo, alpha-1-antitrypsin, alpha-1-glycoprotein, ASO, beta 2 microglobulin, ceruloplasmin, IgE, others — AFP, anti-HAV IgG, anti-HBc, vitamin B12, folate, vitamin D, NGAL, carbamazepine, gentamicin, methotrexate, Tg —	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, free T3, free T4, T-uptake, total T3, total T4, TSH, cyclosporine, sirolimus, tacrolimus  HE-4, anti-HBs, HBsAg, HBsAg confirmatory — AFP, HE-4, ProGRP, NGAL, vitamin B12, folate, anti-HAV IgG, anti-HBc, anti-HBs, HBsAg, HBsAg confirmatory, MPO, SCC, testosterone, CMV IgG, CMV IgG avidity, CMV IgM, rubella IgG, rubella IgM, Toxo IgG, Toxo IgG avidity, Toxo IgM, syphilis, HIV Ag/Ab combo — AFP, anti-HAV IgG, anti-HBc, vitamin B12, folate, vitamin D, NGAL, carbamazepine, gentamicin, methotrexate, Tg —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	— — —	— — —
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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	photometric, potentiometric, & CHEMIFLEX (enhanced chemiluminescence) 93 93 220 93/50-1,700 3 days/28 days/yes yes yes yes/assay name, reagent No., lot No., tests per kit, expiration date, others open system/SmartWash technology 300/367/>75,000 yes/liquid both disposable and semi-permanent glass/1,200 or 165/330 yes/as needed, 1-year minimum 2 µL 50 µL yes/yes yes/25 L per hour (ci8200)/52 L per hour (ci16200) 48-70 decibels no yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes/yes yes/yes yes/yes yes/yes yes/yes no/no <20 seconds yes 2 or 6 pt. no/28 days yes/yes from 2 levels after calibration, to 3 per 24 hours yes/yes —/no/10 minutes	chemiluminescence/magnetic particle 25 25 none 25/25-100 —/30 days/yes yes yes yes/assay No., reagent serial No., lot No., test per kit, exp. onboard stability time, others no/<0.1 PPM 3 hrs/65/25 no/liquid yes/360 no/— 60 µL 60 µL/50 µL yes/no no/— 50 decibels during normal operation, 62 decibels maximum no/— yes/pediatric, 5, 7, 10 mL tubes and sample cups/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no <20 seconds yes 2-6 pt. curve no/minimum 30 days or once per lot yes/yes from 2 levels for qualitative to 3 levels every 24 hrs yes/yes no/no/6.5 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	<15.6 minutes <20 seconds 400/1,200 yes/yes onboard/no all major LIS vendors yes no — yes (broadcast download & host query) yes no yes/yes/yes yes, AbbottLink 8 business hours 10.4 weeks/— yes daily: <15 min, weekly: <35 min, monthly: 15 min (for manual & 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 no — yes (broadcast download & host query) yes yes yes/yes/yes yes 12 business hours —/— yes daily: 10 min, weekly: 17 min, monthly: 90 min. yes/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/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 TAT, 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; see operations manual for additional information	streamlined workload mgmt., contin. access to reagents, samples, and supplies, 65 samp. load cap., 13 univ. bay, up to 7 custom. priority bays, refig. reagent carousel w/25x100 test kit sizes, reagents stable onboard up to 30 days, priority tests, 15.6-min. TAT on stat assays; see operations manual for additional information

## Automated immunoassay analyzers

Part 3 of 31	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. Joel Greiner jcgreiner@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 Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	ChemWell/1998/U.S. U.S./open system 50+/2,500+ batch, random access/benchtop/rack 16 x 34 x 20/4	Access/Access 2 Immunoassay System/2001/U.S. U.S./U.S, France, Ireland >2,400/>4,000 continuous random access/benchtop/rack 18.5 x 39 x 24/6.5
Tests available on instrument in U.S.	unlimited—open system	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase, ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total B <sub>h</sub> CG and Dil B <sub>h</sub> CG, unconjugated estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thyroglobulin, thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO PSA, WHO free PSA
Tests cleared but not clinically released 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
Research-use-only assays Tests in development	unlimited—open system —	IL-6, PAPP-A vitamin D, PIGF, sVEGF R1
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	general biochemistries —	— —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes up to 12 min. strip, 8; max. full plate, 96	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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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 up to 12 unlimited unlimited 27/assay dependent assay dependent/assay dependent/yes (10°C below ambient) yes yes no no/none assay dependent/96/12 yes/liquid yes/96 yes/assay dependent 2 µL 2 µL/— no/no no — no yes/12 x 100 mm/no no/— — yes no/no yes no/yes no/no yes/no yes/yes assay dependent no assay dependent yes/assay dependent yes/yes shortest interval: each run; longest: daily yes/yes yes/yes/2 minutes	chemiluminescence/magnetic particle 24 24 0 24/100 tests per kit; 50 tests per cartridge 336 hours/28 days/yes (3° to 10°C) yes yes yes/specific cartridge ID, expiration date, lot No., unique reagent pack ID No. no/<10 ppm up to 180 based on consumable capacity/60/assay dependent no/liquid yes/294 no/— specimen container dependent 5 µL/100 µL no/no no/— <70 decibels yes/100 µL yes/12 x 75, 13 x 75 & 100, 16 x 75 & 100/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes no yes/yes yes yes/yes (Access 2 only) no/no no/no no/no 36 seconds no assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	assay dependent 30 seconds assay dependent yes/yes onboard/yes (included) — no no — yes (broadcast download & host query) yes no yes/yes/yes no within 48 hours —/— yes daily: <10 min; weekly: <10 min; monthly: <10 min no/no	15 minutes ≥36 seconds 33/100 (36 seconds) yes/yes onboard/yes (included or additional cost—negotiable) all major LIS vendors yes no — yes (broadcast download & host query) yes no no/no/no no per negotiated service contract —/— yes daily: 15 min; weekly: 30 min yes (Access 2 only)/online help with maintenance instructions
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$25,000/up to 500 tests per day \$4,000 3 days on site/no	\$149,800/all volumes & hospital sizes \$15,800 yes/yes (Access 2 only)
Distinguishing features (supplied by vendor)	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

## Automated immunoassay analyzers

Part 4 of 31	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Joel Greiner jcgreiner@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 Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	UniCel Dxl 600 Access Immunoassay System/2007/U.S. U.S./U.S., France, Ireland >200/>100 continuous random access/floor standing/rack, direct track sampling 67 × 61.5 × 37.5/16.02	UniCel Dxl 800 Access Immunoassay System/2003/U.S. U.S./U.S., France, Ireland >500/>500 continuous random access/floor standing/rack, direct track sampling 67 × 67.5 × 37.5/17.6
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development  User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostease, ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG, unconjugated estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thyroglobulin, thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO PSA, WHO free PSA — — HAV Ab, HAV IgM, HBc Ab, HBe IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM IL-6, PAPP-A vitamin D, PIGF, sVEGF R1 — —	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostease, ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG, unconjugated estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thyroglobulin, thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO PSA, WHO free PSA — — HAV Ab, HAV IgM, HBcAb, HBe IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM IL-6, PAPP-A vitamin D, PIGF, sVEGF R1 — —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	chemiluminescence/magnetic particle 50 50 — 50/100 and 300 tests per kit; 50 tests per cartridge  336 hours/28 days/yes (3°–10°C) yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration yes/<10 ppm 180 to 240 based on consumable capacity/60/assay dependent closed/liquid yes/1,000 no/— specimen container dependent 5 µL/80 µL no/no no/— <60 decibels yes/100 µL yes/12 × 75, 13 × 75 & 100, 16 × 75 & 85 & 100 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 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	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) yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration yes/< 10 ppm 180 to 240 based on consumable capacity/120/assay dependent no/liquid yes/>1,000 no/— specimen container dependent 5 µL/160 µL no/no no/— <60 decibels yes/100 µL yes/12 × 75, 13 × 75 & 100, 16 × 75, 85, & 100 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no  36 seconds yes assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	15 minutes 18 seconds —/200 (18 seconds) yes/yes onboard/yes (included in instrument price & additional cost) all major LIS vendors yes no — yes (broadcast download & host query) yes yes, Beckman Coulter automation systems yes/yes/yes no per negotiated contract —/— yes daily: <10 min yes/online help with maintenance instructions	15 minutes 18 seconds ≤133/≤400 (9–18 seconds) yes/yes onboard/yes (included or additional cost—negotiable) all major LIS vendors yes no — yes (broadcast download & host query) yes yes (Beckman Coulter automation systems) yes/yes/yes no per negotiated contract —/— yes daily: <10 min yes/online help with maintenance instructions
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/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 \$29,900 yes/yes
Distinguishing features (supplied by vendor)	integrates with UniCel DxC chemistry systems; uses chemiluminescent technology and same reagent packs to deliver consistent results with other UniCel immunoassay systems; allows operators to load consumables on-the-fly, without interacting with the system	high-throughput immunoassay analyzer; integrates w/UniCel DxC chemistry systems; uses chemiluminescent technology and same reagent packs for consistent results w/other UniCel systems; allows operators to load consumables on-the-fly, without interacting with the system

## Automated immunoassay analyzers

Part 5 of 31	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Joel Greiner jcgreiner@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 Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	UniCel DxC 600i Synchron Access Clinical System/2006/U.S. U.S./U.S., France, Ireland >400/100 continuous random access/floor standing/rack-closed tube 62 x 128 x 48/42.7	UniCel Dxl 660i Synchron Access Clinical System/2009/U.S. U.S./U.S., France, Ireland >75/>50 continuous random access/floor standing/rack closed-tube 68 x 147 x 48/49
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase, ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG, unconjugated estriol, free T3, free T4, fast hTSH, HYPERSensitive hTSH, thyroglobulin, thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO PSA, WHO free PSA, >100 Synchron chemistry tests (critical care, general esoterics, urine & CSF chemistries, DATs, TDMs, proteins, serologies) — — HAV Ab, HAV IgM, HbCAb, HbC IgM, HbSAb, HbSAg, HbSAg confirmatory, CMV IgG, CMV IgM, rubella IgM (BVID assays can only be run on the Access 2 portion of DxC 600i in standalone mode) IL-6, PAPP-A vitamin D, PIGF, sVEGF R1 — —	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase, ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG, unconjugated estriol, free T3, free T4, fast hTSH, HYPERSensitive hTSH, thyroglobulin, thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO PSA, WHO free PSA, , plus >100 Synchron chemistry tests, including critical care, general esoterics, urine & CSF chemistries, DATs, TDMs, proteins, serologies) — — HAV Ab, HAV IgM, HbCAb, HbC IgM, HbSAb, HbSAg, HbSAg confirmatory, CMV IgG, CMV IgM, rubella IgM — — IL-6, PAPP-A vitamin D, PIGF, sVEGF R1 — —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	chemiluminescence, enzyme immunoassay/magnetic particle 89 89 100 89/100 tests per kit (immunoassay); 300 tests per container (gen. chem.) 336 hours/28 days/yes (3° to 10°C)/yes yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration yes/<10 ppm 60/76/assay dependent no/liquid yes/125 yes/— container dependent 3 µL/20 µL (gen. chem.) yes/yes yes/16 L per hour — yes/— yes/13 x 75 & 100, 15 x 75 & 92, 16 x 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes (gen. chem.) yes/yes yes/yes chemistry dependent dependent assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode	chemiluminescence, enzyme immunoassay/magnetic particle 115 115 100 115/100 tests per kit (immunoassay); 300 tests per container (gen. chem.) 336 hours/28 days/yes (3° to 10°C) yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No. calibration expiration, within lot calibration yes/<10 ppm 60/76/assay dependent closed/liquid yes/125 yes/— container dependent 3 µL/20 µL (gen. chem.) yes/yes yes/up to 16 L per hour — yes/— yes/13 x 75 & 100, 15 x 92 & 75, 16 x 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes (gen. chem.) yes/yes yes/yes chemistry 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 aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	15 minutes 1 minute (gen. chem.) 90/720 (40 seconds) (gen. chem.) yes/yes optional add-on/yes (additional cost) all major LIS vendors yes no — yes (broadcast download & host query) yes yes (Beckman Coulter automation systems) yes/yes/validate for the DxC 600i no per negotiated service contract —/— yes — yes/online help with maintenance instructions	15 minutes 1 minute (gen. chem.) 90/720 (40 seconds) (gen. chem.) yes/yes —/— — yes no — yes (broadcast download & host query) yes yes, Beckman Coulter automation systems yes/yes/yes no per negotiated service contract — yes — yes/online help with maintenance instructions
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$325,000/moderate volume, <300 samples per day per negotiated contract yes/yes	\$575,000/high volume, 300–750 samples per day per negotiated contract yes/yes
Distinguishing features (supplied by vendor)	performs parallel processing of immunoassay and chemistry tests on one system; ClozCap technology (closed-tube aliquot and closed-tube sampling) eliminates manual processes; chemistry and immunoassay reagent packs are identical across the UniCel family of systems	performs parallel processing of immunoassay and chemistry tests on one system; ClozCap technology (closed-tube aliquot and closed-tube sampling) eliminates manual processes; chemistry and immunoassay reagent packs are identical across the UniCel family of systems

## Automated immunoassay analyzers

Part 6 of 31	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Joel Greiner jcgreiner@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 Dimensions in inches (H x W x D)/Instrument footprint in sq. feet	UniCel DxC 680i Synchron Access Clinical System/2009/U.S. U.S./U.S., France, Ireland 4/2 continuous random access/floor standing/rack closed-tube 68 x 153 x 48/51	UniCel Dxl 860i Synchron Access Clinical System/2009/U.S. U.S./U.S., France, Ireland 8/0 continuous random access/floor standing/rack closed-tube 68 x 155 x 48/51.7
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development  User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase, ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG, unconjugated estradiol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thyroglobulin, thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO PSA, WHO free PSA, >100 Synchron chemistry tests (critical care, general esoteric, urine & CSF chemistries, DATs, TDMs, proteins, serologies) — — HAV Ab, HAV IgM, HbCAb, HbC IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM IL-6, PAPP-A vitamin D, PIGF, sVEGF R1 — —	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostase, ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total BhCG and Dil BhCG, unconjugated estradiol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thyroglobulin, thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO PSA, WHO free PSA, >100 Synchron chemistry tests (critical care, general esoteric, urine & CSF chemistries, DATs, TDMs, proteins, serologies) — — HAV Ab, HAV IgM, HbCAb, HbC IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM IL-6, PAPP-A vitamin D, PIGF, sVEGF R1 none —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	chemiluminescence, enzyme immunoassay/magnetic particle 115 115 100 115/100 tests per kit (immunoassay); 300 tests per container (gen. chem.) 336 hours/28 days/yes (2° to 10°C) yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No. calibration expiration, within lot calibration yes/<10 ppm 60/76/assay dependent closed/liquid yes/125 yes/— container dependent 3 µL/20 µL (gen. chem.) yes/yes yes/up to 16 L per hour — yes/— yes/13 x 75 & 100, 15 x 75 & 92, 16 x 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes (gen. chem.) yes/yes yes/yes chemistry dependent — assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode	chemiluminescence, enzyme immunoassay/magnetic particle 120 120 100 120/100 tests per kit (immunoassay); 300 tests per container (gen. chem.) 336 hours/28 days/yes (2° to 10°C) yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration yes/<10 ppm 60/112/assay dependent closed/liquid yes/125 yes/— container dependent 3 µL/20 µL (gen. chem.) yes/yes yes/up to 16 L per hour — yes/— yes/13 x 75 & 100, 15 x 75 & 92, 16 x 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes chemistry dependent — assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	15 minutes 1 minute (gen. chem.) 90/720 (40 seconds) (gen. chem.) yes/yes —/— — yes no — yes (broadcast download & host query) yes yes, Beckman Coulter automation systems yes/yes/validate for the DxC 600i no per negotiated service contract — yes — yes/online help with maintenance instructions	15 minutes 1 minute (gen. chem.) 90/720 (40 seconds) (gen. chem.) yes/yes —/— — yes no — yes (broadcast download & host query) yes yes, Beckman Coulter automation systems yes/yes/yes no per negotiated service contract — yes — yes/online help with maintenance instructions
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$610,000/high volume, 300–750 samples per day per negotiated contract yes/yes	\$615,000/high to very high volume, 500–1,500 samples per day per negotiated contract yes/yes
Distinguishing features (supplied by vendor)	performs parallel processing of immunoassay and chemistry tests on one system; ClozCap technology (closed-tube aliquot and closed-tube sampling) eliminates manual processes; chemistry and immunoassay reagent packs are identical across the UniCel family of systems	performs parallel processing of immunoassay and chemistry tests on one system; ClozCap technology (closed-tube aliquot and closed-tube sampling) eliminates manual processes; chemistry and immunoassay reagent packs are identical across the UniCel family of systems

## Automated immunoassay analyzers

Part 7 of 31	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd, Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Binding Site Faranak Atrzadeh faranak.atrzadeh@thebindingsite.com 5889 Oberlin Drive, Suite 101, San Diego, CA 92121 800-633-4484 www.thebindingsite.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) 20.5 × 31.5 × 25.2/14
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	68 × 161 × 48/53.7	20.5 × 31.5 × 25.2/14
Tests available on instrument in U.S.	cortisol (serum, plasma, urine), total IgE, EPO, ferritin and Dil ferritin, folate, intrinsic factor Ab, RBC folate, sTfR, vitamin B12, intact PTH (routine or intraoperative), ostease, ultrasensitive hGH, CK-MB, digoxin, myoglobin, triage BNP, ultrasensitive insulin, rubella IgG, toxo IgG, toxo IgM II, AFP (ONTD) and Dil AFP, DHEA-S, estradiol, hFSH, hLH, inhibin A, progesterone, prolactin, SHBG, testosterone, total hCG and Dil hCG, unconjugated estriol, free T3, free T4, fast hTSH, HYPERsensitive hTSH, thyroglobulin, thyroglobulin Ab II, thyroid uptake, total T3, total T4, TPOAb, CEA, BR monitor (CA 15-3), GI monitor (CA 19-9), OV monitor (CA 125), Hybritech PSA, Hybritech free PSA, WHO PSA, WHO free PSA, >100 Synchron chemistry tests (critical care, general esoterics, urine, and more)	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, T. tox plasma screen only (RUO)
Tests cleared but not clinically released 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	— — IgA1, IgA2
Research-use-only assays Tests in development	IL-6, PAPP-A vitamin D, PIGF, sVEGF R1	tetanus toxoid hevyLite IgG kappa, hevyLite Ig lambda, hevyLite IgA kappa, hevyLite IgA lambda, hevyLite IgM Kappa, hevyLite IgM lambda, C3, C4, CH50
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— —	— —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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	chemiluminescence, enzyme immunoassay/magnetic particle 120 120 100 120/100 tests per kit (immunoassay); 300 tests per container (gen. chem.) 336 hrs/28 days/yes (2° to 10°C) yes yes yes/specific cartridge ID, No. of available tests, expiration date, lot No., calibration expiration, within lot calibration	turbidimetry 24 — — 24/100 672 hrs/30 days/yes (9° to 12°C) yes yes yes/—
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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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/<10 ppm 60/112/assay dependent closed/liquid no/125 yes/— container dependent 3 µL/20 µL (gen. chem.) yes yes/up to 16 L per hour — yes/— yes/13 × 75 & 100, 15 × 75 & 92, 16 × 100 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes (gen. chem.) yes yes/yes chemistry dependent — assay dependent no/28 days yes/yes 24 hrs yes/yes no/no/remains in ready mode	no/— ~60/45/6 closed/liquid no/60 yes/when it reaches threshold OD (0.33), cuvettes should be changed. 150 µL 3 µL/150 µL yes/no no/3.5 L — no/— yes/most tube sizes including 12 × 75 mm/no yes (Codabar, codes 39 & 128)/— yes no yes/yes yes no/no no/no yes yes/yes — yes 6 no/— yes/— — yes/no no/no/<15 min
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	15 minutes 1 minute (gen. chem.) 90/720/40 seconds (gen. chem.) yes/yes —/— —	— — 35/106/10.5 min incubation yes/yes optional add-on/no Cerner Classic, Cerner Millenium, SCC Soft Computer, Cyberlab, Sunquest, Meditech Middleware, Creative Computing Applications Inc., Data Innovations
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	yes no — yes (broadcast download & host query) yes yes, Beckman Coulter automation systems yes/yes/yes no per negotiated service contract —/— yes — yes/online help with maintenance instructions	yes no — yes (broadcast download & host query) yes no no/no/no no 24 hrs 258 days, with 2 scheduled preventative maintenance visits/4 hrs on-site yes daily: <10 min; weekly: <10 min; monthly: <15 min no/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$650,000/high to very high volume, 750–2,250 samples per day — —/—	— — 5 days (includes installation)/yes
Distinguishing features (supplied by vendor)	performs parallel processing of immunoassay and chemistry tests on one system; ClozCap technology eliminates manual processes; chemistry and immunoassay reagent packs are identical across the UniCel family of systems	low maintenance; prozone detection, autodilution; dual compartment reaction cuvettes, air pressure mixing system and extensive washing processes; ideal for latex assays



## Automated immunoassay analyzers

Part 9 of 31	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 × W × D)/Instrument footprint in sq. feet	PR 3100TSC Photometer/2006/Austria Austria/U.S. 30/— batch/benchtop/rack 7 × 13 × 13/2	PhD System/2000/Belgium France/U.S. 200/300 batch/benchtop/rack 35 × 66 × 35/16
Tests available on instrument in U.S.	contact Bio-Rad representative	EIA testing to include: ANA, CCP, tTG IgA/IgG, glaidin IgA/IgG, dsDNA, ENA, SSA, SSB, SM, SM/RNP, Jo-1, SCL-70, anti-cardiolipin G/A/M, B2GPI G/A/M, anti-phosphotyrosine G/A/M, anti-prothrombin G/M, anti-saccharomyces cerevisiae, lyme, CMV G/M, EBV VCA G/M, EBNA G, H. pylori G/A, HSV G, measles G, mumps G, rubella G/M, toxoplasma G/M, VZV G; IFA testing to include: Hep-2, crithidia, mouse stomach/kidney, ANCA (formalin & ethanol)
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for clearance	none	—
Tests not available in U.S. but available in other countries	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, toxo IgM, rubella IgG, rubella IgM, EBV VCA IgM, EBV VCA IgG, CMV IgG, measles IgG, mumps IgG, VZV IgG	—
Research-use-only assays	not in U.S.	—
Tests in development	—	—
User-defined methods implemented for what analytes	none	—
Tests not available on other manufacturers' analyzers	none	—
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	—	1
No. of wells in microplate	min. strip: 1; max. full plate: 96	min. strip: 1; max. full plate: 96
Methods supported/Separation methods	EIA/coated microwell	EIA & IFA/coated microwell or slide
No. of different measured assays onboard simultaneously	1	8 EIA or 4 IFA
No. of different assays programmed, calibrated at once	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	0/—	8/192
Shortest/Median onboard reagent stability/Refrigerated onboard	—/—/no	4 hours/—/no
Multiple reagent configurations supported	no	yes
Reagent container placed directly on system for use	no	requires operator prehandling/preparation
Reagents bar coded/Information in bar code	no/—	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/—	yes/—
Walkaway capacity in minutes/Specimens/Tests-assays	1/up to 96/1	—/192/—
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum specimen vol. required	10 µL	1 µL specimen
Minimum sample vol. aspirated precisely at once/Min. dead vol.	—/—	1 µL/200 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/no
Requires dedicated water system/Water consumption	no/—	no
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	no/—	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/—/no	yes/micro—100 mm height/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/no
Bar-code placement per CLSI standard Auto2A	no	yes
Onboard test auto inventory (determines vol. in container)	no	no
Measures No. of tests remaining/Short sample detection	no/no	no/yes
Auto detection of adequate reagent or specimen	no	yes
Clot detection/Reflex testing capability	no/no	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	no/no	yes/no
Sample vol. 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 & reaspiration of sample for rerun	—	—
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	assay dependent	1–5
Calibrants can be stored onboard/Avg. calibration frequency	no/weekly	no/each run
Multipoint calib. supported/Multiple calibs. stored for same assay	no/no	yes/no
How often QC required	shortest interval: weekly; longest interval: monthly	each run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	—/no	no/no
Automatic shutdown/Startup is programmable/Startup time	no/no/5 min	no/no/5 minutes
Stat time to completion of β-hCG test	—	—
Time delay from ordering stat test to aspir. of sample	—	—
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	—/—	—/—
Can auto transfer QC results to LIS/Onboard capability to review QC	no/no	no/yes
Data-management capability/Instrument vendor supplies LIS interface	no/no	onboard/no
Interfaces up and running in active user sites with	—	—
LIS interface operates simultaneously w/running assays	no	yes
Uses LOINC to transmit orders and results	no	can be customized
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	no	yes
Results transmitted to LIS as soon as test time complete	yes (via USB thumb drive to separate you)	yes
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	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
Onboard error codes to facilitate troubleshooting	no	yes
Avg. time to complete maintenance by lab personnel	daily: 0; weekly: 5 minutes; monthly: 5 minutes	daily: 5 min; weekly: 15 min; monthly: 30 min
Onboard maintenance records/Maintenance training demo module	no/—	no/no
List price/Targeted bed size or daily volume	\$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 w/purchase/Advanced operator training	1 day on site	2 days on site/no
Distinguishing features (supplied by vendor)	compact, standalone 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

## Automated immunoassay analyzers

Part 10 of 31	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. Pat Ahmad pat_ahmad@ivaxdiagnostics.com 2140 N. Miami Ave., Miami FL 33127 305-324-2300 www.diamedix.com
Name of instrument/First year sold/Where designed	Evolis/2001/Germany	Mago Plus Automated EIA Processor/1997/Italy (MAGO 4S to be added)
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	Germany/U.S. 225/1,160 batch/benchtop/rack 37 × 44 × 30/10	Italy/U.S. 250/— batch, random access/benchtop/rack 28 × 48 × 26/8.7
Tests available on instrument in U.S.	contact Bio-Rad representative	autoimmune: ANA ELISA screen, ENA-6 screen, SSA, SSB, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, β2 glycoprotein IgG/IgM, cardiolipin screen/IgA/IgG/IgM, gliadin IgA/IgG, MPO, PR3, TPO, TG, RF; infectious disease: toxoplasma IgG/IgM, rubella IgG/IgM, CMV IgG/IgM, B burgdorferi IgG/IgM, EBV VCA IgG/IgM, EBNA IgG/IgM, EBV-EA IgG/IgM, HSV 1&2 IgG/IgM, <i>H. pylori</i> IgG, measles IgG, mumps IgG, VZV IgG, mycoplasma IgG
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	— — HIV Ab, HIV Ab/Ag, HIV Ag, HBsAg, HBe Ab, HCV Ab, HTLV-1, anti-HBs, toxo IgG, toxo IgM, rubella IgG, EBV VCA IgG, EBV VCA IgM, EBV EAD, EBV EBNA, syphilis total Ab, CMV total Ab	— — contact company
Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	not in U.S. infectious disease & autoimmune panels contact Bio-Rad representative none	— — 96-well plate enzyme immunoassays —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes — min. strip, 1; max. full plate, 96	yes 1 analyte per well min. 1 × 8 wells; max. 96 wells
Methods supported/Separation methods	EIA/coated microwell	EIA/coated microwell (MAGO 4S, EIA & IFA in parallel)
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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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 μL 10 μL/200 μL yes/no no 60 decibels no yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/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 min	9 ~50 currently preprogrammed assays 20 per diskette, unlimited diskette capability 9/96 —/—/no yes yes yes/ lot No., expir. date no/not susceptible, continuous cleaning up to 2.5 hours—assay dependent/120/384 yes/liquid yes/120 no/— 50 μL (pediatric) 4 μL/25 μL (pediatric) yes/no no/— — yes/— yes/11-15 mm × 75-100 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes — — yes/yes yes no/no no/no yes/no no/no — no assay dependent, 2-6 yes/per run yes/no per run yes/yes —/—/ <5 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	— — assay dependent yes/yes onboard/yes in development	— — 120/360 (2.5 hours—assay dependent) yes/yes onboard/yes (included in price) Cerner, Misys, others
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	yes no — yes (broadcast download) yes no yes/no/no no 24 hours —/— yes daily: 5 min; monthly: 60 min yes/no	yes no — yes (broadcast download & host query) yes no no/no/no no 24 hours —/— yes daily: <5 minutes; weekly: <10 minutes; monthly: none no/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$65,000/30-500 tests per day inquire 4 days in Redmond, Wash./no	\$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)	FDA-cleared system (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).

## Automated immunoassay analyzers

Part 11 of 31	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. Greta Schwichtenberg greta.schwichtenberg@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 Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	ETI-MAX 3000/2002/Germany Germany/U.S., Italy 160/972 batch, random access/benchtop/rack 40 × 45 × 30/10	LIAISON/1997/Germany Germany/U.S., Italy 250/3,000 batch, continuous random access/benchtop/rack 63 × 136 × 66 cm/9.9
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-Sci-70, anti-MPO, anti PR3 (cANCA), anti-TPO, anti-cardiolipin, IgG, IgM, anti-CCP, anti-B2 glycoprotein 1 IgG and IgM, anti-mitochondria, anti-thyroglobulin, anti-cardiolipin total	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
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	— — contact company	— cortisol, ACTH, dsDNA, CEA, PSA, fPSA, CA 15-3, CA-125, CA 19-9, TPA-M, toxo IgG avidity, HSV I/II IgM, HSV I/II IgG, HCG, β-2-microglobulin, prolactin, LH, FSH, S-100, AFP, HCG, ferritin, TSH, FT <sub>3</sub> , FT <sub>4</sub> , T <sub>3</sub> , T <sub>4</sub> , anti-TG, TG, anti-TPO, rubella IgM, HBsAg, HBsAg confirmatory, anti-HBs, anti-HBc, HBc IgM, HBeAg, anti-HBe, troponin I, CK-MB, myoglobin, C-peptide, Brahms procalcitonin, borrelia IgG & IgM, tTG IgA, testosterone, NSE, progesterone, estradiol, VZV IgM, calcitonin, ANA screen, ENA screen, direct renin, BAP OSTASE, biotrin parvovirus B19 IgG and IgM
Research-use-only assays	S100	S100, TK
Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— — HBeAg, anti-HBe	cardiolipin, measles IgG, mumps IgG — 25 hydroxy vitamin D total, Borrelia burgdorferi, VZV IgG, CMV IgM, HSV-1 type specific IgG, HSV-2 type specific IgG, biotrin parvovirus B19
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes — min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate up to 7 plates at a time	no — —/—
Methods supported/Separation methods	EIA/coated microplate	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 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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	open open 0 volume dependent no/no/no yes yes yes/— yes/no assay dependent/180/variable no/liquid no no 10 µL 10 µL/200 µL yes/no no/no — no yes (multiple)/no yes/yes yes yes yes/yes yes yes/no no/no yes/no no/no — no varies per kit no/each run yes/no per run yes/yes no/yes/5 minutes	15 15 0 15/100 7/28 days/yes (12°C) no yes yes/all lot information no/no 360/144/1,500 no/liquid yes/720 no assay dependent 5 µL/200 µL yes/no no/— — no/75 µL yes/—/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes yes/no 2 minutes no 2 yes/28 days yes/no 24 hours no/yes no/no/2 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	— — assay dependent yes/yes yes/yes yes yes — yes yes no no/no/no no 24 hours —/— yes daily: 5 minutes; weekly: 30 minutes yes/no	— 2 minutes — yes/yes yes/yes (additional) Cerner, Soft, others yes — — yes (host query) yes no no/no/no no 24 hours —/— yes daily: 10 minutes; weekly: 20 minutes; monthly: 30 minutes no/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$79,000 (includes first year of service)/all bed sizes, all test volumes \$10,500 3 days/yes	\$145,000/all bed sizes, all volumes inquire 3 days on site/yes
Distinguishing features (supplied by vendor)	selectively open system; 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 offering; up to 15 assays onboard with ready-to-use, reagent-integral, random-access, batch & stat operation

## Automated immunoassay analyzers

Part 12 of 31	Grifols USA, LLC Stephanie Sorensen stephanie.sorensen@grifols.com 2410 Lillyvale Ave., Los Angeles, CA 90032 323-227-7415 www.grifols.com	Hycor Biomedical Inc. Alex Draffan adraffan@hycorbiomedical.com 7272 Chapman Ave., Garden Grove, CA 92841 714-933-30000 www.hycorbiomedical.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	Triturus/1999/Spain Spain/Spain, U.S., Italy >200/>1,700 batch, random access & cont. random access/benchttop/universal carousel 28.3 x 41.3 x 34.3/10	HYTEC 288 PLUS/outside U.S. 1998, U.S. 1999/Netherlands Netherlands/U.S., Scotland 60/175 random batches/benchttop/rack-robotics 29.5 x 42.5 x 27.5/8
Tests available on instrument in U.S.	system is completely open; any U.S. clinically cleared and research-use-only EIA procedure can be programmed; infectious diseases, autoimmune diseases, bone markers, endocrinology, hemostasis, oncology markers, hepatitis, and HIV profiles	total/specific IgE, ANA scr, TG, TPO, dsDNA, RF IgG, RF IgM, RF IgA, PR-3 (c-ANCA), MPO (p-ANCA), anti-mitochondrial, ENA-6 Scr., SS-A, SS-B, Sm, Sm/RNP, Scl-70, Jo-1, gliadin IgA & IgG, GBM, GPC, anti-cardiolipin IgG & IgM, anti-cardiolipin scr., $\beta$ -2 BPI IgG, IgA & IgM, user-defined channels anti-tissue transglutaminase IgA and IgG
Tests cleared but not clinically released	—	—
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 rheumatoid factor, anti-tissue transglutaminase IgA and IgG, circulating immune complex -C1q and circulating immune complex -C3d
Research-use-only assays	—	—
Tests in development	—	ANCA profile, centromere, CCP
User-defined methods implemented for what analytes	—	—
Tests not available on other manufacturers' analyzers	—	—
Fully automated microplate system	yes	yes
No. of each analyte performed in separate disposable unit	8	8 (1 analyte per well; multiple analytes per well/screens; up to 8 analytes per run)
No. of wells in microplate	96, 1 minimum strip, 4 maximum full plate	96—min. strip: 1 strip/8 wells; max. full plate: 12 strips/96 wells
Methods supported/Separation methods	EIA, EIA-coated microwell plates, onboard shaker, four individually temperature-controlled microplate positions/coated microwell	EIA, tube-based & microplate-based assays/activated cellulose & coated well
No. of different measured assays onboard simultaneously	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	8	multiple
No. of user-definable (open) channels	—	3
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	8/48	varies by assay, up to 288 allergens or 8 autoimmune
Shortest/Median onboard reagent stability/Refrigerated onboard	—/—/no	8 hours/12 hours/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	minimal operator preparation, handling	yes
Reagents bar coded/Information in bar code	no	no
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/no	yes/<1 part in 10,000
Walkaway capacity in minutes/Specimens/Tests-assays	180/92/8	assay dependent/100/288
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	no	no
Uses washable cuvettes/Replacement frequency	no	no
Minimum specimen vol. required	300 $\mu$ L	10 $\mu$ L, 110 $\mu$ L w/ dead vol.
Minimum sample vol. aspirated precisely at once/Min. dead vol.	2 $\mu$ L/200 $\mu$ L	10 $\mu$ L–50 $\mu$ L, assay dependent/100 $\mu$ L
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	has external waste port to drain into sink or floor drain	—
Has dedicated pediatric sample cup/Dead vol.	no/—	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/12, 13, 16 mm/no	yes/—/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/—
Bar-code placement per CLSI standard Auto2A	yes	no
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/yes	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample vol. 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 & reaspiration of sample for rerun	—	—
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	1–14	1–6
Calibrants can be stored onboard/Avg. calibration frequency	no/check every month	no/monthly
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	each run	every assay
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/no	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/1–2 minutes	yes/no/2–3 minutes
Stat time to completion of $\beta$ -hCG test	system is open, depends on reagent methodology	—
Time delay from ordering stat test to aspir. of sample	—	—
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	dependent on reagent methodology/—	—
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	yes, onboard/no	onboard/optional
Interfaces up and running in active user sites with	CHCS, Softmax, Sunquest	25
LIS interface operates simultaneously w/running assays	yes	no
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	LIS—unidirectional or bidirectional	—
Bidirectional interface capability	yes (host query & broadcast download)	yes
Results transmitted to LIS as soon as test time complete	yes	optional
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	within 24 hours	48 hours
Mean time between failures/To repair failures	—/—	7 months/4 hours
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5–20 minutes	daily: 10–15 minutes; weekly: 20–25 minutes; monthly: 20–25 minutes
Onboard maintenance records/Maintenance training demo module	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	\$79,000/300+	\$55,000/all sites, variable test vols.
Annual service contract cost (24 hours/7 days)	varies, multiple types available	\$5,500
Training provided w/purchase/Advanced operator training	—/yes	3 days on site/yes
Distinguishing features (supplied by vendor)	multibatch 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; able to use fixed probes or disposable tips	fully automated allergy and autoimmune testing; user-defined software channels for microtiter plate and tube-based assays

## Automated immunoassay analyzers

Part 13 of 31	<b>Immunodiagnostic Systems Inc. (IDS Inc.)</b> Ken Gibbs kenneth.gibbs@idsplc.com 8425 N. 90th Street, Suite 8, Scottsdale, AZ 85258 480-278-8333 www.idsplc.com	<b>Inova Diagnostics</b> 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	IDS-iSYS/2009/France France/Belgium —/74 continuous random access/benchtop/sample loading rack 28 × 42 × 28/—	DS2/2006/U.S. U.S./U.S., U.K. —/— batch, with continuous load/benchtop/rack 30 × 17 × 26/3.07
Tests available on instrument in U.S.	—	ANA screen, ENA screen, dsDNA, SS-A, SS-B, Sm, Sm/RNP, Jo-1, Scl-70, GBM, MPO, PR3, Tg-TPO, cardiolipin screen & IgG, IgA, IgM, B2GP-1 screen & IgG, IgA, IgM, phosphatidylserine screen, IgG/IgA/IgM, C1q, gliadin IgG/IgA & screen, +TG IgA/IgG, RF, A-CCP, histone, ASCA IgA/IgG, tetanus toxoid, diphtheria toxoid, EBV VCA IgG, IgM, EBV-EA IgG, EBV EBNA-1 IgG/IgM, toxo IgG/IgM, rubella IgG/IgM, CMV IgG/IgM & IgG capture, HSV 1/2 IgG, HSV type specific 1&2, measles IgG/IgM, mumps IgG, high avidity dsDNA, PLAC test, others
Tests cleared but not clinically released	—	none
Tests not available in U.S. but submitted for clearance	—	—
Tests not available in U.S. but available in other countries	25-hydroxyvitamin D, intact PTH, hGH, IGF-1, intact PINP, N-MID Osteocalcin	open system—ELISA
Research-use-only assays	25-hydroxyvitamin D	open system
Tests in development	CTX-I, BAP, Bone Trap (TRAcP 5b), IGFBP3, aldosterone, renin, PTH 1-34, bioactive PTH (1-84)	—
User-defined methods implemented for what analytes	—	open system
Tests not available on other manufacturers' analyzers	—	open system
Fully automated microplate system	no	yes
No. of each analyte performed in separate disposable unit	—	—
No. of wells in microplate	—	min. strip 1 × 8; max. full plate: 96 wells × 2 plates
Methods supported/Separation methods	chemiluminescence/magnetic particle	EIA/coated microwell
No. of different measured assays onboard simultaneously	15	12 assays per plate
No. of different assays programmed, calibrated at once	15	unlimited
No. of user-definable (open) channels	0	unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	15/100	8/96
Shortest/Median onboard reagent stability/Refrigerated onboard	48 hours/7 days/yes (8°–10°C)	24 hours/—/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	no, requires operator prehandling/preparation	yes
Reagents bar coded/Information in bar code	yes/LOT key, No. within lot, XML	yes/yes
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/—	—/0 with disposable tips
Walkaway capacity in minutes/Specimens/Tests-assays	—/64/960	assay dependent/98/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	yes/960	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum specimen vol. required	10 µL	200 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/tube dependent ~80 µL	5 µL/200 µL (50 µL with microtubes)
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/—
Requires dedicated water system/Water consumption	no/—	no
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	yes/80 µL	yes/50 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/all up to 16 × 100 mm/no	yes/—/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	—	yes
Onboard test auto inventory (determines vol. in container)	yes	no
Measures No. of tests remaining/Short sample detection	yes/yes	no/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/yes	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/no
Sample vol. 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 & reaspiration of sample for rerun	—	—
Autocalibration or autocalibration alert	yes	no
No. of calibrators required for each analyte	2	varies
Calibrants can be stored onboard/Avg. calibration frequency	no/test dependent ~7 days	yes/each assay
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/no
How often QC required	—	each assay
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/no
Automatic shutdown/Startup is programmable/Startup time	yes/yes/10 minutes	no/yes/1–2 minutes
Stat time to completion of β-hCG test	—	—
Time delay from ordering stat test to aspir. of sample	—	—
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	—	assay dependent
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	—/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/no, additional cost	onboard/yes (additional cost)
Interfaces up and running in active user sites with	—	—
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	yes (host query)	yes (host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	yes	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	24 hours	—
Mean time between failures/To repair failures	—/—	—/ <24 hours
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 15 min; weekly: 30 min; monthly: 15 min	daily: 5 minutes; weekly: —; monthly: —
Onboard maintenance records/Maintenance training demo module	yes, includes audit trail/no	yes/no
List price/Targeted bed size or daily volume	—/—	\$50,000/100–200 beds
Annual service contract cost (24 hours/7 days)	—	\$7,000
Training provided w/purchase/Advanced operator training	—/yes	8 days on site/yes
Distinguishing features (supplied by vendor)	unique analytical platform combining three technologies: luminometry, potentiometry, and spectrophotometry	graphical interface with drag-and-drop icons; large sample throughput for a two-plate microplate system, with 98 samples and continuous load feature; consumable status window shows location and volume requirements during loading

## Automated immunoassay analyzers

Part 14 of 31	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 x W x D)/Instrument footprint in sq. feet	DSX/2000/Guernsey, U.K. U.S./U.K. 300/>500 batch/benchtop/rack 32 x 42 x 36/7	ASP1200/2008/UK U.K./U.K. 2/24 batch/benchtop/rack 22 x 20 x 24/2
Tests available on instrument in U.S.	ANA screen, ENA scr., SS-A, SS-B, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, GBM, MPO, PR3, TG, TPO, cardiolipin IgG/IgM/IgA & scr, B2GP1 IgG/IgM/IgA & scr, phosphatidylserine IgG/IgM/IgA, C1q CIC, gliadin IgG/IgA & scr, tTG IgA, tTG IgG, RF, anti-CCP, histone, EBV VCA IgG/IgM, EBV EA-D IgG, EBV EBNA-1 IgG/IgM, toxo IgG/IgM, rubella IgG/IgM, CMV IgG/IgM, IgM capture, HSV 1/2 IgG, measles IgG/IgM, mumps IgG, VZV IgG, IgM, lyme IgM/IgG & scr, <i>H. pylori</i> , syphilis, chlamydia, mycoplasma, legionella IgG/IgM, legionella UA, CCP, HSV 1/2 IgG type specific, tetanus toxoid, ASCA IgG/IgA, diphtheria toxoid, high avidity dsDNA, PLAC test	ANA, dsDNA, ANCA, GBM, EMA
Tests cleared but not clinically released	none	—
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	—
Research-use-only assays	open system	—
Tests in development	—	—
User-defined methods implemented for what analytes	open system	—
Tests not available on other manufacturers' analyzers	open system	—
Fully automated microplate system	yes	no
No. of each analyte performed in separate disposable unit	—	5–24
No. of wells in microplate	min. strip: 1 x 8; max. full plate: 96 x 4 plates	—
Methods supported/Separation methods	EIA/coated microwell	fluorescence, immunoperoxidase/substrate
No. of different measured assays onboard simultaneously	12 assays per plate	4
No. of different assays programmed, calibrated at once	unlimited	4
No. of user-definable (open) channels	unlimited	unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	25/96 per 4 plates	4/250
Shortest/Median onboard reagent stability/Refrigerated onboard	24 hours/—/no	8 hours/1 day/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	requires operator prehandling/preparation	yes, some pouroff required
Reagents bar coded/Information in bar code	yes/yes	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/0	no/—
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/92/assay dependent	105/96/96
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	open/liquid
Uses disposable cuvettes/Max. No. stored	no	no/—
Uses washable cuvettes/Replacement frequency	no	—/—
Minimum specimen vol. required	200 µL	250 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/200 µL (50 µL with microtubes)	5 µL/250 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no	no/—
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	yes/50 µL	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/various/no	yes/—/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/—	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	yes	—
Onboard test auto inventory (determines vol. in container)	no	no
Measures No. of tests remaining/Short sample detection	no/yes	no/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/no	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	—/—
Time between initial result & reaspiration of sample for rerun	—	—
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	assay specific	—
Calibrants can be stored onboard/Avg. calibration frequency	yes/once per analyte per plate	yes/—
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	no/no
How often QC required	per plate	each run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/no	no/no
Automatic shutdown/Startup is programmable/Startup time	yes/—/1–2 minutes	no/no/—
Stat time to completion of β-hCG test	—	—
Time delay from ordering stat test to aspir. of sample	—	—
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	assay dependent	32/96/1 hour and 45 min.
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	no/—
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional)	no/yes, included in price
Interfaces up and running in active user sites with	Cerner Classic & Millennium, Misys, SoftComp, Live Link, Triple G, FCC, ACA, LCW, LabLink	—
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	yes (host query)	no
Results transmitted to LIS as soon as test time complete	yes (manual transmission available)	no
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes	no/—/—
Can order (via modem) malfunctioning part(s) w/o operator	no	—
On-site response time of service engineer	within 24 hours	24 hours
Mean time between failures/To repair failures	—/ <24 hours	227 days/4 hours
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 minutes; weekly: none; monthly: none	daily: 2 min; weekly: 15 min
Onboard maintenance records/Maintenance training demo module	no/no	no/—
List price/Targeted bed size or daily volume	\$125,000 (dependent on modules)/200+ beds	\$37,450/50 tests per day
Annual service contract cost (24 hours/7 days)	\$12,950	\$3,000
Training provided w/purchase/Advanced operator training	8 days on site, 2 days at vendor offices/yes	yes/yes
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	download of worklist from LIS; sample/reagent retry option immediately rectifies sampling errors; automated monkey kidney GBM

## Automated immunoassay analyzers

Part 15 of 31	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	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.	open system, Inova autoimmune, diaDexus PLAC test, Trinity assays, TrepSure	Inova autoimmune menu
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for clearance	—	—
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	—	—
Tests in development	—	—
User-defined methods implemented for what analytes	—	IFA slides
Tests not available on other manufacturers' analyzers	—	—
Fully automated microplate system	yes	yes
No. of each analyte performed in separate disposable unit	1	—
No. of wells in microplate	96	96
Methods supported/Separation methods	fluorescence, enzyme EIA/coated microwell	enzyme immunoassay, IFA slides/coated microwell
No. of different measured assays onboard simultaneously	9	9
No. of different assays programmed, calibrated at once	—	—
No. of user-definable (open) channels	open system	open system
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	9/88	—/EIA: 180; IFA: 240
Shortest/Median onboard reagent stability/Refrigerated onboard	24 hrs/—/no	—/—/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	requires operator prehandling/preparation	placed directly on system
Reagents bar coded/Information in bar code	—/—	yes/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	—/ <10	no/ <10 <sup>-6</sup>
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/up to 240/9 quantitative, 21 qualitative	240/96/192
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum specimen vol. required	200 µL	100 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/200 µL	5 µL/150 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	no/—	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10 to 16 mm/no	yes/10 to 16 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
Bar-code placement per CLSI standard Auto2A	—	—
Onboard test auto inventory (determines vol. in container)	no	no
Measures No. of tests remaining/Short sample detection	no/yes	no/yes
Auto detection of adequate reagent or specimen	no	—
Clot detection/Reflex testing capability	yes/no	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	—/—	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	—/—	—/—
Time between initial result & reaspiration of sample for rerun	—	—
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	assay dependent	varies
Calibrants can be stored onboard/Avg. calibration frequency	yes/per run	—/varies
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/—
How often QC required	per run	per run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	no/—
Automatic shutdown/Startup is programmable/Startup time	no/no/2 min	no/—/—
Stat time to completion of β-hCG test	—	—
Time delay from ordering stat test to aspir. of sample	—	—
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	—/—	—/—
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/—
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	onboard/yes (additional cost)
Interfaces up and running in active user sites with	3	—
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	yes (host query)	yes (broadcast download, host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	no/no/no	no/—/—
Can order (via modem) malfunctioning part(s) w/o operator	no	—
On-site response time of service engineer	24 hrs	24 hrs
Mean time between failures/To repair failures	8-9 months/less than 2 hours	6-8 months/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 10 min	daily: 5 min; weekly: 10 min; monthly: 10 min
Onboard maintenance records/Maintenance training demo module	no/—	no/—
List price/Targeted bed size or daily volume	\$125,000/500 tests/day	\$64,995/150-350 tests/day
Annual service contract cost (24 hours/7 days)	\$14,250	\$9,500
Training provided w/purchase/Advanced operator training	yes (8 days on site)/yes	yes (4-8 days on site)/—
Distinguishing features (supplied by vendor)	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

## Automated immunoassay analyzers

Part 16 of 31	Inverness Medical Professional Diagnostics Michelle Fradette michelle.fradette@invmed.com 2 Research Way, Princeton, NJ 08540 877-546-8633 www.invernessmedicalpd.com	Inverness Medical Professional Diagnostics Michelle Fradette michelle.fradette@invmed.com 2 Research Way, Princeton, NJ 08540 609-627-8029 www.invernessmedicalpd.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	AtheNA/2002/U.S. U.S./U.S. 150/— batch/benchtop/multichannel pipetting or automated with front end 9.5 x 17 x 20/—	AIMS/2007/Switzerland Switzerland/U.S. 15/— batch/benchtop/rack 40 x 67 x 35/—
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development  User-defined methods implemented for what analytes  Tests not available on other manufacturers' analyzers	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, varicella zoster), HSV 1&2 IgG (herpes simplex virus, type 1 & type 2) — ToRCH IgG, borrelia VisE-1/pepC10 — — HIV-1, cardiolipin IgG, syphilis — —	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, varicella zoster), HSV 1&2 IgG (herpes simplex virus, type 1 & type 2) and wampole ELISA II assays — ToRCH IgG, borrelia VisE-1/pepC10 — — HIV-1, cardiolipin IgG, syphilis — —
Fully automated microplate system No. of each analyte performed in separate disposable unit  No. of wells in microplate	no 1-10  min. strip: 1; max. full plate: 96-well plate	yes assay dependent  min. strip: 8; max. full plate: 96-well plate
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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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/bead 10 10 0 —/96 —/—/no no no, requires operator prehandling/preparation no/— no/<0.9% 30 ±10/—/— open/liquid no/— no/— 10 µL —/— yes/no no/— — no/— no/—/— yes (2 of 5 interleaved, Codabar, codes 39 & 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	enzyme immunoassay, multiflexing/bead, coated microwell 4 multiple unlimited 4/96 —/—/no yes yes no/— yes/3% assay dependent/240/4 open/liquid no/— no/— 210 µL based on 16-mm tube 10 µL/200 µL based on 16-mm tube yes/no no/— — no yes/10 x 16 mm outer dimensions/no yes (2 of 5 interleaved, Codabar, codes 39 & 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
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	— — 48/84 no/yes yes, onboard/yes (additional cost) Cerner, Sunquest	— — assay dependent/—/— —/yes yes, onboard/yes (additional cost) —
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	no no — no yes yes, AIMS no/—/— — 24-48 hours 6 months/<1 day yes daily: 15 min; weekly: 30 min; monthly: 5 min no/—	no — — — yes — no/—/— — 24-48 hours —/— yes daily: 15 minutes; weekly: 20 minutes; monthly: 20 minutes no/—
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$60,000/8 tests per day \$8,000 yes/—	\$149,900/>150 beds \$19,500 5 days on site
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 MultiLyte multiplexing assays and ELISA on one platform

## Automated immunoassay analyzers

Part 17 of 31	Inverness Medical Professional Diagnostics Michelle Fradette michelle.fradette@invmed.com 2 Research Way, Princeton, NJ 08540 609-627-8029 www.invernessmedicalpd.com	Inverness Medical Professional Diagnostics Michelle Fradette michelle.fradette@invmed.com 2 Research Way, Princeton, NJ 08540 609-627-8029 www.invernessmedicalpd.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	DS2/2007/U.S. U.S./U.S. — batch/benchtot/rack 27 x 21 x 26/4	DSX/2004/U.S. U.S./U.S. approx. 500/— batch/benchtot/rack 32 x 42 x 36/7
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development  User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	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 — — — — AtheNA Multi-Lyte as well as infectious disease, autoimmune, and Enterics ELISA II assays enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko	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 — — — — AtheNA Multi-Lyte as well as infectious disease, autoimmune, and Enterics ELISA II assays enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes 1 analyte per well, multiple analytes per well 96 (min: 1; max: 96)	yes 1 analyte per well, multiple analytes per well 96 (min: 1; max: 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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	enzyme immunoassay/coated microwell 24 24 unlimited 18/24 8 hrs/1 day/no yes placed directly on system no/— no/0 120 min/98/24 yes/liquid no/— no/— 10 µL 10 µL/50 µL no/no no/— — no/— yes/primary, pouroff/no yes (2 of 5 interleaved, Codabar, codes 39 & 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 min	enzyme immunoassay/coated microwell 48 unlimited 24/48 8 hrs/1 day/no yes placed directly on system no/— no/0 120 min/98/48 yes/liquid no/— no/— 10 µL 5 µL/50 µL yes/no no/— — no/— yes/primary, pouroff/no yes (2 of 5 interl., Codabar, codes 39 & 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 min
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with  LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	— — —/— yes/yes onboard/yes (additional cost) Cerner, Millenium, Sunquest, Soft, Mysis, etc.  yes no — yes (host query) yes no no/yes/no no 24 hrs — (recently launched)/— yes daily: 5 min; weekly: 20 min; monthly: 20 min no/no	— — —/— yes/yes onboard/yes (additional cost) Cerner, Millenium, Sunquest, Soft, Mysis, etc.  yes no — yes (host query) yes no no/yes/no no 24 hrs 4 months/2 hrs yes daily: 10 min; weekly: 20 min; monthly: 20 min no/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$48,200/<350 beds \$9,000 3 days on site/yes	\$76,660/>350 beds \$10,000 3 days on site/no
Distinguishing features (supplied by vendor)	combined with the Inverness ELISA product line and the ability to automate enteric assays and front-end dilute Inverness AtheNA assays, the DS2 provides an efficient, open, fully automated solution for customers looking for laboratory automation	open DSX platform enables customers to run virtually any ELISA-based assay; modular design allows users to customize the system to their unique needs by adding extra incubators, incorporating a bar-code scanner, or choosing among certain types of sample racks; work list load wizard walks you through set up; shows graphically where to place your reagents, samples, and plates at the beginning of each run; complete daily maintenance in less than 5 min, including removal of consumables and rinsing the washer

## Automated immunoassay analyzers

Part 18 of 31	Ortho Clinical Diagnostics Kunal Chokshi kchokshi@its.jnj.com 1001 US Highway Route 202, Raritan, NJ 08869 908-218-8172 www.orthoclinical.com	Ortho Clinical Diagnostics Kunal Chokshi kchokshi@its.jnj.com 1001 US Highway Route 202, Raritan, NJ 08869 908-218-8172 www.orthoclinical.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	VITROS Eci Immunodiagnostic System/1997/U.S. U.S./U.K. >3,000 worldwide cont. random access/floor standing/universal sample trays (circular) accommodate primary & secondsondary containers without need for adapters 51 × 44 × 29/8.9	VITROS 3600 Immunodiagnostic System/2009/U.S. U.S./UK >150 worldwide continuous random access/floor standing/universal sample trays (circular) accommodate primary & secondary containers without need for adapters 68 × 83.5 × 34.9/20.2
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	3rd-gen. TSH, TT3, TT4, FT3, FT4, T3-uptake, total β-hCG, estradiol, progesterone, LH, FSH, prolactin, N-telopeptide, 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 — aHBe, HBeAg aHBe, HBeAg, toxo IgG, rubella IgM, toxo IgM, CMV IgG, CMV IgM — iPTH, HIV Combo, syphilis (Ex-U.S.) — NTx	3rd-gen TSH, TT3, TT4, FT3, FT4, T3-uptake, total B-hCG, LH, FSH, CEA, AFP, ferritin, CK-MB, troponin I, NT-proBNP, equimolar PSA, myoglobin, B12, RBC folate, CA 19-9, CA 125 II, cortisol (serum, urine), testosterone, prolactin, estradiol, progesterone, rubella IgG, NTx, aHBs, HBsAg, HBsAg(conf), aHCV, aHbC, aHbC IgM, aHIV 1+2 — aHBe, HBeAg, toxo IgG, rubella IgM, toxo IgM, CMV IgG, CMV IgM — iPTH, HIV Combo, aHBe (U.S.), HbeAg (U.S.), syphilis (Ex-U.S.) — NTx
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes	chemiluminescence (enhanced)/individual coated microwell 20 20 programmed & calibrated at once; up to 25 lots calibrated per assay  0 20/100 56 days/56 days/yes (2°–8°C) yes yes yes/test ID, expir., lot No., pack ID —/zero carryover 720/60/800 (with EPM—enhanced productivity module) no/liquid no no 10 µL 10 µL/80 µL no but it is available/no no/— 60 decibels no yes/mult. ped., microtainers & cups, 5 mL, 7 mL, 10 mL on same univ. sample tray/no	chemiluminescence, enhanced chemiluminescence/coated microwell 31 31 programmed and calibrated at once, up to 25 lots calibrated per assay  — 31/100 1,008 hours/56 days/yes (2°–8°C) yes yes yes/test ID, expiration date, lot No., pack ID no/— varies/90/3,100 closed/liquid no/— no/— 10 µL 10 µL/35 µL no/no no/— — no/— yes/1.5 mL micro-collection containers, 0.5- and 2.0-mL cups, 5 mL, 7mL, 10 mL on same universal sample tray—no adapters/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Sample bar-code reading capability/Autodiscrimination Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no assay dependent yes 1–3 no/28 days yes/yes once per 24 hours yes/yes yes/yes/immediate upon completion of last sample metering	yes yes yes/yes yes yes/yes yes/yes yes/yes yes/yes no/no assay dependent yes 1–3 depending on assay no/28 days yes/yes once per 24 hours yes/yes —/—/0
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with  LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	24 minutes immediate upon completion of last sample metering 30/90 (40 seconds) yes/yes onboard/no Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, PHCP, INS, Siemens, Dawning yes yes — yes (broadcast download) yes yes (all systems) yes/yes/yes no <4 hours (contract dependent) —/dependent on corrective action yes daily: <5 minutes; weekly: <30 minutes; monthly: <10 minutes no/yes	24 minutes immediate upon completion of last sample metering assay dependent/assay dependent (19 seconds) yes/yes yes, onboard and optional add-on (Data Innovations)/yes, additional cost Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, PHCP, INS, Siemens, Dawning yes no — yes (broadcast download & host query) yes yes, enGen yes/yes/yes no <4 hours (contract dependent) dependent on corrective action/dependent on corrective action yes daily: 10 minutes; weekly: 25 minutes; monthly: 15 minutes yes, includes audit trail/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$140,000/flexible for majority of customer demand varies w/ service level choices 3.5 days at vendor offices/yes, as needed on site	—/350 tests per day varies —/yes
Distinguishing features (supplied by vendor)	uses proprietary Intellilock technology to perform, monitor, document, and verify diagnostic checks throughout sample and assay processing to reduce the potential of misreported results; IntelliReport provides real-time status and traceability on the quality of reported results; uses enhanced chemiluminescence, MicroWell technology; provides simple-to-use, fully automated, true random access stat testing for routine and specialty immunodiagnostic testing	diagnostic checks throughout sample and assay processing reduces misreported results; real-time status and traceability on the 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 eliminates carryover; measures and flags results, if hemolysis, icterus, and turbidity levels might affect results

## Automated immunoassay analyzers

Part 19 of 31	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 x W x D)/Instrument footprint in sq. feet	Phadia Laboratory System 250/2004/Japan, Sweden Japan, Sweden/Sweden — continuous random access/floor standing/racks 73 x 50 x 30 + 26-in. wide computer stand/—	Phadia Laboratory System 1000/2003/Japan, Sweden Japan, Sweden/Sweden — continuous random access/floor standing/racks 83 x 71 x 40 + 26-in. wide computer stand/—
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance  Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	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 $\beta$ 2-glycoprotein I IgG and ELiA $\beta$ 2-glycoprotein I IgM, ELiA gliadin DP IgA/IgG ELiA PR3S, ELiA GBM, ELiA MPO, ELiA CTD Screen, ELiA Cardiolipin IgA, ELiA $\beta$ 2 GPI IgA, ELiA PM/Sc, ELiA Fibrillarin, ELiA RNA Pol III, ELiA PCNA, ELiAMI-2, ELiA Borrelia, ELiA M2, ELiA MPOS, ELiA Anti-IgA — — — Phadia US Inc. ImmunoCAP specific IgE blood tests and ELiA autoimmune assays	hundreds of ImmunoCAP specific IgE tests and ImmunoCAP total IgE — — — Phadia US Inc. ImmunoCAP specific IgE blood tests
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.  Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells 3 methods not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory 0, closed system 3/400 or 100 depending on the conjugate type 5 days/1 year/yes (2°-8°C) yes yes (wash solution requires preparation) yes/product name, lot No., expiration date no/— 470/50 simultaneously/370 tests no/liquid no — 40 $\mu$ L for ImmunoCAP tests and 50 $\mu$ L for ELiA tests 40 $\mu$ L/40-200 $\mu$ L for ImmunoCAP tests and 50 $\mu$ L/50-200 $\mu$ L for ELiA tests (varies w/tube type) yes/no no/10 L 65 decibels no yes/10-17 mm x 50-105 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes no yes yes/yes yes yes/yes no/no yes/yes no/no 100 minutes yes 6 per analyte for calibration run, 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	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells 3 methods not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory 0, closed system 3/400 or 100 depending on the conjugate type 5 days/1 year/yes (2°-8°C) yes yes (wash solution requires preparation) yes/product name, lot No., expiration date no/zero carryover (disposable sample tips) 460/200 simultaneously/2,400 tests no/liquid no — 40 $\mu$ L per test 40 $\mu$ L/40-200 $\mu$ L (varies with tube type) yes/no no/10 L 68 decibels no yes/10-17 mm x 50-105 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes no yes yes/yes yes yes/yes no/no no/yes no/no 100 minutes yes 6 per analyte for calibration run, 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
Stat time to completion of $\beta$ -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with  LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	— 6 minutes 20 specimens/60 (100 minutes to first result, then 1 result per 60 seconds ) yes/yes onboard/yes (instrument side only) Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others yes no — yes (broadcast download & host query) yes yes yes/yes/yes no <24 hours —/— yes daily: 1 minute; weekly: 10 minutes; monthly: 15 minutes yes/—	— 6 minutes 80 specimens/240 (100 minutes to first result, then 1 result per 15 seconds ) yes/yes onboard/yes (instrument side only) Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others yes no — yes (broadcast download & host query) yes yes yes/yes/yes no <24 hours —/— yes daily: 1 minutes; weekly: 10 minutes; monthly: 15 minutes yes/—
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$75,000/>20,000-95,000 tests per year — 3.5 days at vendor offices/yes	\$235,000/>95,000 tests per year — 4.5 days at vendor offices/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; innovative products, comprehensive clinical and technical research, and extensive medical information and education, makes ImmunoCAP a choice for IgE testing worldwide; 3 automated ImmunoCAP instruments offer labs the ability to measure and report specific IgE quantitative results accurately across the clinical range	provides accepted technology for serologic, specific IgE testing with the ImmunoCAP family of products; innovative products, comprehensive clinical and technical research, and extensive medical information and education, make ImmunoCAP a choice for IgE testing worldwide; three automated ImmunoCAP instruments offer laboratories the ability to measure and report specific IgE quantitative results accurately and precisely across the clinical range

## Automated immunoassay analyzers

Part 20 of 31	<b>Phadia</b> Nicole Vosters nicole.vosters@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us	<b>Radiometer Medical ApS</b> info@radiometeramerica.com 810 Sharon Drive, Westlake, OH 44145 +1 (440) 871-8900 www.radiometeramerica.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	Phadia Laboratory System 100 <sup>F</sup> /1995/Sweden Sweden/Sweden — batch/benchtop/carousel 18 × 28 × 24 + computer/—	AQT90/2008/Denmark Denmark/Finland —/— random access/benchtop/inlet 17.7 × 18.1 × 18.9/2.4
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance  Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development  User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	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 β2-glycoprotein I IgG and ELiA β2-glycoprotein I IgM, ELiA gliadin DP IgA/IgG ELiA PR3S, ELiA GBM, ELiA MPO, ELiA CTD Screen, ELiA Cardiolipin IgA, ELiA B2 GPI IgA, ELiA PM/Sc, ELiA Fibrillarin, ELiA RNA Pol III, ELiA PCNA, ELiAMI-2, ELiA Borrelia, ELiA M2, ELiA MPOS, ELiA Anti-IgA — — — Phadia US Inc. ImmunoCAP specific IgE blood tests and ELiA autoimmune assays	— — — Tnl, CKMB, MYO, NT-proBNP, βhcG, CRP, D-dimer — BNP, TnT, hsCRP, APTT, PT-INR — —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol.  Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells 4 7 0, closed system 48–96 depending on the conjugate type — yes yes (wash solution requires preparation) yes/product name, lot No., expiration date no/— 180 minutes/varies with analyte/48 no/liquid no/— —/— 40 μL for ImmunoCAP tests and 50 μL for ELiA tests 40 μL/40–200 μL for ImmunoCAP tests and 50 uL/50–200 μL for ELiA tests (varies with tube type) yes/no no/1 L per run — no yes/10–16 mm × 50–105 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes no no no/yes yes yes/yes no/no yes/yes no/no 2.5 hours–batch run yes 6 per analyte for calibration run, 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/20 minutes including request entry or downloading	time-resolve fluorescence/coated microwell 6 6 0 15/16 96 hours/7 days/no yes yes yes/lot number, expiry date, checksum, parameter code, cartridge ID no/<100 ppm —/2/10 tests yes (home brew methods can be used)/dry no/— no/— 2 μL 2.5 μL/53.5 μL no/no no/— — no/— yes/11 × 66 to 13 × 78 mm/yes yes (2 of 5 interleaved, Codabar, codes 39 & 128)/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
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with  LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	— — batch analyzer/48/180 minutes processing time for batch to finish yes/yes onboard/yes, instrument side only (included) Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others yes no — yes (broadcast download & host query) yes yes yes/yes/yes no —, swap —/— yes daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes yes/no	18 minutes 30 seconds 10/30 yes/yes onboard/no — yes no — yes (broadcast download & host query) yes no yes/yes/yes no per negotiated contract —/— — — yes, includes audit trail/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$22,000/>7,000–20,000 tests per year — 3.5 days at vendor offices/yes	—/— flexible options available —
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; innovative products, comprehensive clinical and technical research, and extensive medical information and education, makes ImmunoCAP a choice for IgE testing worldwide; 3 automated ImmunoCAP instruments offer labs the ability to measure and report specific IgE quantitative results accurately across the clinical range	POC instrument measures whole blood with lab quality; broad menu and parameter flexibility; closed tube and closed waste system

## Automated immunoassay analyzers

Part 21 of 31	<b>Randox Laboratories Ltd.</b> Gareth Soye evidence.support@randox.com 55 Diamond Road, Crumlin, County Antrim, BT29 40Y 0044 28 9442 2413 www.randox.com	<b>Roche Diagnostics</b> Adam Sterle adam.sterle@roche.com 9115 Hague Rd., 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 Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	Evidence/2002/Northern Ireland Northern Ireland/Northern Ireland 8/27 batch/floor standing/carousel 68 × 78 × 39/22.75	Elecsys 2010/1996/— Japan/Germany >800/>6,000 cont. random access/benchttop/rack or disk 22.1 × 47.2 × 28.7/9.4
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays  Tests in development  User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	cocaine, methamphetamine, PCP, opiates, cannabinoids, barbiturates, benzodiazepine, progesterone, prolactin, LH, FSH, estradiol  — MDMA, LSD, fentanyl, propoxyphene, methaqualone, generic opioids, ketamine, buprenorphine TT4, FT4, TT3, FT3, TSH, AFP, CEA, hCG, fPSA, tPSA, testosterone, CK-MB, cTNI, myoglobin, FABP GPBB, CA III, VCAM-1, ICAM-1, E-selectin, P-selectin, L-selectin, IL-2, IL-3, IL-4, IL-6, IL-7, IL-8, IL-10, IL-13, IL-23, IL-23p70, VEGF, TNFα, IFNγ, IL-1a, IL-1b, MCP-1, EGF, GFAP, S100B, hsCRP, BDNF, D-dimer, NSE, NGAL, thrombomodulin, sIL-2Ra, sIL-6R, sTNFR1, sTNFR2, MMP-9, IL5, IL15, GM-CSF, MIP-1α, TNFα, endocrine array IL1-1Ra, IGF-1 free, RANTES, PDGF-AA, PDGF-BB, eotaxin, IP-10, cortisol, DHEA-S, leptin, 17-OH progesterone, IL12-p40, maternal screening array, sepsis array, metabolic arrays, and additional drugs-of-abuse arrays  — GPBB, FABP, CA III, VCAM-1, ICAM-1, E-selectin, P-selectin, L-selectin, IL-2, IL-4, VEGF, IFNγ, IL-1a, MCP-1, EGF, BDNF, NGAL, thrombomodulin, sIL-6R, sTNFR1, sTNFR2, MMP-9	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 & βHCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, HBsAg, HBeAg, HBeI, anti-HBe, anti-HBs, IgE, PTH, beta crosslaps, osteocalcin, toxo IgG, rubella IgG, anti-TSH receptor, anti-CCP  — anti-HBc IgM, anti HCV, anti HAV IgM  TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV IgM, anti-HBc, anti-Hbe, HBeAg, HIV antigen, HIV antigen confirmatory, P1NP, 25-OH vitamin D3  — interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, NSE, cyfra 21-1, anti-HBc, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM, HIV combi, He4, vitamin D 25-OH toxo IgM, rubella IgM  — 9-minute PTH, Tnt
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	chemiluminescence/— 8 12 0 96/360  assay dependent/1–14 days/yes (2°–8°C) yes yes yes/product component, size, lot No., expir. date no/— 100/180/540–1,080 no/liquid no/— no/— 7 µL 7 µL/7–350 µL (varies with cup type) no/no no/— 60 decibels yes/100 µL yes/12 mm, 16 mm/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes no/yes no/no no/no no/no 12 min no 9 (multi-analyte calibrators) yes/weekly (dependent on panel) yes/yes user defined yes/yes yes/no/13 minutes	electrochemiluminescence/magnetic particle 15 60 0 15/100–200 tests per kit  56 days/56 days/yes (20°C) yes yes yes/calib. curve, application params., lot No., expir., reagent name 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 diam./no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/no yes/yes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	— — 108/324 (5 minutes)  yes/yes onboard/Randox, included in price yes yes no — yes (host query) yes no yes/yes/yes  no <24 hours (contract dependent) —/— yes daily: 5 min; weekly: 10 min; monthly: 30 min no/—	9 minutes (hCG intact) 42 seconds 30/88 (42 seconds)  yes/yes onboard/yes (additional cost) all major LISs yes no — yes (broadcast download & host query) yes yes (CLAS & Roche task targeted automation) no/yes/no  no <24 hours —/— yes daily: 1 minutes; weekly: 5 minutes; biweekly: 25 minutes; monthly: none no/no (training CD-ROM)
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	contract dependent/500+ contract dependent —/yes	varies based on contract included w/ reagent rental 3 days at Indianapolis offices/yes
Distinguishing features (supplied by vendor)	biochip enables simultaneous analysis of multiple parameters in a single patient sample; max. throughput of 1,188 test results per hour; unreported tests can be retrieved retrospectively; arrays contain multiple tests applicable to clinical and research applications	liquid ready-to-use reagents; autocalib., autodil.; ECL technology for broad dynamic ranges, and fast turnaround time, stat interrupt; onboard reagent storage; minimal maintenance

## Automated immunoassay analyzers

Part 22 of 31	Roche Diagnostics Adam Sterle adam.sterle@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us	Roche Diagnostics Nathan Patton nathan.patton@roche.com 9115 Hague Rd., 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.	cobas e411/2006/Japan Japan/Germany —/—	MODULAR ANALYTICS E170/2001/Japan Japan/Germany >500/>300 (combination of E and EE systems) and >25 Integrated Modular Systems (U.S. only)
Operational type/Model type/Sample handling system	continuous random access/benchtop/rack, disk	continuous random access/floor-standing/rack
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	31.4 × 47.2 × 28.7 (disk); 31.4 × 67 × 37.4 (rack)/94 (disk), 17.4 (rack)	47 × 47 × 31.5 (Modular E configuration)/approx. 60 (one module system)
Tests available on instrument in U.S.	ferritin, folate II, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, total PSA (monitoring), ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone, prolactin, SHBG, testosterone, total & βHCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps, osteocalcin, toxo IgG, rubella IgG, total PSA (screening), free PSA, HBsAg, HBsAg conf, anti-HBs, anti-TSH receptor, anti-CCP	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 βhCG, 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, HBsAg confirmatory, anti-HBs, toxo IgG, rubella IgG, anti-TSH receptor
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	anti-HCV anti HAV IgM, anti Hbc IgM	anti-HCV anti HAV IgM, PCT, anti Hbc IgM
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, P1NP, 25-OH vitamin D3	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, 25-OH vitamin D3
Research-use-only assays Tests in development	— interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, NSE, cyfra 21-1, anti-HBc, HBc IgM, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM, HIV combi, He4, vitamin D 25-OH toxo IgM, rubella IgM	— 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
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— 9-minute PTH and cardiac assays, 9-minute PTH, TnT	— TnT
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	—	—
No. of wells in microplate	—	—
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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	electrochemiluminescence, magnetic particle/magnetic particle 18 18 0 18/100–200 tests per kit —/56 days/yes (20°C) yes yes yes/calib. curve, application params., lot No., expir., reagent name no/zero carryover (disposable sample tips) disk: 120/30/180; rack: —/100/18 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 & 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	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/calib. curve, application params., lot No., expir., reagent name —/zero, uses disposable sample tips 360/—/1,006 no/liquid yes/1,006 no 10 µL —/100 µL yes/yes yes/30 L per hour in full operation <65 decibels yes/100 µL yes/13 × 75 to 16 × 100/no yes (2 of 5 interleaved, Codabar, codes 39 & 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
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	9 minutes 42 seconds 30/86 (42 seconds) yes/yes onboard/yes (additional cost) — yes no — yes (broadcast download & host query) yes yes no/yes/no no <24 hours —/— yes daily: 5 minutes; weekly: 6 minutes; monthly: 10–15 minutes no/no	18 minutes — 56/176 (21 seconds) yes/yes onboard/yes (add'l cost) all major LISs yes no — yes (broadcast download & host query) yes yes (Roche MODULAR PRE-ANALYTICS systems and task targeted automation) yes/yes/no no ≤24 hours —/— yes daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes yes/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	varies based on contract/varies; primary IA system or back-up unit included with reagent rental 4 days on site/yes	varies, based on contract included with reagent rental 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	liquid ready-to-use reagents; ECL technology for broad dynamic ranges; fast TAT; stat interrupt; minimal maintenance	expandable liquid ready-to-use reagents that are compatible with other Elecsys systems, compatible with Pre-Analytic Automation; ECL technology provides broad measuring range and market, low-end sensitivity, troponin T, auto-rerun and dilute

## Automated immunoassay analyzers

Part 23 of 31	Roche Diagnostics Sheila Brewer sheila.brewer@roche.com 9115 Hague Rd., Indianapolis, IN 46250-0457 800-428-5074 www.roche.com/labsystems/us	Siemens Healthcare Diagnostics Pamela Curtin pamelacurtin@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 914-524-3824 diagnostics.siemens.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	cobas e601/2006/— Japan/Germany >500/— continuous random access/floor-standing/rack 46.1 × 71.8 × 40/19.73	Dimension Vista 500 Intelligent Lab System/2009/U.S. U.S./U.S., Germany 117/22 continuous random access/floor standing/rack and aliquot plate system, batch 55.5 × 84.75 × 43.8/26
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development  User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	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, gentamicin, theophylline, tobramycin, valproic acid, vancomycin, cortisol, toxo IgG, rubella IgG, HBsAg, HBsAg conf, anti-HBs, total PSA (screening), free PSA, anti-TSH receptor, 9-minute (STAT) assays for myoglobin, CK-MB, PTH, HCG, Tnl anti-HCV anti HAV IgM, PCT, anti HbC 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, 25-OH vitamin D3, HIV combi, He4, vitamin D 25-OH, toxo IgM, rubella IgM — 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 — TnT	>125 (includes vendor supported applications), 35 general chemistry, 16 immunoassay, 14 TDM, 17 DATs, 36 plasma proteins  — — PSA, FPSA, 4 IgG subclasses  — CA 125, CA 15-3, CA 19-9, additional cancer markers fertility panel, plasma proteins, hormones, infectious disease  — specialty chemistry, plasma proteins, TDMs, DATs LOCI immunoassay, nephelometric assays, general chemistry
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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	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/calib. curve, application params., lot No., expir., reagent name —/zero, uses disposable sample tips 360/300/1,000 no/liquid yes/1,006 no/— 10 µL 10 µL/100 µL yes/yes yes/up to 30 L/hour in full operation <65 decibels yes/100 µL yes/13 × 75 to 16 × 100/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/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	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 × 50, 10 × 65, 13 × 65, 13 × 75, 13 × 100, 15 × 92, 16 × 100, 13 × 90/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes 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
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with  LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	18 minutes 42 seconds 56/176 (21 seconds) yes/yes onboard/yes (additional cost) all major laboratory information systems  yes yes Web site yes (broadcast download & host query) yes yes (Roche Modular Pre-Analytics) yes/yes/no no ≤24 hours —/— yes daily: 5 minutes.; weekly: 10 minutes; monthly: 15 minutes yes (includes audit trail of who replaced parts)/yes	10 <2 minutes 200/600 (variable 3.6 to 20 seconds) yes/yes onboard/Misys, Soft, Mediatech, Cerner, others —  yes no — yes (broadcast download & host query) yes yes, StreamLAB automation system in development yes/yes/yes  no 2 to 8 hours —/— yes daily: <10 min; monthly: 10 to 20 min no/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	varies, based on contract/— — 5 days at vendor offices/yes	—/1,500 tests per day per system — 4 days on site, 4 days at vendor offices/yes
Distinguishing features (supplied by vendor)	ECL technology provides broad measuring ranges and low-end sensitivity; TnT; ready to use bar-coded reagents compatible with other Elecsys Systems; compatible with Modular Pre-Analytics for walkaway automation	ultra-integrated chemistry platform with LOCI advanced chemiluminescence, and nephelometry onboard; enhanced workflow efficiency with automated features like autocalibration and auto QC and system twinning; proactive service and support through RealTime Solutions

## Automated immunoassay analyzers

Part 24 of 31	Siemens Healthcare Diagnostics Louise Chang louise.chang@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 310-645-8200 x7035 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Louise Chang louise.chang@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 310-645-8200 x 7035 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	ADVIA Centaur CP Immunoassay System/2005/U.S. Germany/U.S. >200/>400 batch, random access, continuous random access/benchtop/7 × 12 position racks	ADVIA Centaur XP/2006/U.S. Ireland/U.S. 475/425 continuous random access/floor standing/5-position multiple size rack or puck via ADVIA LabCell and WorkCell
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	43 × 29/8.7	51.5 × 72.4 × 41/20.6
Tests available on instrument in U.S.	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, theophylline, tobramycin, valproic acid, vancomycin, cyclosporine, aTG, aTPO, FT3, FT4, TSH, 3g-TSH, T-uptake, total T3, total T4, iPTH, CA15-3, CEA, CA-125, PSA, cPSA, BR27-29, CA19-9, HER2/neu-serum	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, eHIV, toxo IgG, toxo IgM, rubella IgG, rubella IgM, AFP, estradiol-6, estradiol-6 III, FSH, total hCG, LH, progesterone, prolactin, testosterone, DHEAS, carbamazepine, digitoxin, digoxin, gentamicin, phenobarbital, phenytoin, theophylline, tobramycin, valproic acid, vancomycin, cyclosporine, aTG, aTPO, FT3, FT4, TSH, 3g-TSH, T-uptake, total T3, total T4, iPTH, CA15-3, CEA, CA-125, PSA, cPSA, BR27-29, CA19-9, HER2/neu-serum
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	— cyclosporine, DHEAs, SHBG, digitoxin, aTG, aTPO, TSH3 ultra, Her2/neu, HBsAg/confirmatory, HBsAb, HBcTotal, Hbc IgM, HCV, rubella IgG, rubella IgM, toxo IgG, toxo IgM, fPSA, procalcitonin, syphilis	— —
Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— — SHBG, toxo IgG, toxo IgM, D-dimer, fPSA, HBeAg, anti-HBe, eHIV — cPSA, HER-2/neu	— — SHBG, procalcitonin, HBeAg, anti-HBe, fPSA, D-dimer — cPSA, Her2/neu
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	chemiluminescence/magnetic particle 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 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes yes/yes 20 seconds yes 2 no/varies, avg. 21 days yes/yes user defined yes/yes yes/yes/<5 minutes	chemiluminescence/magnetic particle 30 primary reagents 65 — 30/50, 100, 200 tests per pack 96 hours/28 days/yes (4°C) yes yes yes/assay name, lot No., expiration date, pack ID, No. of tests —/none—uses zero carryover 280/180/840 no/liquid yes/1,000 no 10 uL—assay 10 uL/50 uL yes/no no/2.5 L per hour 61.3 decibels no yes/—/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no (does have autodilution)/no (does have autodilution) 15 seconds yes 2 no/average 28 days yes/yes 22 hours/24 hours yes/yes no/no/none, always ready
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	15.6 minutes <1 to 2 minutes 50 seconds 60/180 (20 seconds) yes/yes onboard/no Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLFC, DI, Triple G, and most other major vendors	18 minutes 15 seconds 80/240/15 seconds yes yes/yes onboard/yes (LIS allowance)
LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	yes no — yes (broadcast download & host query) yes no yes/yes/— no 4 hours, 24 hours max. not available/not available yes daily: 15 minutes; weekly: 20 minutes; monthly: 30 minutes yes/yes	Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Triple G, others yes no yes (broadcast download & host query) yes yes/ADVIA WorkCell, ADVIA LabCell, others yes/yes/yes no 4-24 hours max —/— yes daily: 3 minutes; weekly: 20 minutes; monthly: 30 minutes yes/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	depends on GPO affiliation/community hospitals, satellite labs — 3 days at vendor sites plus online training/yes	\$225,000/300+ beds or 400 tests per day varies, GPO dependent —/4.5 days on site/yes
Distinguishing features (supplied by vendor)	automates routine operations, including ability to access/change solutions, waste, disposables, and reagents without pausing sampling or processing; onboard automatic dilutions, repeats, STATs and cascade reflex testing; disposable tips; uses same reagents/consumables as ADVIA Centaur/ADVIA Centaur XP with concordant results; throughput 180 tests/hour; average time to first result ~15.6 minutes	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.; comprehensive hep. A, B, C, and HIV testing (incl. acute hepatitis panel); automated SMART algorithm for rerun/confirm. testing for HBsAg testing

## Automated immunoassay analyzers

Part 25 of 31	Siemens Healthcare Diagnostics Colleen Grier colleen.m.grier@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 302-631-8773 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Jason Ong jason.f.ong@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 × W × D)/Instrument footprint in sq. feet	Dimension Vista 1500 Intelligent Lab System/2006/U.S. U.S./U.S. and Germany 350/110 batch, random access continuous random access/floor standing/sample rack and aliquot plate system 55 <sup>5</sup> / <sub>8</sub> × 84 <sup>7</sup> / <sub>8</sub> × 43 <sup>3</sup> / <sub>8</sub> /26	Dimension Xpand Plus Integrated Chemistry System/2004/U.S. U.S./U.S. —/— random access, cont. random access/floor-standing/racks 45 × 51 × 31 (without monitor)/10.6
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development  User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	>125 (includes vendor supported applications), 35 general chemistry, 6 thyroids, 4 cardiac, 14 TDM, 17 DATs, 36 plasma proteins, 3 anemia, 2 cancer markers (AFP, CEA), fertility (HCG)  — — PSA, FPSA, 4 IgG subclasses — CA 125, CA 15-3, CA 19-9, fertility panel, cancer markers, plasma proteins, hormones, cardiac, infectious disease TDM, DAT LOCI technology, nephelometry, general chemistry	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, transferrin, cyclosporine extended range, hemoglobin A1c, carbamazepine, cyclosporine, digoxin, digitoxin, gentamicin, lidocaine, lithium, N-acetylprocainamide, phenobarbital, phenytoin, procainamide, tacrolimus, theophylline, tobramycin, vancomycin, valproic acid, acetaminophen, ethyl alcohol, salicylate, serum barbiturates, serum benzodiazepines, serum tricyclic antidepressants, myeloperoxidase, sirolimus, others  — — — — mycophenolic acid  — performs heterogeneous immuno. & general assays on single platform—fully auto. ISD assays
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	chemiluminescence, enzyme immunoassay, ACMA, EMIT, LOCI, PETINIA, NEPH/none >100 >100 10 >100/20 to 1,200  72 hours/30 days/yes (2°–8°C) no yes yes/test ID, lot No., individual-sequence No., exp. date yes/<1 ppm >45/150/61,404 yes/liquid yes/>2,000 yes/automatic, as needed 2 µL analytical, 50 µL aliquot 2 µL (GLU=1.2)/20 µL yes/no no/20 L per hour 67 decibels no (can use small sample cup)/10 µL yes/10 × 50, 10 × 65, 13 × 65, 13 × 75, 13 × 100, 15 × 92, 16 × 100, 13 × 90/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes no/no (does have autodilution)  <2 min yes varies, 2–6 yes/30–90 days yes/yes shortest interval: 24 hours/— yes/yes no/no/always ready	ACMA, EMIT, PETINIA, Photometry, Potentiometry/heterogeneous, magnetic particle 91 190 10 47/15–360  48 hours/30 days/yes (2°–8°C) yes yes yes/lot No., unique flex ID, stability, expiration date yes/— due to probe washing can be hours/60/>2,000 yes/reconstitutes onboard, no reagent prep required by operator/liquid yes/12,000 no/— 2 µL 2 µL/primary tube capable yes/no yes/up to 2 L per hours <70 decibels no/can use small sample cup/10–20 µL yes/5, 7, 10 mL/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes yes/yes  <20 seconds yes varies—3 levels for most assays yes (Na, K, Cl)/most 90 days yes/yes 24 hours no/yes not required
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with  LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	10 minutes <2 minutes 200/600 (variable 3.6–20 seconds)  yes/yes yes/yes Mysis, Soft, Mediatech, Cerner, others  yes no — yes (broadcast download & host query) yes yes (StreamLab, ADVIA LabCell in development) yes/yes/yes  no 2–8 hours —/— yes daily: <10 minutes; weekly: none; monthly: 10–20 minutes no/no/yes	16 minutes 24 seconds up to 83/up to 250 (14.4 seconds)  yes/yes optional/yes (additional) all major LIS vendors  yes no — yes (broadcast download & host query) yes yes yes/yes/yes  no 2–8 hours —/— yes daily: <5 minutes; weekly: 10 minutes; monthly: 15 minutes yes/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$552,240/>4,000 tests per day inquire 4 days on site, 4 days at vendor offices/yes	—/— multiple types 5 days on site; 4 days at vendor offices/no
Distinguishing features (supplied by vendor)	homogeneous LOCI tech. for high-sensitivity IA assays; fast analytical time, 10-min. cardiac markers, 21-min. anemia methods; ultra-integrated platform w/nephelometry eliminates sample sharing/splitting and streamlines lab workflow; can be configured as a Dimension Vista 3000T twin system; enhances operator efficiency with automatic calib. & AC processing; support through RealTime Solutions	consolidated low-volume workstation that integrates immunoassays onboard with other chemistries; allows single platform to meet more than 95 percent of testing needs; eliminates sample splitting, aliquotting

## Automated immunoassay analyzers

Part 26 of 31	Siemens Healthcare Diagnostics Christina Tassone christina.tassone@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 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	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.
Country where manufactured/Where reagents manufactured	U.S./U.S.	U.S./U.S.
No. of units in clinical use in U.S./Outside U.S.	—/—	—/—
Operational type/Model type/Sample handling system	batch, random access, cont. random access/floor-standing/racks	batch, random access, continuous random access/floor standing/racks
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
Tests available on instrument in U.S.	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, transferrin, cyclosporine extended range, hemoglobin A1c, carbamazepine, cyclosporine, digoxin, digitoxin, gentamicin, lidocaine, lithium, N-acetylprocainamide, phenobarbital, phenytoin, procainamide, tacrolimus, theophylline, tobramycin, vancomycin, valproic acid, acetaminophen, ethyl alcohol, salicylate, serum barbiturates, serum benzodiazepines, serum tricyclic antidepressants, myeloperoxidase, sirolimus, others	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, phenobarbital, phenytoin, procainamide, tacrolimus, theophylline, tobramycin, vancomycin, valproic acid, hemoglobin A1c, thyronine uptake, total T4, acetaminophen, ethyl alcohol, salicylate, urine ecstasy, LOCI free thyroxine, LOCI thyroid stimulating hormone, LOCI cardiac troponin I, LOCI LV NT-pro BNP, urine screens: amphetamine, barbiturates, benzodiazepines, cannabinoids, cocaine metabolite, methadone, opiates, phencyclidine; serums: TCA, barbiturates, benzodiazepine; propoxyphene, methaqualone, C3, C4, IgA, IgG, IgM, transferrin, general chemistry menu, sirolimus
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for clearance	—	—
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	—	—
Tests in development	mycophenolic acid	LOCI free T3, LOCI B12, LOCI folate, MPA, total PSA, free PSA
User-defined methods implemented for what analytes	—	—
Tests not available on other manufacturers' analyzers	system performs heterogeneous immunoassays and general assays on a single platform—fully automated ISD assays	system performs homogeneous LOCI and heterogeneous immunoassays plus complete routine gen. chemistry menu on single platform; fully auto., no-pretreatment ISD assays
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	—	—
No. 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 homogeneous
No. of different measured assays onboard simultaneously	91 (with optional reagent management system)	91
No. of different assays programmed, calibrated at once	190	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	Max=47, Max Suite=91/15 to 360	91/15–360
Shortest/Median onboard reagent stability/Refrigerated onboard	48 hours/30 days/yes (2°–8°C)	72 hours/30 days/yes (2°–8° C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	placed directly on system
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
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/— due to probe washing	yes/none (due to probe washing)
Walkaway capacity in minutes/Specimens/Tests-assays	can be hours/60/>2,000/>5,000	can be hours/60/>2,000
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)
Uses disposable cuvettes/Max. No. stored	yes/12,000	yes/12,000
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum specimen vol. required	2 µL	2 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	2 µL/primary tube capable	2 µL/primary tube capable
Supplied with UPS (backup power)/Requires floor drain	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
Noise generated	<70 decibels	<75 decibels
Has dedicated pediatric sample cup/Dead vol.	yes/10–20 µL	yes/30 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5, 7, 10 mL/no	yes/5, 7, 10 mL/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Bar-code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	no/yes	no/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	yes/yes	yes/no
Time between initial result & reaspiration of sample for rerun	<20 seconds	<20 seconds
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	varies—3 levels for most assays	varies (3 levels for most assays)
Calibrants can be stored onboard/Avg. calibration frequency	yes (Na, K, Cl)/most 90 days	yes (Na, K, Cl)/most 90 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	24 hours	24 hours or with lot change
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	no/yes
Automatic shutdown/Startup is programmable/Startup time	not required	no/no/not required
Stat time to completion of β-hCG test	16 minutes	16 minutes
Time delay from ordering stat test to aspir. of sample	24 seconds	24 seconds
Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	up to 166/up to 500 (7.2 seconds)	up to 146/437 (7.2 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	optional/yes (additional cost)	onboard, optional add-on (EasyLink Informatics System)/yes (additional cost)
Interfaces up and running in active user sites with	all major LIS vendors	all major LIS vendors
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download, host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	yes	yes
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	2–8 hours	2–8 hours
Mean time between failures/To repair failures	—/—	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 minutes, weekly: 10 minutes, monthly: 15 minutes	daily: <5 minutes; weekly: 10 minutes; monthly: 23 minutes
Onboard maintenance records/Maintenance training demo module	yes/yes	no/no
List price/Targeted bed size or daily volume	—/—	—
Annual service contract cost (24 hours/7 days)	multiple types	multiple types
Training provided w/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
Distinguishing features (supplied by vendor)	analyzer integrates heterogeneous immunoassays onboard with other chemistries; allows single platform for more than 95 percent of most requested tests; eliminates sample splitting between general tests and immunoassays	analyzer integrates homogeneous LOCI and heterogeneous immunoassays onboard w/ other chemistries; allows single platform for >95 percent of most tests; eliminates sample splitting between gen. chemistry tests and immunoassays; fully auto. onboard ISD assays

## Automated immunoassay analyzers

Part 27 of 31	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 Martu Richards martu.richards@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 914-524-3828 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 1000/1993; IMMULITE Turbo/1999; IMMULITE 1000/2002/U.S. U.S./U.S., U.K. >7,000 worldwide continuous random access/benchttop/loading platform 19 x 46 x 26/7.98	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
Tests available on instrument in U.S.	3gAllergy specific IgE, ACTH, AFP, androstenedione, anti-HBc IgM, anti-HBc total, anti-HBs, anti-TG Ab, anti-TPO Ab, beta-2 microglobulin, BR-MA (CA 15-3), calcitonin, canine TLI, canine total T4, canine TSH, carbamazepine, CEA, CK-MB, CMV IgG, cortisol, C-peptide, DHEA-SO4, digoxin, EPO, estradiol, ferritin, folic acid, free PSA, free T3, free T4, FSH, gastrin, growth hormone (hGH), H. pylori IgG, HBs Ag, HBs Ag confirmatory, HCG, herpes I & II IgG, high sensitivity CRP, homocysteine, IGFBP-3, IGF-I, insulin, intact PTH, LH, microalbumin, myoglobin, OM-MA (CA 125), PAP, phenobarbital, phenytoin, progesterone, prolactin, PSA, PYRILINKS-D, rapid TSH, RBC folate, rubella IgM, rubella quantitative IgG, SHBG, TBG, theophylline, 3gPSA, 3gTSH, thyroglobulin, thyroid uptake, total IgE, total T3, total T4, total testosterone, toxoplasma quant. IgG, Troponin I, Unconjugated Estriol, Valproic Acid, Vitamin B12; Turbo STAT menu: CK-MB, HCG, Intact PTH, Myoglobin, Troponin I, others none	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), H. pylori IgG, HBs Ag, HBs Ag confirmatory, HCG, herpes I & II IgG, high sensitivity CRP, homocysteine, IGFBP-3, IGF-I, insulin, intact PTH, LH, microalbumin, myoglobin, OM-MA (CA 125), PAP, phenobarbital, phenytoin, progesterone, prolactin, PSA, PYRILINKS-D, rapid TSH, RBC folate, rubella IgM, rubella quantitative IgG, SHBG, TBG, theophylline, 3gPSA, 3gG TSH, thyroglobulin, thyroid uptake, total IgE, total T3, total T4, total testosterone, toxoplasma quant. IgG, troponin I, unconjugated estriol, valproic acid, others none
Tests cleared but not clinically released 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 $\beta$ -hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, osteocalcin, NT-proBNP, CMV IgM, ECP, cannabinoids (THC), D-dimer	— GI-MA (CA 19-9), nicotine metabolite, free $\beta$ -hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, osteocalcin, NT-proBNP, CMV IgM, allergen-specific IgG4, ECP, cannabinoids (THC), D-dimer
Research-use-only assays Tests in development	— D-dimer, turbo D-dimer, CMV IgM	— anti-CCP IgG, D-dimer, CMV IgM, HBsAb quantitative, EBV-EBNA IgG, EBV-VCA IgG, EBV-VCA IgM, Lyme screen
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none IGF-I, IGFBP-3, androst., 3rd-gen PSA, gastrin, canine TLI, canine TSH	none 3gPSA, IGF-I, IGFBP-3, H. pylori IgG, androst., gastrin, canine TLI, canine TSH
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	chemiluminescence/bead, centrifugation 12 unlimited 0 12; 5 for Turbo/100; 50 for Turbo i-PTH —/30 days/yes (15°C) yes yes yes/test, lot No., expir. no/<10 ppm 100/—/70 no/liquid yes/— no 5 $\mu$ L 5 $\mu$ L/100 $\mu$ L yes/no no/0.5 L per hour 55-68 decibels no/— no/—/— yes — yes yes/yes yes no/no no/no yes/no no/no — yes 2-level adjustors, supplied in kit no/1-4 weeks (assay dependent); 2 weeks for Turbo no/yes customer determined no/yes no/no/5 minutes	chemiluminescence/bead, centrifugation 24 unlimited — 24/200 —/90 days/yes (4°C) yes yes yes/test, lot No., expir. no/<3 ppm 300/90/1,300 no/liquid yes/1,300 no/— 5 $\mu$ L to 100 $\mu$ L sample 5 $\mu$ L/50 $\mu$ L yes/no no/— 52 decibels yes/50 $\mu$ L yes/75-100 mm height; 12-16 mm width/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes —/— yes/yes no/no min. 18 seconds yes 2-level adjustors, supplied in kit no/1-4 weeks (assay dependent) yes/yes customer determined yes/yes yes/no/4 minutes
Stat time to completion of $\beta$ -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	42 minutes; 15 minutes for Turbo (total hCG) 2.5 minutes 120/120 (—) no/yes onboard/yes (additional cost) CIS, CPSI, CCA, Mysis, McKesson, Cerner, Antek, CSS, others yes no — yes (broadcast download & host query) yes no yes/yes/no yes no yes/yes/no no 4 hours 10 months/4 hours yes daily: 5 minutes; weekly: 10 minutes; monthly: 20 minutes —/yes	35 minutes (total HCG) 18 seconds 200/200 (18 seconds) yes/yes onboard/yes (additional cost) Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Mediatech, McKesson, Mysis, SCC, others yes no — yes (broadcast download & host query) yes yes (universal interface) yes/yes/yes no 4 hours 3 months/5 hours yes daily: 5 to 10 minutes; weekly: 20 minutes; monthly: 20 to 30 minutes no/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$75,000; Turbo: \$77,500/>1,000 tests per month \$8,000 3.5 days at vendor offices/yes	\$124,500/>6,000 tests per month \$16,500 (RealTime Solutions) varies on site, 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	system reliability and performance; large test menu	high-throughput system, combines specific allergens & routine esoteric testing on one platform; clot detection; sample/reagent level detection; autodilution & autoreflex testing; remote diagnostics; QM & logistics reports

## Automated immunoassay analyzers

Part 28 of 31	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 2500 SMS/2004/U.S. U.S./U.S., U.K. >600 worldwide continuous random access/floor standing/rack 79 x 112 x 40/30.69	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.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development  User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	3gAllergy specific IgE, ACTH, AFP, androstenedione, Anti-TG Ab, Anti-TPO Ab, beta-2 microglobulin, BR-MA (CA15-3), calcitonin, carbamazepine, CEA, CK-MB, CMV IgG, cortisol, C-peptide, DHEA-SO4, digoxin, EPO, estradiol, ferritin, folic acid, free T3, free T4, FSH, gastrin, growth hormone (hGH), H. pylori IgG, HCG, herpes I & II IgG, high sensitivity CRP, IGFBP-3, IGF-I, insulin, intact PTH, LH, microalbumin, myoglobin, OM-MA (CA125), phenobarbital, phenytoin, progesterone, prolactin, PSA, Pylilinks-D, rapid TSH, RBC folate, rubella IgM, rubella quantitative IgG, SHBG, TBG, theophylline, 3gPSA, 3gTSH, thyroglobulin, thyroid uptake, total IgE, total T3, total T4, total testosterone, toxoplasma IgM, toxoplasma quant. IgG, troponin I, turbo CKMB; Turbo STAT menu: Intact PTH, myoglobin, troponin I, unconjugated estradiol, valproic acid, vitamin B12 none — GI-MA (CA 19-9), nicotine metabolite, free $\beta$ -hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, osteocalcin, NT-proBNP, CMV IgM, allergen-specific IgG4, ECP, cannabinoids (THC), D-dimer — — none 3gPSA, IGF-I, IGFBP-3, H. pylori IgG, androst., gastrin, canine TLI, canine TSH	mass CK-MB, myoglobin, $\beta$ -hCG, D-dimer, NT-proBNP, high-sensitivity troponin I, CardioPhase hsCRP  — — — — — —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	chemiluminescence/bead, centrifugation 24 unlimited — 24/200 —/90 days/yes (4°C) yes yes yes/test, lot No., expiration no/<3 ppm 300/275/1,300 no/liquid yes/1,300 no/— 5 $\mu$ L to 100 $\mu$ L sample 5 $\mu$ L/50 $\mu$ L yes/no no/— 52 decibels yes/50 $\mu$ L yes/75–100 mm height; 12–16 mm width/no yes (2 or 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes —/— yes/yes no/no min. 18 seconds yes 2-level adjusters, supplied in kit no/1–4 weeks (assay dependent) yes/yes customer determined yes/yes yes/no/4 minutes	fluorescence, EIA, dendrimer technology/fiber matrix filter up to 4 1 0 up to 4 TestPaks/unit dose TestPak — yes yes yes/assay ID, lot No., expir., calib. param. no/zero carryover 14 minutes to 1st result, subsequent results in 4 minutes intervals/1/up to 4 no/liquid no no 2.5 mL whole blood 50–90 $\mu$ L/— optional/no no/— <65 decibels no yes/4 or 5 mL/yes yes (2 of 5 interleaved, Codabar, codes 39 & 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 $\beta$ -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	15 minutes (total HCG) 18 seconds 200/200 (18 seconds) yes/yes onboard/yes (additional cost) Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, others yes no — yes (broadcast download & host query) yes yes (universal interface) yes/yes/yes no 4 hours 3 months/5 hours yes daily: 5 to 10 minutes; weekly: 20 minutes; monthly: 20 to 30 minutes no/yes	14 minutes immediately 3/9 yes/yes yes/yes (additional cost) all major LIS vendors yes no — no yes no no/yes/yes no 2 to 8 hours >225 days/2.9 hours yes daily: none; weekly: none; monthly: 10 minutes no/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$200,000 includes SMS & RealTime Solutions/200+ beds \$21,500 (RealTime Solutions with SMS) varies on site, 5 days at vendor offices/yes	—/any size emergency department multiple types 3 days on site/no
Distinguishing features (supplied by vendor)	large automated IA test menu; 15-minute stat assays, flexible sample handling, user-definable testing; runs specific allergen testing alongside routine IAs; flexible connectivity to automation via SMS; autoreflex, autodilute; QM and 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 standalone workstation featuring its own cart, refrigerator, & uninterruptible power supply



## Automated immunoassay analyzers

Part 30 of 31	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. 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 x W x D)/Instrument footprint in sq. feet	AIA-360/2004/Japan Japan/Japan 775/2,347 continuous random access/benchtop/carousel 21 x 19 x 16/2.1	AIA-1800/2003/Japan Japan/Japan 80/550 continuous random access/floor standing/rack, sort drawer, standard and LA 65 x 50 x 37/12.8
Tests available on instrument in U.S.	10 minutes short time (ST) assays: TSH, FT4, T3, T4, T-uptake, FT3, $\beta$ -hCG, estradiol, FSH, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, $\beta$ -2-microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen., ferritin, testosterone, CA 19-9, intact PTH	TSH, 3rd-gen. TSH, FT4, T3, T4, T-uptake, FT3, TPO Ab, Tg Ab, $\beta$ hCG, estradiol, FSH, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, $\beta$ -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
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— cystatin C, HbA1c BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, cTnl 3rd gen., PSA II — ACTH, DHEA-S — —	— cystatin C, HbA1c BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, cTnl 3rd gen., PSA II — ACTH, DHEA-S — —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	— — —	— — —
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard 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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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, EIA/beam 25 entire menu 0 —/unitized test cup 72hours/72hours/— yes yes yes/lot No., test code no/zero carryover 58/25/25 no/dry no no 500 $\mu$ L tube, 100 $\mu$ L cup 10 $\mu$ L/500 $\mu$ L tube, 100 $\mu$ L cup no/no no/— — no yes/primary draw tubes: 13 x 75 & 100; 16 x 75 & 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	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 $\mu$ L tube, 100 $\mu$ L cup 10 $\mu$ L/500 $\mu$ L tube, 100 $\mu$ L cup yes/no no/— — no yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100; 13 x 75 & 100/no yes/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 to 8 minutes
Stat time to completion of $\beta$ -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface	~18 minutes 60 seconds 12/36 (1 minutes) yes/no Antek, Schuyler House, more	~18 minutes 40 seconds 60/180 (20 seconds) yes/yes yes/no
Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	— — yes package insert no yes no no/no/no no — >6 months/24 hours yes daily: 5 minutes no/no	yes yes yes package insert yes (broadcast download & host query) yes yes (Hitachi, Siemens, Thermo, iLAS) no/no/no no 24 hours 5 months/24 hours yes daily: 5 to 8 minutes; weekly: 5 minutes; monthly: none yes (includes audit trail of who replaced parts)/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$25,000/200 to 1,000 tests per month \$2,050-\$3,500 training DVD; on-site install	\$175,000/65+ beds, 1,500 to 2,000 tests \$11,458 4 days at vendor offices/no
Distinguishing features (supplied by vendor)	unitized test cups; primary tube sampling; no reagent preparation, room-temp. stability for five days; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use; compact size; four tests per sample; random access	two models: standard and LA; unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room-temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use

## Automated immunoassay analyzers

Part 31 of 31	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	Trinity Biotech Marlene Jinks marlene.jinks@trinityusa.com 4 Connell Drive, Ste. 7100, Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.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-600 II/2000/Japan Japan/Japan 555/1,398 cont. random access/benchtop/chain 19.8 × 31.6 × 29.1/6.4	Nexgen Four/2003/Italy Italy/U.S., Italy, Ireland —/— batch, random access, continuous random access/benchtop/ring (carousel) 28 × 53.2 × 29.5 (includes carousel)/—
Tests available on instrument in U.S.	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	open system—any microplate assay
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— cystatin C, HbA1c HBsAg, HBsAb, HBeAg, HbcAb, HbeAb, BNP, cTnI 3rd gen., PSA II — ACTH, DHEA-S none none	open system—any microplate assay open system—any microplate assay open system—any microplate assay open system—any microplate assay open system—any microplate assay open system—any microplate assay
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no — —	yes — min. strip: 1; max. full plate: 96 × 4 plates
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/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. 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 vol. 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 vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. 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, EIA/bead 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 & 10 mL or 15 × 75 & 100, 13 × 75 & 100/100 yes/yes 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	EIA/coated microwell 500+ 500+ 500+ 16/manufacturer defined —/—/no yes requires operator prehandling, preparation yes/— yes/zero carryover with plastic tips varies/varies/varies yes/liquid yes/— yes/— 200 μL dead vol. plus amount required by test 10 μL/200 μL yes/no no/— — no/— yes/—/no yes (2 or 5 interleaved, Codabar, codes 39 & 128)/— yes yes no/yes yes yes/yes no/no yes/no no/no — — manufacturer dependent manufacturer dependent/manufacturer dependent yes/manufacturer dependent manufacturer dependent —/— no/no/10 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hour for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data-management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete 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) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	~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) Schuyler House, Fletcher Flora yes yes package insert yes (broadcast download & host query) yes no no/no/no no 24 hours 98% uptime/— yes daily: 5 minutes; weekly: 5 minutes; monthly: none no/no	manufacturer dependent — —/open system—depends on kit yes/yes onboard/yes — — — yes yes no yes/yes/yes no by contract —/— yes daily: 5 minutes; weekly: 5 to 10 minutes; monthly: 10 to 15 minutes —/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$70,000/500–2,500 tests per month \$5,941 3 days at vendor offices/no	\$72,900/>100 varies 3–4 days on site/no
Distinguishing features (supplied by vendor)	unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room-temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use	dual-arm pipetting with independent wash capabilities; specimen delivery with metal needle or plastic tip within same run; continuous loading; remote desktop operation via Internet/modem; touchscreen