

Automated immunoassay analyzers

Part 1 of 27	Abbott Diagnostics Chuck Gorman paul.gorman@abbott.com 1921 Hurd Drive, Irving, TX 75038 972-518-7592 www.abbott.com	Abbott Diagnostics Chuck Gorman paul.gorman@abbott.com 1921 Hurd Drive, Irving, TX 75038 972-518-7592 www.abbott.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. 2,000/14,000 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. 272/4,096 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	ultra hTSH II, TT3, TT4, FT3, FT4, T-uptake, total β HCG, FSH, LH, progester., estrad., prolac., testosterone, CK-MB, homocysteine, myoglobin, trop. I, tPSA, fPSA, CEA, CA 125, CA 15-3, AFP, CMV IgG, rubella IgG & IgM, toxo IgG & IgM, carbamazep., digox., gentamicin, NAPA, phenytoin, phenobarb., procain., quinidine, theoph., tobramycin, valp. acid, vanc., amph/meth, barbit., benzodiazep., cannab., cocaine met., methadone, opiates, PCP, acetamin., ethanol, salicylates, tricyc., cortisol, BNP, anti-HCV, HAVAB 2.0, HAVAB-M2.0, ferritin, B12, folate, anti-HAV, anti-HBc IgM, anti-HAV IgM, anti-HBs, anti-HBc, HBsAg/HBsAg confirm, holoTc, anti-CCP, anti-TPO, anti-Tg, HbA1c, Barbs-U — — CA 19-9, HAVAB 2.0 Quant, CMV IgM, β -2-microglobulin, insulin, 3rd gen TSH, digitoxin, HBe, anti-HBe, HIV 1/2gO, HIV Ag/Ab combo, D-dimer — —	cardiac: (STAT) troponin I, CK-MB, myoglobin (i2000SR, i4000SR); fertility: total beta-hCG, LH, FSH, prolactin, progesterone, estradiol, DHEA-S; cancer: total PSA, free PSA, AFP, CA 125 II, CA 15-3, CA 19-9XR, CEA; thyroid: TSH, free T3 & T4, total T3 & T4, T-uptake, anti-Tg, anti-TPO; metabolic: BNP, ferritin, cortisol, insulin; hep/retro/congenitals: HBsAg, HBsAg confirm., anti-HCV, AUSAB (anti-HBs), CORE-M (anti-HBc IgM), SHBG, iPTH, theophylline, sirolimus, tacrolimus, HAVAB-M, HAVAB — TDM: phenytoin, phenobarbital; transplant: cyclosporine; hep/retro/congenitals: CORE-M, rubella IgG fertility: testosterone; cancer: SCC, AFP; metabolic: B12, folate; hep/retro/congenitals: HIV Ag/Ab combo, syphilis, HBeAg, anti-HBe, HAVAB-G, anti-HBc, CMV IgG, CMV IgM, rubella IgM, rubella IgG, homocysteine, MPO, CMV IgG Avidity, Toxo IgG Avidity — cardiac: MPO, homocysteine; thyroid: Tg; metabolic: C-peptide, vitamin D, B12; hep/retro/congenitals U.S. only: CORE, HAVAB-G, HIV combo; outside U.S.: HCV Ag/Ab combo, HCV core Ag, HTLV I/II, toxo IgG, toxo IgM, C-peptide, Tg none 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 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	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 μ L/150 μ L 10 μ L/73 μ L for sample cup, 450 μ L 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 interl., 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., 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/<0.1 ppm 300/135/12,500 no/liquid yes/1,200 no/— 50 μ L 150 μ L/50 μ L for all tube types yes/no no/— 48–70 decibels no yes/5, 7, 10 mL/no yes (2 of 5 interl., 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 hours 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	Chemiflex tech. delivers excellent sensitivities and extended linearities; RSH allows priority and routine samples to be processed simultaneously w/o compromising stats

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Part 2 of 27	Abbott Diagnostics Mark Jackman mark.jackman@abbott.com 1921 Hurd Drive, Irving, TX 75038 972-518-6775 www.abbott.com	Abbott Diagnostics Chuck Gorman paul.gorman@abbott.com 1921 Hurd Drive, Irving, TX 75038 972-518-7592 www.abbott.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	ARCHITECT ci8200, ci16200/2003, 2007/U.S. U.S./U.S. 251 (ci8200), 3 (ci16200)/1,245 (ci8200), 53 (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. —/— 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	cardiac: (STAT) troponin I, CK-MB, myoglobin (i2000SR, i4000SR); fertility: total beta-hCG, LH, FSH, prolactin, progesterone, estradiol, DHEA-S; cancer: total PSA, free PSA, AFP, CA 125 II, CA 15-3, CA 19-9XR, CEA; thyroid: TSH, free T3 & T4, total T3 & T4, T-uptake, anti-Tg, anti-TPO; metabolic: BNP, ferritin, cortisol, insulin; hep/retro/congenitals: HBsAg, HBsAg confirm., anti-HCV, AUSAB (anti-HBs), CORE-M (anti-HBc IgM), SHBG, iPTH, theophylline, sirolimus, tacrolimus, HAVAB-M, HAVAB — TDM: phenytoin, phenobarbital; transplant: cyclosporine; hep/retro/congenitals: CORE-M, rubella IgG fertility: testosterone; cancer: SCC, AFP; metabolic: B12, folate; hep/retro/congenitals: HIV Ag/Ab combo, syphilis, HBeAg, anti-HBe, HAVAB-G, anti-HBc, CMV IgG, CMV IgM, rubella IgM, rubella IgG, homocysteine, MPO, CMV IgG Avidity, Toxo IgG Avidity — cardiac: MPO, homocysteine; thyroid: Tg; metabolic: C-peptide, vitamin D, B12; hep/retro/congenitals U.S. only: CORE, HAVAB-G, HIV combo; outside U.S.: HCV Ag/Ab combo, HCV core Ag, HTLV I/II, toxo IgG, toxo IgM, C-peptide, Tg none none	anti-Tg, anti-TPO, free T3, free T4, total T3, total T4, TSH, T-uptake, B-hCG, estradiol, FSH, LH, progesterone, prolactin, DHEA-S, SHBG, BNP, CK-MB, ferritin, insulin, intact PTH CA 125-II, CA 15-3, CA 19-9XR, CEA, tacrolimus, sirolimus, theophylline vancomycin, cortisol, homocysteine, HAVAB-M, troponin-I, phenytoin, phenobarbital, cyclosporine free PSA, SCC, total PSA, AFP, anti-HBc, anti-HBc IgM, anti-HBe, anti-HBs, anti-HCV, HAVAB-IgM, rubella IgG, others — free PSA, total PSA, AFP, B12 none none
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 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	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 interl., Codabar, codes 39 & 128)/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 interl., Codabar, codes 39 & 128)/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 hours 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; large reagent capacity of 93 assays, with sample load up to 367	streamlined workload mgmt.; continuous access to reagents, samples, and supplies; 65 samp. load cap., 13 universal bay; up to 7 customizable priority bays, reagent carousel w/25 x 100 test kit sizes, reagents stable onboard for up to 30 days; priority tests, 15.6 min. turnaround time on stat assays

Automated immunoassay analyzers

Part 3 of 27	Awareness Technology Inc. Chris Schneider info@awaretech.com 1935 SW Martin Hwy., Palm City, FL 34990 772-283-6540 www.awaretech.com	Beckman Coulter Inc. Linh Ho ltho@beckman.com 200 S. Kraemer Blvd., Brea, CA 92821 714-993-8736 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	ChemWell/1998/U.S. U.S./open system 10/900+ batch, random access/benchtop/rack 16 × 34 × 20/4	Access/Access 2 Immunoassay System/2001/U.S. U.S./U.S. & France >2,400/>3,700 cont. random access/benchtop/rack 18.5 × 39 × 24/6.5
Tests available on instrument in U.S.	unlimited—open system	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor (CA 15-3 antigen), GI monitor (CA 19-9 antigen), AFP and Dil AFP, CK-MB, digoxin, myoglobin, AccuTnl troponin I, BNP, free T3, free T4, hypersensitive hTSH, fast hTSH, thyroglobulin, thyroglobulin Ab, thyroid uptake, total T3, total T4, TPOAb, EPO, ferritin and Dil ferritin, folate/RBC folate, vitamin B12, intrinsic factor AB, AFP (ONTD) and Dil AFP, estradiol, hFSH, hLH, progesterone, DHEA-S, prolactin, testosterone, total βhCG and Dil βhCG, unconjugated estriol, inhibin A, ultrasensitive insulin, ostase bone alkaline phosphatase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgG, toxo IgM II, total IgE, cortisol
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	— soluble transferrin receptor HIV ½, HBsAg, HBsAg confirm., HBsAB, HCV Ab, HAV Ab, HAV IgM, HBeAb, HBe IgM, IL-6, rubella IgM
Research-use-only assays Tests in development	unlimited—open system —	IL-6 CMV IgG & IgM, BPH-A, p2PSA, ANA, PIGF, sVEGF R1 (preeclampsia), PAPP-A, SHBG, HBeAg, HBeAb, HIV combo
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	general biochemistries —	none intrinsic factor Ab, inhibin A
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 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	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 × 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 (4°C) yes yes yes/assay No., lot No., expir., unique reagent pack ID No. no/≤ 10 ppm 180/60/300 no/liquid yes/294 no specimen container dependent 5 μL/100 μL yes (when networked)/no no <70 decibels yes/100 μL yes/13 × 75 & 100, 16x75 & 100, 2 μL & 3 μL cups; 13x75, 13x100 aliquot tubes/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes no/yes no/no yes/yes no/no 36 seconds no assay dependent, 6 or 7 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 hours 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 yes/yes/yes no 24 hours max., usually within 6 hours —/— yes daily: 15 min; weekly: 30 min; monthly: none yes/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/up to 500 tests per day \$4,000 3 days on site/no	\$149,800/all volumes & hospital sizes \$15,800 4 days at vendor offices/yes
Distinguishing features (supplied by vendor)	ability to perform general biochemistries; optional reagent cooling module	ability to network up to four Access 2s using a single LIS interface with remote diagnostics, fully automated user-defined reflex testing; onboard context sensitive help, aliquot tube capability; continuous random-access benchtop analyzer; chemiluminescence methodology; assays: TSH, FT4, UE3, hybritech PSA, fPSA, B12, fol., AccuTnl

Automated immunoassay analyzers

Part 4 of 27	Beckman Coulter Inc. Leonard Bachicha LABachicha@beckman.com 200 S. Kraemer Blvd., Brea, CA 92821 (714) 961-6698 www.beckmancoulter.com	Beckman Coulter Inc. Mark Watanabe mswatanabe@beckman.com 200 S. Kraemer Blvd., Brea, CA 92821 714-961-3779 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 DxI 800/2003/U.S. U.S./U.S., France >400/>400 cont. random access/floor standing/rack, direct track sampling 66.7 x 67.5 x 37.7/17.7	UniCel DxS 600i Synchron Access Clinical System/2006/U.S. U.S./U.S. >115/>115 continuous random access/floor standing/rack-closed tube 62 x 126.5 x 48/42.16
Tests available on instrument in U.S.	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor (CA 15-3 antigen), GI monitor (CA 19-9 antigen), AFP and Dil AFP, CK-MB, digoxin, myoglobin, AccuTnl troponin I, BNP, free T3, free T4, hypersensitive hTSH, fast hTSH, thyroglobulin, thyroglobulin Ab, thyroid uptake, total T3, total T4, TPOAb, EPO, ferritin and Dil ferritin, folate/RBC folate, vitamin B12, intrinsic factor AB, AFP (ONTD) and Dil AFP, estradiol, hFSH, hLH, progesterone, DHEA-S, prolactin, testosterone, total β hCG and Dil β hCG, unconjugated estriol, inhibin A, ultrasensitive insulin, ostase bone alkaline phosphatase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgG, toxo IgM II, total IgE, cortisol	CEA, Hybritech PSA, Hybritech free PSA, OV Monitor (CA 125 antigen), BR Monitor (CA 15-3 antigen), GI Monitor (CA 19-9 antigen), AFP and Dil AFP, CK-MB, Digoxin, Myoglobin, AccuTnl Troponin I, BNP, Free T3, Free T4, Hypersensitive hTSH, Fast hTSH, Thyroglobulin, Thyroglobulin Ab, Thyroid Uptake, Total T3, Total T4, TPOAb, EPO, Ferritin and Dil Ferritin, Folate/RBC Folate, Vitamin B12, Intrinsic Factor AB, AFP (ONTD) and Dil AFP, Estradiol, hFSH, hLH, Progesterone, DHEA-S, Prolactin, Testosterone, Total bhCG and Dil bhCG, Unconjugated Estriol, Inhibin A, Ultrasensitive Insulin, Ostase Bone Alkaline Phosphatase, Intact PTH (Routine and Intraoperative), Ultrasensitive hGH, Rubella IgG, Toxo IgG, Toxo IgM II, Total IgE, Cortisol plus >100 Synchron chemistry tests, including critical care, general esoteric, urine and CSF chemistries, DAT, TDMs, proteins, serologies
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	— Soluble transferrin receptor HIV 1/2, HBsAg, HBsAg confirm., HBsAB, HCV Ab, HAV Ab, HAV IgM, HBeAg, HBeAg, HBeAg, HIV combo, ANA, dsDNA Ib, inhibin A, PIGF, sVEGF RI (preeclampsia)	— soluble transferrin receptor IL-6, rubella IgM
Research-use-only assays Tests in development	IL-6 CMV IgG & IgM, BPH-A, p2PSA, PAPP-A, SHBG, HBeAg, HBeAg, HIV combo, ANA, dsDNA Ib, inhibin A, PIGF, sVEGF RI (preeclampsia)	IL-6 ANA screen, CMV IgG, CMV IgM, PIGF (preeclampsia), sVEGF RI (preeclampsia), BPH-A, p2PSA, PAPP-A, SHBG, HBe Ag, HBe Ag, HIV combo
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none intrinsic factor Ab, inhibin A	— intrinsic factor Ab, inhibin A
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/magnetic particle 50 50 0 50/50 tests per cartridge, 100 or 300 tests per kit 336 hours/28 days/yes (3°-10°C) yes yes yes/assay No., lot No., expir., unique reagent pack ID No.	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 (2°-10°C)/yes yes yes yes/specific cartridge ID, No. of tests, available tests, expiration date, lot No., calibration expiration
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	—/< 10 ppm 288 (avg.—assay mix dependent)/120/1,200 (avg.) no/liquid yes/>1,000 no specimen container dependent 5 μ L/160 μ L yes (PC only)/optional no/— <60 decibels yes/100 μ L yes/12 x 75 to 16 x 100 mm/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no <9 seconds (minimum) yes assay dependent, 6 or 7 no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode	no/10 ppm 180/96/5,280 no/liquid yes/294 yes/2-year warranty (gen. chem.) specimen container dependent 5 μ L/100 μ L optional/yes yes/16 L per hour — yes (gen. chem.)/— yes/13 x 75 & 100 to 16 x 100 mm/yes yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes yes/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 hours 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 min. 67, max. 133/min. 200, max. 400 (9 or 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; weekly: TBD; monthly: none yes/yes	15 minutes 36 seconds —/100-immunoassay, 990-gen. chem. (36 seconds) yes/yes optional add-on/yes (additional cost) all major LIS vendors yes yes — yes (broadcast download & host query) yes no no/yes/yes no — —/per negotiated contract yes daily: <15 min; weekly: 36 min; monthly: 11 min yes/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$325,000/300+ beds or >400 tests per day \$29,900 5 days at vendor office for 2 employees/yes	\$400,000/— per negotiated contract yes/yes
Distinguishing features (supplied by vendor)	high-throughput immunoassay analyzer; uses chemiluminescent assay technology and reagent packs to deliver consistent results with other Access systems; allows operators to load consumables on the fly without interacting with system	performs parallel processing of immunoassay and chemistry tests on a single workstation; closed-tube aliquot and closed-tube sampling eliminate manual processes; robust test menu integrates immunoassay and chemistry product lines

Automated immunoassay analyzers

Part 5 of 27	Beckman Coulter Inc. Leonard Bachicha LABachicha@beckman.com 200 S. Kraemer Blvd., Brea, CA 92821 (714) 961-6698 www.beckmancoulter.com	Beckman Coulter Inc. Mark Watanabe mswatanabe@beckman.com 200 S. Kraemer Blvd., Brea, CA 92821 714-961-3779 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 DxI 600 Access Immunoassay System/2007/U.S. U.S./U.S. >40/>40 continuous random access/floor standing/rack 67 x 61.5 x 37.5/16.02	UniCel DxC 880i Synchron Access Clinical System/2008/U.S. U.S./U.S. 3/15 continuous random access/floor standing/track closed tube 68 x 161 x 48/53.66
Tests available on instrument in U.S.	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor (CA 15-3 antigen), GI monitor (CA 19-9 antigen), AFP and Dil AFP, CK-MB, digoxin, myoglobin, AccuTnl troponin I, BNP, Free T3, Free T4, hypersensitive hTSH, fast hTSH, thyroglobulin, thyroglobulin Ab, thyroid uptake, total T3, total T4, TPOAb, EPO, ferritin and Dil ferritin, folate/RBC folate, vitamin B12, intrinsic factor AB, AFP (ONTD) and Dil AFP, estradiol, hFSH, hLH, progesterone, DHEA-S, prolactin, testosterone, total β -hCG and Dil β -hCG, unconjugated estradiol, inhibin A, ultrasensitive insulin, ostase bone alkaline phosphatase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgG, toxo IgM II, total IgE, cortisol	CEA, hybritech PSA, hybritech free PSA, OV monitor (CA 125 antigen), BR monitor (CA 15-3 antigen), GI monitor (CA 19-9 antigen), CK-MB, digoxin, myoglobin, AccuTnl troponin I, BNP, free T3, free T4, Hypersensitive hTSH, fast hTSH, thyroglobulin, thyroglobulin Ab, thyroid Uptake, total T3, total T4, TPOAb, EPO, ferritin and Dil ferritin, folate/RBC folate, vitamin B12, intrinsic factor AB, estradiol, hFSH, hLH, progesterone, DHEA-S, prolactin, testosterone, total β -hCG and Dil β -hCG, unconjugated estradiol, inhibin A, ultrasensitive insulin, ostase bone alkaline phosphatase, intact PTH (routine and intraoperative), ultrasensitive hGH, rubella IgG, toxo IgG, toxo IgM II, total IgE, cortisol plus >100 synchron chemistry tests, including critical care, general esoteric, urine and CSF chemistries, DAT, TDMs, proteins, serologies
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	— soluble transferrin receptor IL-6, rubella IgM	— soluble transferrin receptor HIV 1/2, HBsAg, HBsAg confirm., HBsAb, HCV Ab, HAV Ab, HAV IgM, HBcAb, rubella IgM, HBc IgM, IL-6
Research-use-only assays Tests in development	IL-6 PAPP-A, PIGF (preeclampsia), sVEGF RI (preeclampsia), SHBG, p2PSA, BPH-A, ANA screen, CMV IgG, CMV IgM	IL-6 CMV IgG & IgM, BPH-A, p2PSA, PAPP-A, SHBG, HBcAb, HBeAg, HIV combo, ANA, ds-DNA I _b , PIGF, sVEGF RI (preeclampsia) ecstasy, BARB, BENZ, TCA, amikacin, quinidine, amylase G7 intrinsic factor Ab, inhibin A
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— add Intrinsic factor Ab and inhibin A	—
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	chemiluminescence, enzyme immunoassay/magnetic particle 50 50 — 50/50 336 hours/56 days/yes (4°-10°C) yes yes yes/assay No., lot No., expiration date, unique reagent pack ID No. no/<10 ppm 240/—/— closed/liquid yes/1,800 no assay dependent, ~20 μ L 5 μ L/specimen container dependent yes (PC only)/optional no/— <60 decibels yes/80 μ L yes/12 x 75 to 16 x 85 mm/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no 18 seconds yes assay dependent no/28 days yes/yes 24 hours yes/yes no/no/remains in ready mode	chemiluminescence/magnetic particle 120 120 120 120/100 tests/kit (immunoassay); 300 tests per container (gen. chem.) 3168 hrs/28 days/yes (2°-10°C) yes yes yes/specific cartridge ID, No. of tests, avail. tests, expir. date, lot No., calibration expir. no/<10 ppm assay mix dependant/112/— yes/liquid no/— yes/2-year warranty, semi-permanent 23 μ L 3 μ L/20 μ L yes yes/up to 16 L per hour 64 dBA yes/20 μ L yes/—/yes yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes yes yes/yes — no assay dependant no/up to 90 days yes/yes 24 hrs yes/yes no/no/not required
Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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 9 seconds —/200 (9 seconds) yes/yes optional add-on onboard/yes (included or additional) 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 <10 min; daily: 10 min; weekly: —; monthly: none yes (includes audit trail)/yes	15 minutes 36 seconds 90/270/9 seconds (immuno), 8 seconds (chemistry) yes/yes onboard, optional add on/yes Cerner, Misis, Meditech, Citation, Medlab, CHC, Siemens, McKesson, Labquest, others yes yes customer request yes (broadcast download, host query) yes yes (If cleaved, the Dxl and DxC systems can interface w/Beckman Coulter Automation yes/yes/yes no metro: same day, rural: same or next day —/— yes daily: <10 min; weekly: <10 min; monthly: 18 min 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	\$199,500/200-400 beds/100-300 tests per day per negotiated contract —/yes	\$650,000/300+ beds or >400 tests per day — 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	powerful, flexible, and technologically advanced analyzer targeted to mid- and high-volume laboratories; chemiluminescent technology and the same reagents as Dxl 800 and Access 2; delivers consistent results across platforms; will be integrated with other UniCel systems in 2007	UCTA parallel processing of immunoassay and chemistry tests on single workstation; closed-tube aliquot and closed-tube sampling eliminate manual processes; high-throughput, consistent results; operators can load consumables on the fly

Automated immunoassay analyzers

Part 6 of 27	The Binding Site Inc. Gary Tremain gary.tremain@thebindingsite.com 5889 Oberlin Dr., Ste. 101, San Diego, CA 92121 800-633-4484 www.bindingsite.co.uk	The Binding Site Inc. Gary Tremain gary.tremain@thebindingsite.com 5889 Oberlin Dr., Ste. 101, San Diego, CA 92121 800-633-4484 www.bindingsite.co.uk
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 Automated System/2000/Guernsey, U.K. U.S./U.K. 175/>500 batch/benchtop/rack 32 x 42 x 36/7	DS2/2006/U.S. U.S./U.S., U.K. —/ batch, with continuous load/benchtop/rack 30 x 17 x 26/3.07
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 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 Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	none — open system—any ELISA	none — open system—ELISA
Research-use-only assays Tests in development	open system phosphatidylinositol IgG/IgM, phosphatidylethanolamine IgG/IgM/IgA, phosphatidylglycerol IgG/IgM, phosphatidylcholine IgG/IgM, phosphatidic acid IgG/IgM, prothrombin, C3d CIC, SMA, LKM, modified gliadin peptide	open system phosphatidylinositol IgG/IgM, phosphatidylethanolamine IgG/IgA, phosphatidylglycerol IgG/IgM, phosphatidylcholine, IgG/IgA, phosphatidic Acid, IgG/IgM, prothrombin, C3d, SMA, LKM, modified gliadin peptide
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	open system open system	open system open system
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes — min. strip: 1 x 8; max. full plate: 96 x 4 plates	yes — min. strip 1 x 8; max. full plate: 96 wells x 2 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 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	EIA/coated microwell 12 assays per plate unlimited unlimited 25/96 per 4 plates 24 hours—/no yes requires operator prehandling/preparation no/— yes/0 assay dependent/92/assay dependent yes/liquid no no 200 µL 5 µL/200 µL (50 µL with microtubes) yes/no no — yes/50 µL yes/various/no yes (2 of 5 interl., Codabar, codes 39 & 128)/— yes no no/yes yes yes/no no/no yes/no no/no — no assay specific yes/once per analyte per plate yes/yes per plate yes/no yes/—/1–2 minutes	enzyme immunoassay/coated microwell 12 assays per plate unlimited unlimited 8/96 24 hours—/no yes yes no/— —/0 with disposable tips assay dependent/98/assay dependent yes/liquid no/— 5 µL 5 µL/200 µL yes/— no — yes/50 µL yes/—/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes no no/yes yes yes/no no/no yes/no no/no — no varies yes/each assay yes/no each assay yes/no no/yes/1–2 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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 (additional) Cerner Classic & Millennium, Misys, SoftComp, Live Link, Triple G, FCC, ACA, LCW, LabLink	— — assay dependent —/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	yes no — yes (host query) yes (manual transmission available) no no/yes/yes no within 24 hours —/ <24 hours yes daily: 5 minutes; weekly: none; monthly: none no/no	yes no — yes (host query) yes no no/no/no no — —/ <24 hours yes daily: 5 minutes; weekly: —; monthly: — yes/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$55,000–\$70,000 (dependent on modules)/200+ beds \$12,950 8 days on site, 2 days at vendor offices/yes	\$50,000/100–200 beds \$7,000 8 days on site/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	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 7 of 27	<p>The Binding Site Inc. Gary Tremain gary.tremain@thebindingsite.com 5889 Oberlin Drive, Suite 101, San Diego, CA 92121 800-633-4484 www.bindingsite.co.uk</p>	<p>bioMérieux Inc. Reggie Carr, U.S. Marketing Manager reggie.carr@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-620-2656 www.biomerieux-usa.com</p>
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	<p>ESP600/2008/Switzerland, Italy Switzerland/UK 4/0 batch/benchtop/racks 36 × 47 × 32/10.5</p>	<p>VIDAS Immunoassay Analyzer/1989/U.S. Italy/France 2,200/25,000 batch, random access/benchtop/— Vidas 30 system: 16 × 32 × 2/4.5; mini Vidas system: 21 × 21 × 17/4</p>
Tests available on instrument in U.S.	open system, Binding Site autoimmune and infectious disease menu, diaDexus PLAC test	TSH, FT4, T4, T3, total PSA, HCG, LH, FSH, estradiol 2, prolactin, progesterone, testosterone, ferritin, D-dimer, procalcitonin, troponin I, NT pro BNP, CKMB, C. difficile toxin A&B, measles IgG, mumps IgG, rubella IgG, varicella zoster virus IgG, LYME IgG & IgM, chlamydia & chlamydia blocking, helicobacter pylori, TOXO competition, TOXO IgG, TOXO IgM, rotavirus, CMVM, CMVG, digoxin, lyme IgG & IgM, total IgE
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for clearance	—	tumor markers: CEA, AFP, CA- 125, 15-3, 19-9 & free PSA
Tests not available in U.S. but available in other countries	—	HBs Ag, anti HBs-total, anti-HBc total, anti-HBc IgM, anti HBe, HAV IgG, anti HAV total, HPV, HIV 1/2, HIV duo, myoglobin, B-12 microglobulin, toxo IgG avidity
Research-use-only assays	antiphosphatidylethanolamine, antiphosphatidylcholine, antiphosphatidylinositol, antiphosphatidylglycerol, antiphosphatidic acid	none
Tests in development	deamidated gliadin peptide	vitamin D, EBV
User-defined methods implemented for what analytes	—	none
Tests not available on other manufacturers' analyzers	—	all assays for use on Vidas instruments only
Fully automated microplate system	yes	no
No. of each analyte performed in separate disposable unit	1	1 test per strip
No. of wells in microplate	96	—
Methods supported/Separation methods	fluorescence, enzyme immunoassay/coated microwell	fluorescence, enzyme immunoassay/EIA coated, solid phase receptacle pipetting device
No. of different measured assays onboard simultaneously	9	mini Vidas: 30; Vidas: 12
No. of different assays programmed, calibrated at once	—	total menu
No. of user-definable (open) channels	open system	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	9/88	unit dose format 30 or 60/—
Shortest/Median onboard reagent stability/Refrigerated onboard	1,688 hrs/7/no	—/—/no
Multiple reagent configurations supported	yes	no
Reagent container placed directly on system for use	requires operator prehandling/preparation	placed directly on system
Reagents bar coded/Information in bar code	—/—	yes/assay name, lot No., calibration, expiration
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	—/ <10	no/zero carryover
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/up to 240/9 quantitative, 21 qualitative	assay dependent/12–30/12–30
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	no/dry
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum specimen vol. required	200 µL	100–200 ng/mL dependent on assay
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/200 µL	100 ng/mL dependent on assay/—
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	no/—/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, code 39, code 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/no
Bar-code placement per NCCLS standard Auto2A	—	no
Onboard test auto inventory (determines vol. in container)	no	no
Measures No. of tests remaining/Short sample detection	no/yes	no/no
Auto detection of adequate reagent or specimen	no	no
Clot detection/Reflex testing capability	yes/no	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	—/—	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	no/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	yes
No. of calibrators required for each analyte	assay dependent	—
Calibrants can be stored onboard/Avg. calibration frequency	yes/per run	no/14 or 28 days assay dependent
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	no/yes
How often QC required	per run	shortest interval: 8 hours, longest: 24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/2 min	no/no/always remains ready
Stat time to completion of β-hCG test	—	30 minutes
Time delay from ordering stat test to aspir. of sample	—	no delay
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	—/—	—/Vidas: 20, MiniVidas: 8, Vidas: 60, MiniVidas: 24
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/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	—	Misys, Medttech, McKesson, Advanced Lab systems, Citation, Cemer, Dawning, Genesysis, Compulab, others
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)
Results transmitted to LIS as soon as test time complete	no	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/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	24 hrs	within 24 hrs
Mean time between failures/To repair failures	8-9 months/less than 2 hours	Vidas: 350 days/MiniVidas: 1,000 days
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	weekly: 10–15 min
Onboard maintenance records/Maintenance training demo module	no/—	yes (includes audit trail)/—
List price/Targeted bed size or daily volume	\$95,000/500 tests/day	Vidas 30: \$51,800; Mini Vidas: \$28,100/>400 bed hospitals
Annual service contract cost (24 hours/7 days)	\$14,250	\$2,340–\$4,680
Training provided w/purchase/Advanced operator training	yes (8 days on site)/yes	yes (2–3 days on site/vendor offices)/yes
Distinguishing features (supplied by vendor)	fast processing time; low operating costs due to elimination of disposable tips; completely open high-throughput batch analyzer	routine batch testing as well as emergency stat testing; gold-standard ELISA methodology; dual-function combination solid phase & pipetting device results in no fluid contact with instrument or sample carryover; single-dose assay format readily adaptable to batch or single test runs; broad assay menu (antigen detection, serology, fertility, thyroid, endocrine, coagulation); D-dimer test FDA-cleared for exclusion of PE and DVT (with pre-test assessment); short time-to-results, color-coded test components; very long MTBF intervals; GUI-driven VIDAS PC software can support up to two VIDAS instruments simultaneously

Automated immunoassay analyzers

Part 8 of 27	Bio-Rad Laboratories Clinical Diagnostics Group Craig Cartwright craig_cartwright@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-724-7000 www.bio-rad.com	Bio-Rad Laboratories Clinical Diagnostics Group Greg Stewart greg_stewart@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-724-7000 www.bio-rad.com
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	BioPlex 2200/2006/Australia Australia/U.S. 75/10 continuous random access/floor standing/rack 58 × 72 × 34/12	PR 3100TSC Photometer/2006/Austria Austria/U.S. 15/— batch/benchttop/rack 7 × 13 × 13/2
Tests available on instrument in U.S.	ANA Screen, anti-dsDNA (quant.), anti-SS-A, anti-SS-B, anti-SmRNP, anti-Sm, anti-RNP, anti-Scl-70, anti-Jo-1, anti-centromere B, anti-chromatin, anti-ribosomal P, EBV-nuclear antigen IgG, EBV-viral capsid antigen IgG, EBV-early antigen diffuse IgG, EBV-viral capsid antigen IgM, heterophile antibodies, anti-GBM IgG, anti-MPO IgG, anti-PR3 IgG, syphilis IgG	contact Bio-Rad representative
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	none none none	none none 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, anti-phospholipid 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 Tests in development	none gastrointestinal disease, phospholipid, rheumatoid arthritis, cardiac damage and risk, toxoplasma, rubella, CMV, measles, mumps, VZV, lyme, HSV, HIV and hepatitis	not in U.S. blood virus panel
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none heterophile antibodies	none none
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no — —/—	no — min. strip: 1; max. full plate: 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 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	bead flow cytometric (multiplex)/magnetic particle 440 440 none 440/100 720 hours/30 days/yes (2°–8°C) no yes yes/kit type, lot No., kit serial No. no/2 ppm 480 minutes/280/17,600 closed/liiquid yes/800 no 5µL 5 µL/70 µL yes/no no/0.5 L per hour <67 decibels no yes/10–16mm diameter and 41–100mm height/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/no —/— — yes analyte dependent no/14 days yes/no 24 hours/24 hours no/yes no/no/10 min	enzyme immunoassay/coated microwell 1 1 none 0/— —/—/no no no no/— no/— 1/up to 96/1 no/liiquid no/— no/— — —/— no/no no/— — no/— no/—/no no/no no no/no no/no no/no no/no no/no no/no no/— — no assay dependent no/weekly no/no shortest interval: weekly; longest interval: monthly —/no no/no/5 min
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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	— — 100/300/36 seconds —/yes onboard/no —	— — —/— no/no no/no —
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/yes/yes no — —/— yes daily: 5 minutes; weekly: 30–40 minutes; monthly: none —/—/—	no no — no no no no/yes/yes no units returned for service —/— no daily: 0; weekly: 5 minutes; monthly: 5 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	\$350,000/≥200 tests per day inquire 7 days on site, 7 days at vendor offices/yes	\$9,500/5–500 tests per day inquire 1 day on site
Distinguishing features (supplied by vendor)	fully automated/random access; innovative multiplex chemistry; eFlex software with bi-directional interface	compact, stand-alone microplate photometer; onboard computer allowing user control of instrument and data reduction; colored touchscreen with wizard interface provides streamlined operation of all assays

Automated immunoassay analyzers

Part 9 of 27	Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Drive, Hercules, CA 94547 510-724-7000 www.bio-rad.com	Bio-Rad Laboratories Clinical Diagnostics Group Greg Stewart greg.stewart@bio-rad.com 4000 Alfred Nobel Dr., Hercules, CA 94547 510-724-7000 www.bio-rad.com
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	PhD System/2000/Belgium France/U.S. 200/300 batch/benchtop/rack 35 x 66 x 35/16	Evolis/2001/Germany Germany/U.S. 200/800 batch/benchtop/rack 37 x 44 x 30/10
Tests available on instrument in U.S.	ANA (EIA), anti-centromere (EIA), anti-dsDNA (EIA), anti-ENA (EIA), anti-Jo-1 (EIA), anti-SS-A (qEIA), anti-SS-B (EIA), anti-Scl-70 (EIA), anti-Sm (EIA), anti-SmRNP (EIA), anti-ssDNA (EIA), aCL IgM, aCL IgG, aCL IgA, anti-β2GPI IgG, anti-β2GPI IgM, anti-β2GPI IgA, aPS IgG, aPS IgM, aPS IgA, anti-gliadin IgA/IgG, anti-tTg IgA/IgG, ASCA IgA/IgG, IFA-, HEp-2, crithidia, mouse stomach/kidney, ANCA (formalin & ethanol)	contact Bio-Rad representative
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
Research-use-only assays	—	not in U.S.
Tests in development	—	infectious disease & autoimmune panels
User-defined methods implemented for what analytes	—	none
Tests not available on other manufacturers' analyzers	—	none
Fully automated microplate system	no	yes
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 & IFA/coated microwell or slide	EIA/coated microwell
No. of different measured assays onboard simultaneously	8 EIA or 4 IFA	4-8
No. of different assays programmed, calibrated at once	8 EIA or 4 IFA	4-8
No. of user-definable (open) channels	no limit	closed in U.S. market
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	8/192	4/96
Shortest/Median onboard reagent stability/Refrigerated onboard	4 hours/—/no	30 minutes/assay dependent/—
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	requires operator prehandling/preparation	yes
Reagents bar coded/Information in bar code	no/—	yes
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/—	no/no (disposable tips)
Walkaway capacity in minutes/Specimens/Tests-assays	—/192/—	varies by assay/180/4
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	no/—	microplates
Uses washable cuvettes/Replacement frequency	no/—	microplates
Minimum specimen vol. required	1 µL specimen	0.2 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	1 µL/200 µL	10 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no	no
Noise generated	—	60 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/micro-100 mm height/no	yes/5, 7, 10 mL/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., Codabar, codes 39 & 128)/no	yes (2 of 5 interl., Codabar, codes 39 & 128)/no
Bar-code placement per NCCLS standard Auto2A	yes	no
Onboard test auto inventory (determines vol. in container)	no	yes
Measures No. of tests remaining/Short sample detection	no/yes	no/no
Auto detection of adequate reagent or specimen	yes	no
Clot detection/Reflex testing capability	no/no	yes/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	no	no
No. of calibrators required for each analyte	1-5	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/each run	no/with each run
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/no
How often QC required	each run	user determined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/no	yes/yes (through Unity QC program)
Automatic shutdown/Startup is programmable/Startup time	no/no/5 minutes	no/no/5 min
Stat time to completion of β-hCG test	—	—
Time delay from ordering stat test to aspir. of sample	—	—
Throughput per hours 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	no/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/no	onboard/yes
Interfaces up and running in active user sites with	—	in development
LIS interface operates simultaneously w/running assays	yes	yes
Uses LOINC to transmit orders and results	can be customized	no
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	yes	yes (broadcast download)
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	yes/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	<24 hours	24 hours
Mean time between failures/To repair failures	6 months/4 hours	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 min; weekly: 15 min; monthly: 30 min	daily: 5 min; monthly: 60 min
Onboard maintenance records/Maintenance training demo module	no/no	yes/no
List price/Targeted bed size or daily volume	\$40,000/>50 tests per day	\$65,000/30-500 tests per day
Annual service contract cost (24 hours/7 days)	inquire	inquire
Training provided w/purchase/Advanced operator training	2 days on site/no	4 days in Redmond, Wash./no
Distinguishing features (supplied by vendor)	accurate pipetting at 1 µL; connection of 1-10 pipetting stations together through an ethernet hub, graphical user interface; added module for IFA slide processing	fully automated microplate system that meets the highest 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)

Automated immunoassay analyzers

Part 10 of 27	Diamedix Corp. Pat Ahmad pat_ahmad@ivaxdiagnostics.com 2140 N. Miami Ave., Miami FL 33127 305-324-2300 www.diamedix.com	DiaSorin Inc. Dawn Franzmeier dawn.franzmeier@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	Mago Plus Automated EIA Processor/1997/Italy (MAGO 4 to be added)	ETI-MAX 3000/2002/Germany
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	Italy/U.S. 250/— batch, random access/benchtop/rack 28 x 48 x 26/8.7	Germany/U.S., Italy 165/750 batch, random access/benchtop/rack 40 x 45 x 30/10
Tests available on instrument in U.S.	autoimmune: ANA screen, ENA screen, SSA, SSB, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, β 2 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	HBsAg, HBsAg confirm, anti-HBs, anti-HBc IgM, anti-HBc, HBeAg, anti-HBe, HCV, anti-HAV IgM, anti-HAV, HIV, EA(D) IgG, EBNA-IgG, VCA-IgG, VCA-IgM reverse capture, measles IgG, varicella zoster IgG, mumps IgG, <i>H. pylori</i> IgG, HSV I/II IgG, Trep-Sure syphilis, CMV IgG & IgM capture, rubella IgG, toxoplasma IgG & IgM capture, ANA screen, ENA 6 screen, anti-dsDNA, anti-Sm, anti-Sm/RNP, anti-SS-A, anti-SS-B, anti-Jo-1, anti-Scl-70, anti-histone, anti-MPO, anti PR3 (cANCA), anti-TPO, anti-cardiolipin IgA, IgG, IgM, anti-CCP
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	none none contact company	none none none
Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none none user defined none	none none — HBeAg, anti-HBe
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes 1 analyte per well min. 1 x 8 wells; max. 96 wells	yes — min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate up to 7 plates at a time
Methods supported/Separation methods	EIA/coated microwell (MAGO 4, EIA & IFA in parallel)	EIA/coated microplate
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	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 μ L (pediatric) 4 μ L/25 μ L (pediatric) yes/no no/— — yes/— yes/11–15 mm x 75–100 mm/no yes (2 of 5 interl., 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	open open unlimited volume dependent no/no/no yes yes yes/— yes/no assay dependent/180/variable yes/liquid no no 10 μ L 10 μ L/200 μ L 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
Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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	— — 120/360 (2.5 hours—assay dependent) yes/yes onboard/yes (included in price) Cerner, Misys, others 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	— — 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
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$62,000/all bed sizes, all test volumes service during normal business hours included in reagent rental agreement 1–2 days on site/yes	\$75,000/all bed sizes, all test volumes \$8,500 (additional \$4,500 for 24/7) 3 days/yes
Distinguishing features (supplied by vendor)	FDA-cleared system (instruments and reagents); moderate complexity; strip by strip timing, accommodates primary reagent packaging	selectively open system; multiple assays on a plate; Windows 2000 software; continuous loading of samples, reagents, and microplates; primary tube sampling; bidirectional interface

Automated immunoassay analyzers

Part 11 of 27	DiaSorin Inc. Dawn Franzmeier dawn.franzmeier@diasorin.com 1951 Northwestern Ave., Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com	Grifols USA Inc. Stephanie Sorensen stephanie.sorensen@grifols.com 8784 NW 18th Terrace, Miami, FL 33172 800-379-0957 www.grifols.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	LIAISON/1997/Germany Germany/U.S., Italy >150/>2,200 batch, continuous random access/benchtop/rack 63 x 136 x 66 cm/9.9	Triturus/1999/Spain Spain/U.S., Italy >200/>1,700 batch, random access & cont. random access/benchtop/universal carousel 28.3 x 41.3 x 34.3/10
Tests available on instrument in U.S.	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	system is completely open; any U.S. clinically cleared and research-use-only EIA procedure can be programmed; infectious diseases, autoimmune diseases, bone markers, endocrinology, hemostasis, oncology markers, hepatitis, and HIV profiles
Tests 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	— cortisol, ACTH, dsDNA, CEA, PSA, fPSA, CA 15-3, CA-125, CA 19-9, TPA-M, toxo IgG avidity, HSV 2 IgG, HSV I/II IgM, HSV I/II IgG, HCG, β -2-microglobulin, prolactin, LH, FSH, S-100, AFP, HCG, ferritin, TSH, FT ₃ , FT ₄ , T ₃ , T ₄ , anti-TG, TG, anti-TPO, rubella IgG, rubella IgM, HBsAg, HBsAg confirmatory, anti-HBs, anti-HBc, HBc IgM, HBeAg, anti-HBe, anti-HAV total, anti-HAV IgM, troponin I, CK-MB, myoglobin, C-peptide, Brahms procalcitonin, borrelia IgG & IgM, iTG IgA, testosterone, NSE, progesterone, estradiol, VZV IgM, calcitonin, ANA screen, ENA screen, direct renin, BAP OSTAS E	— — —
Research-use-only assays	—	—
Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	cardiolipin, HSV-1 IgG — 25 hydroxy vitamin D, total, treponema IgG/IgM, Borrelia burgdorferi, VZV IgG, CMV IgM	— — —
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no — —/—	yes 8 min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate 4 plates at a time
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	chemiluminescence/magnetic particle 15 15 0 15/100 7/28 days/yes (12°C) no yes yes/all lot information no/no 75/144/1,500 no/liquid yes/720 no assay dependent 5 μ L/200 μ L yes/no no/— — yes/75 μ L yes/—/no yes (2 of 5 interl., Codabar, codes 39 & 128)/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	EIA/coated microwell, onboard shaker, 4 individually temperature-controlled incubators 1-8 tests on 1-4 plates 8 assays unlimited 8/96 —/—/no yes minimal operator preparation, handling no yes/no 180/92/8 yes/liquid no no 200 μ L 2 μ L/300 μ L yes/no but has external waste port to drain into sink or floor drain no/— — yes/50 μ L yes/12, 13, 14, 16 mm/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes yes/yes — yes 1-14 no/check every month yes/yes each run no/no yes/yes/1-2 minutes
Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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	— 2 minutes — yes/yes no/yes (additional) — yes — — yes (host query) yes no no/no/no no 24 hours —/— yes daily: 10 minutes; weekly: 20 minutes; monthly: 30 minutes no/no	system is open, depends on reagent methodology — depends on reagent methodology yes/yes yes/yes (additional) all major LIS systems yes yes LIS—unidirectional or bidirectional yes (host query & broadcast download) yes no yes/yes/yes no within 24 hours —/— yes daily: 5-20 minutes; weekly: —; monthly: — yes (includes audit trail of who replaced parts)/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$145,000/all bed sizes, all volumes inquire 3 days on site/yes	\$79,000/300+ or higher varies, multiple types available yes/yes
Distinguishing features (supplied by vendor)	benchtop analyzer with high throughput; unique menu offering; up to 15 assays onboard, reagent integral, batch & stat	multibatch or continuous throughput EIA analyzer; user-defined menu, completely open system; easy color-coded worksheet and set up for operator; 2 probes for high-speed processing; unique cross-well washing; able to use fixed probes or disposable tips

Automated immunoassay analyzers

Part 12 of 27	Hycor, An Agilent Technologies Company cs@hycorbiomedical.com 7272 Chapman Ave., Garden Grove, CA 92841 714-933-30000 www.hycorbiomedical.com	Inverness Medical Professional Diagnostics Michelle Fradette michelle.fradette@invmcd.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 × W × D)/Instrument footprint in sq. feet	HY•TEC 288 PLUS/outside U.S. 1998, U.S. 1999/Netherlands Netherlands/U.S., Scotland 55/158 random batches/benchtop/rack-robotics 29.5 × 42.5 × 27.5/8	AIMS/2007/Switzerland Switzerland/U.S. —/— batch/benchtop/rack 35 × 67 × 40/—
Tests available on instrument in U.S.	specific IgE, total IgE, >600 allergens and mixes; ANA scr., TG, TPO, dsDNA, RF IgG, RF IgM, PR-3 c-ANCA, MPO p-ANCA & anti-mitochondrial, ENA-6 scr., SS-A, SS-B, gliadin IgG & IgA, Sm, Sm/RNP, Scl-70, Jo-1, GPC, GBM, cardiolipin IgG & IgM, anti-β-2 GPI; user-definable software	Wampole ELISA II assays, AtheNA multiplexing assays including: ANA test system (ANA screen, dsDNA, Sm, RNP, SSA, SSB, Jo-1, Scl-70, centromere, histone), EBV-G test system (VCA, EBNA, EA), EBV-M test system (VCA), ANCA screen (MPO, PR-3), TPO/Tg, RF, MMV IgG test system (measles, mumps, varicella), MMRV IgG test system (measles, mumps, rubella, varicella), open system for multiplexing & ELISA, HSV (type specific HSV-1, HSV-2), vasculitis IgG test system (MPO, PR3, GBM)
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	anti-tissue transglutaminase IgA and IgG none specific IgG, ssDNA, total rheumatoid factor, anti-tissue transglutaminase IgA and IgG	— celiac IgG (TTG, gliadin), celiac IgA (TTG, gliadin) —
Research-use-only assays Tests in development	none ANCA profile, centromere, CCP	HIV blot syphilis, EBV combo (IgG & IgM in one well), celiac combo (IgG & IgA in one well), Lyme, cardiolipin (IgG, IgA, IgM), ToRCH-G (toxoplasma, rubella, CMV, type specific HSV), ToRCH-M (toxoplasma, rubella, CMV, HSV 1/2)
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— allergy & autoimmune testing on fully automated system	— —
Fully automated microplate system No. of each analyte performed in separate disposable unit	yes 8 (1 analyte per well; multiple analytes per well/screens; up to 8 analytes per run)	yes assay dependent
No. of wells in microplate	96—min. strip: 1 strip/8 wells; max. full plate: 12 strips/96 wells	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 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	EIA, tube-based & microplate-based assays/activated cellulose & coated well varies by assay, up to 288 allergens or 8 autoimmune multiple unlimited varies by assay, up to 288 allergens or 8 autoimmune 8 hours/12 hours/no yes yes no yes/<1 part in 10,000 assay dependent/100/288 yes/liquid no no 10 µL, 110 µL w/ dead vol. 10 µL–50 µL, assay dependent//100 µL yes/no no/— — no yes/—/no yes (2 of 5 interl., codabar, codes 39 & 128)/— no yes yes/yes yes no/no no/no yes/no no/no — yes 1–5 no/monthly yes/yes every assay yes/yes yes/no/2–3 minutes	enzyme immunoassay, multiflexing/bead, coated microwell 4 multiple unlimited 4/96 —/—/no yes yes no/— yes/— 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 × 16 mm outer dimensions/no yes (2 of 5 interl., codabar, codes 39 & 128)/— — yes no/yes yes yes/no no/no yes/no —/— — — assay dependent — — 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 hours 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/optional 25 no no — yes optional no yes/yes/no no 48 hours 7 months/4 hours yes daily: 10–15 minutes; weekly: 20–25 minutes; monthly: 20–25 minutes yes (includes audit trail of who replaced parts)/yes	— — assay dependent/—/— —/yes —/yes — no — — yes (broadcast download) — — 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	\$55,000/all sites, variable test vols. \$5,500 3 days on site/yes	\$149,900/>150 beds \$18,500 5 days on site
Distinguishing features (supplied by vendor)	fully automated allergy and autoimmune testing; >600 allergens and mixes; user-definable software	fully automated integrated open system that allows processing of Athena MultiLyte multiplexing assays and ELISA on one platform

Automated immunoassay analyzers

Part 13 of 27	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	DSX/2004/U.S. U.S./U.S. approx. 500/— batch/benchtop/rack 32 x 42 x 36/7	DS2/2007/U.S. U.S./U.S. recently launched batch/benchtop/rack 27 x 21 x 26/4
Tests available on instrument in U.S.	ID: chlamydia, CMV, EBV-EA, EBNA, EBV-VCA, <i>H. Pylori</i> , HSV, legionella, Lyme, measles, mumps, myco, rubella, syphilis, toxo, VZV; AI: ANCA, ANA, CCP, ASCA, beta 2, cardios, dsDNA, ENA, gliadin, histone, Jo-1, mitochondria, MPO, PR-3, RF, ribosomal P, Scl-70, SM, SM/RNP, SS-A, SS-B, TPO, TG, TTG; osteo: NTx. bladder cancer-NMP22; enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. 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
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 enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko	AtheNA Multi-Lyte enterics: tox AB, GDH, crypto, giardia, E histo, ASCA, IBD. leuko
Fully automated microplate system No. of each analyte performed in separate disposable unit	yes 1 analyte per well, multiple analytes per well	yes 1 analyte per well, multiple analytes per well
No. of wells in microplate	96 (min: 1; max: 96)	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 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	enzyme immunoassay/coated microwell 48 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, pour-off/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	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, pour-off/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 hours 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	— — —/— yes/yes onboard/yes (additional cost) Cerner, Millenium, SunQuest, Soft, Mysis, etc.	— — —/— yes/yes onboard/yes (additional cost) Cerner, Millenium, SunQuest, Soft, Mysis, etc.
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 (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	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
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$62,900/350+ beds \$7,500 3 days on site/no	\$45,000/<350 beds \$7,500 3 days on site/yes
Distinguishing features (supplied by vendor)	open DSX platform enables customers to run virtually any ELISA-based assay; modular design allows user 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	open DS2 platform enables customers to run virtually any ELISA-based assay. DS2 is new to the marketplace and offers a small automated option for manual customers looking to automate

Automated immunoassay analyzers

Part 14 of 27	Olympus America Inc. Lorraine Damico lorraine.damico@olympus.com 3500 Corporate Pkwy., Center Valley, PA 18034 800-223-0125 www.olympusamerica.com/AU3000i	Ortho Clinical Diagnostics, a Johnson & Johnson Company Matthew Stephenson mstephe10@ocdus.jnj.com 1001 U.S. Highway 202, Raritan, NJ 08869 800-828-6316 or 908-218-1300 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	AU3000i Immunoassay System/2007/Japan Japan/Ireland 2/30 continuous random access/floor standing/racks	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 & secondary containers without need for adapters 51 × 44 × 29/8.9
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	57 × 67 × 47/22 plus computer	
Tests available on instrument in U.S.	TSH, T3, T4, FT4, FT3, t-uptake, LH, FSH, PROL, PROG, TSH, T3, T4, FT4, FT3, T-uptake, LH, FSH, PROL and PROG	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
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	— β-hCG AFP, CEA, PSA, fPSA, GI-TC (CA19-9), BR-TC (CA15-3), CKMB, CKMB-short — β-hCG-short, E2, testosterone, troponin I, Tni-stat, BNP, ferritin, folate, B12, vitamin D, PTH, IgE, OV-TC (CA125), anti-TG and anti-TPO	— — fβ-hCG, a-HBe, HBeAg, toxo IgG, rubella IgM, toxo IgM, CMV IgG, CMV IgM — iPTH, HIV Ab/Ag, preeclampsia, pre-diabetes diagnostics
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— TSH, 4th generation	— 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	chemiluminescence/magnetic particle 24 180 0 24/assay dependent (200 or 100) 14 days/yes (4°–12° C) yes yes yes/lot specific master calibration information; calibrator set points; internal QC targets; product name, lot information, expiration date	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
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	no/no, disposable tips used to prevent carryover up to 240/300/1,000 no/liquid yes/1,000 with on-the-fly bulk refill no 10–100 μL (test dependent) 10 μL/100 μL yes/no yes/8 L per hour at max. throughput <60.7 decibels no/— yes/11.5–16 mm (width) and 55–102 mm (height); microcups/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes yes/no 1–2 minutes yes 1 or 2 point master curves (test dependent) yes/28 days yes/yes user-defined yes/yes yes/yes/~5 minutes	—/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 yes (2 of 5 interl., Codabar, codes 39 & 128, & ISBT 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no assay dependent yes 1–3 no/28 days yes/yes once per 24 hours yes/yes yes/yes/immediate upon completion of last sample metering
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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	18 minutes 2 minutes 80/240 (15 seconds after 1st result with 300 sample tube continuous loading) yes/yes onboard/yes (additional cost) —	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
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 yes/yes/yes no — TBD/TBD yes daily: <5 minutes; weekly: <30 minutes; monthly: 10 minutes yes/yes	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
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$274,558 including ancillaries/>200—volume varies (contact Olympus rep) \$18,850 4.5 days on site, 4.5 days at vendor offices/yes	\$140,000/flexible for majority of customer demand varies w/ service level choices 3.5 days at vendor offices/yes, as needed on site
Distinguishing features (supplied by vendor)	10-position racks simplify testing of assays; standardized graphical user interface simplifies training and ease of use; Supportvision for secure Web tracking and proactive service monitoring; crash prevention and liquid-sensing probes; on-the-fly bulk loading of pipette tips and cuvettes with 1,000-tip and 1,000-cuvette capacity	uses proprietary Intellicheck Technology to perform, monitor, document, and verify diagnostic checks throughout sample and assay processing to reduce the potential of misreported results; IntelliReport providing 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

Automated immunoassay analyzers

Part 15 of 27	Ortho Clinical Diagnostics, a Johnson & Johnson Company Matthew Stephenson mstephe10@ocdus.jnj.com 1001 U.S. Highway 202, Raritan, NJ 08869 800-828-6316 or 908-218-1300 www.orthoclinical.com	Phadia Nicole Lampas nicole.lampas@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	VITROS EciQ Immunodiagnostic System/2004/U.S. U.S./U.K. >3,000 worldwide cont. random access/floor standing/circular universal sample trays accommodate primary & second/secondary containers without need for adapters 51 × 44 × 29/8.9	ImmunoCAP 250 system/2004/Japan, Sweden Japan, Sweden/Sweden 150/600 continuous random access/floor standing/racks 73 × 50 × 30 + 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	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, equimolar PSA, ferritin, B12, folate, RBC folate, cortisol (serum and urine), CK-MB, troponin I, myoglobin, HBsAg, aHBs, aHCV, HBsAg (conf.), aHbC, aHbC IgM, testosterone, NT-proBNP, CA 19-9, aHAV total, aHAV IgM, rubella IgG, aHIV 1+2 — — a-HBe, HBeAg, free β-hCG, toxo IgG, rubella IgM, toxo IgM, CMV IgG, CMV IgM none iPTH, HIV Ab/Ag, preeclampsia, pre-diabetes diagnostics none N-telopeptide	more than 550 ImmunoCAP specific IgE tests, ImmunoCAP total IgE, and ImmunoCAP specific IgG**, specific IgG4**, ECP**, tryptase**, and TG and TOP tests, ELiATM auto-immune products, tTg (tissue transglutaminase), IgA, IgG, gliadin IgA, IgG, CCP (cyclic citrullinated peptide), dsDNA, Symphony ANA — — — — **specific IgG, specific IgG4, ECP, and tryptase are investigational use only — — Phadia US Inc. ImmunoCAP specific IgE blood tests and ELiATM autoimmune 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.	chemiluminescence (enhanced)/individual coated microwell 20 20; up to 25 lots calibrated per assay 0 20/100 56 days/56 days/yes (2°–8°C) yes yes yes/test ID, expir., lot No., pack ID yes/zero carryover 720/60/800 (with EPM—enhanced productivity module) no/liquid no no 10 μL 10 μL/80 μL	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 μL for ImmunoCAP tests and 50 μL for ELiA tests 40 μL/40–200 μL for ImmunoCAP tests and 50 μL/50–200 μL for ELiA tests (varies with tube type) yes/no no/10 L 65 decibels no yes/10–17 mm × 50–105 mm/no yes (2 of 5 interl., 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
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	no, but it is available/no no/— 60 decibels no yes/mult. ped., microtainers & cups, 5mL, 7mL, 10mL on same univ. sample tray/no yes (2 of 5 interl., Codabar, codes 39 & 128, & ISBT 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no assay dependent yes 1–3 no/28 days yes/yes once per 24 hours yes/yes yes/yes/immediate upon completion of last sample metering	yes/no no/10 L 65 decibels no yes/10–17 mm × 50–105 mm/no yes (2 of 5 interl., 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
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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, others yes yes — yes (broadcast download) yes yes (all systems) yes/yes/yes no <4 hours (contract dependent) dependent on corrective action/dependent on corrective action yes daily: <5 minutes; weekly: <30 minutes; monthly: <10 minutes no/yes	— 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/—
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$150,000/flexible for majority of customer demand varies w/ service level choices as needed on site, 3.5 days at vendor offices/—	\$75,000/>20,000–95,000 tests per year — 3.5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	uses Intellicheck Technology to perform, monitor, document, and verify diagnostic checks throughout sample and assay processing to reduce the potential of misreported results; IntelliReport providing 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; features enhanced ergonomics	provides widely 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 the specialist's 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

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Part 16 of 27	Phadia Nicole Lampas nicole.lampas@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us	Phadia Nicole Lampas nicole.lampas@phadia.com 4169 Commercial Ave., Portage, MI 49002 800-346-4364 www.phadia.us
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	ImmunoCAP 1000 system/2003/Japan, Sweden Japan, Sweden/Sweden 150/600 continuous random access/floor standing/racks 83 × 71 × 40 + 26-in. wide computer stand/—	ImmunoCAP 100 ^E system/1995/Sweden Sweden/Sweden 600/12,000 batch/benchttop/carousel 18 × 28 × 24 + computer/—
Tests available on instrument in U.S.	more than 550 ImmunoCAP specific IgE tests, ImmunoCAP total IgE, and ImmunoCAP specific IgG**, specific IgG4**, and ECP** tests	more than 550 ImmunoCAP specific IgE tests, ImmunoCAP total IgE, gliadin, ImmunoCAP specific IgG tests**, ECP**, tryptase**, ELiATM autoimmune products, tTg (tissue transglutaminase) IgA, IgG, specific IgG4**, specific IgA**, TG and TPO, gliadin IgA, IgG, CCP (cyclic citrullinated peptide), dsDNA, Symphony ANA
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	**specific IgG, specific IgG4, and ECP are investigational use only	**ImmunoCAP specific IgG, specific IgG4, specific IgA tests, ECP, tryptase are investigational use only
Tests in development	—	—
User-defined methods implemented for what analytes	—	—
Tests not available on other manufacturers' analyzers	Phadia US Inc. ImmunoCAP specific IgE blood tests	Phadia US Inc. ImmunoCAP specific IgE blood tests and ELiATM autoimmune 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 No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	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	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells 4 7
No. of user-definable (open) channels	0, closed system	0, closed system
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	3/400 or 100 depending on the conjugate type	48–96 depending on the conjugate type
Shortest/Median onboard reagent stability/Refrigerated onboard	5 days/1 year/yes (2°–8°C)	—
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes (wash solution requires preparation)	yes (wash solution requires preparation)
Reagents bar coded/Information in bar code	yes/product name, lot No., expiration date	yes/product name, lot No., expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover (disposable sample tips)	no/—
Walkaway capacity in minutes/Specimens/Tests-assays	460/200 simultaneously/2,400 tests	180 minutes/varies with analyte/48
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	no	no/—
Uses washable cuvettes/Replacement frequency	—	—/—
Minimum specimen vol. required	40 µL per test	40 µL for ImmunoCAP tests and 50 µL for EiiA tests
Minimum sample vol. aspirated precisely at once/Min. dead vol.	40 µL/40–200 µL (varies with tube type)	40 µL/40–200 µL for ImmunoCAP tests and 50 µL/50–200 µL for EiiA tests (varies with tube type)
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/10 L	no/1 L per run
Noise generated	68 decibels	—
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10–17 mm × 50–105 mm/no	yes/10–16 mm × 50–105 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes (2 of 5 interl., Codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	no	no
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/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	no/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	no/no	no/no
Time between initial result & reaspiration of sample for rerun	100 minutes	2.5 hours–batch run
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	6 per analyte for calibration run, and 2 per analyte when using stored curve	6 per analyte for calibration run, and 2 per analyte when using stored curve
Calibrants can be stored onboard/Avg. calibration frequency	yes/28 days or sooner if conjugate lots change	yes/28 days or sooner if conjugate lots change
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	once per work shift (user defined)	once per work shift (user defined)
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/30 minutes unattended	yes/yes/20 minutes including request entry or downloading
Stat time to completion of β-hCG test	—	—
Time delay from ordering stat test to aspir. of sample	6 minutes	—
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	80 specimens/240 (100 minutes to first result, then 1 result per 15 seconds)	batch analyzer/48/180 minutes processing time for batch to finish
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (instrument side only)	onboard/yes, instrument side only (included)
Interfaces up and running in active user sites with	Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others	Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others
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	<24 hours	—, swap
Mean time between failures/To repair failures	—/—	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 1 minutes; weekly: 10 minutes; monthly: 15 minutes	daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes
Onboard maintenance records/Maintenance training demo module	yes/—	yes/no
List price/Targeted bed size or daily volume	\$235,000/>95,000 tests per year	\$22,000/>7,000–20,000 tests per year
Annual service contract cost (24 hours/7 days)	—	—
Training provided w/purchase/Advanced operator training	4.5 days at vendor offices/yes	3.5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	provides widely 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 the specialist's 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	provides widely 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 the specialist's 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

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Part 17 of 27	Randox Laboratories Ltd. David Ferguson evidence.support@randox.com Diamond Road, Crumlin, County Antrim, BT29 40Y +44 28 94 422413 www.randox.com	Roche Diagnostics Sheila Brewer sheila.brewer@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 x W x D)/Instrument footprint in sq. feet	Evidence System/2004/United Kingdom United Kingdom/United Kingdom —/— batch/floor standing/carousel 68 x 78 x 39/35.75	Elecsys 2010/1996/— Japan/Germany >800/>6,000 cont. random access/benchtot/rack or disk 22.1 x 47.2 x 28.7/9.4
Tests available on instrument in U.S.	cocaine, methamphetamine, amphetamine, methadone, PCP, opiates, cannabinoids, barbiturates, benzodiazepine, progesterone, prolactin, LH, FSH, estradiol	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 & β CG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, HBsAg, HBsAg confirmatory, anti-HBs, IgE, PTH, beta crosslaps, osteocalcin
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance	none MDMA, LSD, fentanyl, propoxyphene, methaqualone, oxycodone, oxymorphone, hydro-morphone, ketamine, buprenorphine	— toxog IgG/IgM, rubella IgG/IgM, anti-HBc IgM
Tests not available in U.S. but available in other countries	TT4, FT4, TT3, FT3, TSH, AFP, CEA, hCG, fPSA, tPSA, testosterone, CK-MB, cTNI, myoglobin	TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV, anti-HAV IgM, anti-HBc, anti-Hbe, HBeAg, HIV antigen, HIV antigen confirmatory, HIV combi, P1NP, 25-OH vitamin D3
Research-use-only assays	GPBB, FABP, 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-12p70, VEGF, TNF α , IFN γ , IL-1 α , IL-1 β , MCP-1, EGF, GFAP, S100B, hsCRP, BDNF, D-dimer, NSE, NGAL, vWF, thrombomodulin, sIL-2Ra, sIL-6r, sTNFR1, sTNFR2, MMP-9	—
Tests in development	IL1-1Ra, IGF-1 free, RANTES, PDGF-AA, PDGF-BB, eotaxin, IP-10, IL-5, IL-15, GM-CSF, MIP-1 α , TNF β , maternal screening array, sepsis array, endocrine array, metabolic arrays, and additional drugs of abuse array	interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, anti-TSH receptor, NSE, cyfra 21-1, anti-HBc, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none GPBB, FABP, CA III, VCAM-1, ICAM-1, E-selectin, P-selectin, L-selectin, IL-2, IL-4, VEGF, IFN γ , IL-1 α , MCP-1, EGF, BDNF, NGAL, thrombomodulin, sIL-6r, sTNFR1, sTNFR2, MMP-9	— 9-minute PTH, Tnt
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	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/— 100/180/540–1,980 no/liquid no/— no/— 7 μ L 7 μ L/70–350 μ L (varies with cup type) no/no no/— — no/— yes/12 mm, 16 mm/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes no/yes no/no no/no —/— — 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 μ L 10 μ L/100 μ L —/no no/3 L for 250 tests — no yes/13–16 mm diam./no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/no no/no — yes 2 no/monthly yes/yes once per 24 hours yes/yes no/no/4 minutes
Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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 no/yes/yes no — —/— yes daily: <5 minutes; weekly: 10 minutes; monthly: 30 minutes 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 (GLAS & 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	varies/500+ varies 5 days on site/—	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; maximum 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

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Part 18 of 27	Roche Diagnostics Sheila Brewer sheila.brewer@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us	Roche Diagnostics 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.	cobas e411/2006/Japan Japan/Germany —/—	MODULAR ANALYTICS E170/2001/Japan Japan/Germany >250/>300 (combination of E and EE systems) and >25 Integrated Modular Systems (U.S. only) continuous random access/floor-standing/rack 47 × 47 × 31.5 (Modular E configuration)/approx. 60 (one module system)
Operational type/Model type/Sample handling system Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	continuous random access/benchttop/rack, disk 31.4 × 47.2 × 28.7 (disk); 31.4 × 67 × 37.4 (rack)/94 (disk), 17.4 (rack)	continuous random access/floor-standing/rack 47 × 47 × 31.5 (Modular E configuration)/approx. 60 (one module system)
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 & βCG, 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/IgM, rubella IgG/IgM, total PSA (screening), free PSA, HBsAg, HBsAg conf, anti-HBs 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 — interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, anti-TSH receptor, NSE, cyfra 21-1, anti-HBc, HBc IgM, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM — 9-minute PTH ANO cardiac assays, 9-minute PTH, TnT	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 hCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps, osteocalcin HBsAg, HBsAg confirmatory, anti-HBs toxo IgG/IgM, rubella IgG/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 — interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, anti-TSH receptor, NSE, cyfra 21-1, anti-HBc, HBc IgM, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM — —
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	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 no/no no/3 L for 250 tests <70 decibels no yes/13–16 mm diameter/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/no no/no — 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 interl., 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 hours 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, best low-end sensitivity, troponin T, auto-rerun and dilute

Automated immunoassay analyzers

Part 19 of 27	Roche Diagnostics Jeremy Lynn jeremy.lynn@roche.com 9115 Hague Rd., Indianapolis, IN 46250-0457 800-428-5074 www.roche.com/labsystems/us	Siemens Healthcare Diagnostics, Inc. Kimberly Richman kimberly.richman@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 914-631-8000 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	cobas e601/2006/— Japan/Germany >100/— continuous random access/floor-standing/rack 46.1 x 71.8 x 40/19.73	ADVIA Centaur CP Immunoassay System/2005/U.S. Germany/U.S. >200/>400 batch, random access, continuous random access/benchtop/7 x 12 position racks 43 x 29/8.7
Tests available on instrument in U.S.	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	T4, free T4, free T3, TSH, TSH3, T-uptake, T3, intact PTH, digoxin, BNP, CKMB, homocysteine, myoglobin, Tnl-ultra, E26III, FSH, LH, tHCG, progesterone, prolactin, testosterone, AFP, PSA, cPSA, CEA, BR 27.29, CA 15-3, ferritin, vit. B12, folate, RBC folate, cortisol, theophylline, carbamazepine, cyclosporine, valproic acid, vancomycin, gentamicin, tobramycin
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for clearance	toxog IgG/IgM, rubella IgG/IgM, HBsAg, HBsAg conf, anti-HBs, total PSA (screening), free PSA	CA 19-9, insulin, C-peptide, HAV-T, HAV -M, DHEAs, HBsAg, HBsAb, Hbc-total, Hbc-IgM, HCV, D-dimer, TSH 3 II, SHBG, free PSA, HBe Ag, HBeAb, procalcitonin
Tests not available in U.S. but available in other countries	TG, CA 72-4, cyfra 21-1, S-100, digitoxin, anti-HAV, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, HIV antigen, HIV antigen confirmatory, HIV combi, P1NP, 25-OH vitamin D3	—
Research-use-only assays	—	—
Tests in development	interleukin-6, anti-CMV IgG, anti-CMV IgG, thyroglobulin, anti-TSH receptor, NSE, cyfra 21-1, anti-HBc, Hbc IgM, HBeAg, anti-HBe, anti-HAV, anti-HAV IgM	cyclosporine, tacrolimus, EHIV, toxo G/M, rubella G/M, CMV G/M, syphilis, fPSA, HER-2/neu, anti-Tg, anti-TPO, TrA
User-defined methods implemented for what analytes	—	—
Tests not available on other manufacturers' analyzers	—	cPSA, HER-2/neu
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 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	electrochemiluminescence/magnetic particle 25 per module 25 per module — 25 per module/100-200 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 μ L 10 μ L/100 μ L yes/yes yes/up to 30 L/hour in full operation <65 decibels yes/100 μ L yes/13 x 75 to 16 x 100/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes (with middleware) no/no yes/yes yes/yes — yes 2 no/every 28 days yes/yes 24 hours yes/yes yes/yes/11 minutes	chemiluminescence/magnetic particle 15 31 (65 planned for 2008) — 15/50-100 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 interl., Codabar, codes 39 & 128)/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
Stat time to completion of β -hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	18 minutes 42 seconds 56/176 (21 seconds)	15.6 minutes <1 to 2 minutes 50 seconds 60/180 (20 seconds)
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	yes/yes onboard/yes (additional cost) all major laboratory information systems	yes/yes onboard/no Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLFC, DI, Triple G, and most other major vendors
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 Web site yes (broadcast download & host query) yes yes (Roche MODULAR PRE-ANALYTICS) yes/yes/no no \leq 24 hours —/— yes daily: 5 minutes.; weekly: 10 minutes; monthly: 15 minutes yes (includes audit trail of who replaced parts)/yes	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
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	depends on GPO affiliation/community hospitals, satellite labs — 3 days at vendor sites plus online training/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	add reagents, consumables, samples without interruption; uses same reagents/consumables as ADVIA Centaur; throughput 180 tests/hour; current average time to first result, 15.6 minutes

Automated immunoassay analyzers

Part 20 of 27	Siemens Healthcare Diagnostics Denise Pastore denise.pastore@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 914-524-5102 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Colleen Grier 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	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 51.5 x 72.4 x 41/20.6	Dimension Vista 1500 Intelligent Lab System/2006/U.S. U.S./U.S. and Germany —/— batch, random access continuous random access/floor standing/sample rack and aliquot plate system 55 5/8 x 84 7/8 x 43 3/8/26
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	anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, TSH-3, TUp, B12, ferritin, folate, estradiol, estradiol III, FSH, HCG, LH, progesterone, prolactin, testosterone, AFP, BR27-29, CA 125 II, CA 15-3, CA 19-9, CEA, Her-2/NEU, PSA, cPSA, BNP, CKMB, homocysteine, myoglobin, Tnl ultra, cortisol, C-peptide (serum), insulin, intact PTH, rublla IgG, rubella IgM, toxoplasma IgG, toxoplasma IgM, anti-HBs, HBsAg, HBsAg confirmatory, anti-HBc (total), anti-HBc (IgM), anti-HCV, HIV 1/0/2, anti-HAV (IgM), anti-HAV (total), anti-Hbe, HbeAg, digoxin, digitoxin, tobramycin, carbamazepine, phenobarbital, phenytoin, gentamicin, theoplylline, valproic acid, vancomycin none — — — — D-dimer, FPSA, HBeAg, anti-HBe, cyclosporine, SHBG, DHEAS, UE3 — complex PSA, HER-2/neu	>100 (includes vendor supported applications), 35 general chemistry, 6 thyroids, 4 cardiac, 14 TDM, 17 DATs, 20 plasma proteins, 3 anemia — — — — CEA, AFP, CA 125, CA 15-3, CA 19-9, fertility panel, cancer markers, plasma proteins, hormones, cardiac, infectious disease — LOCI technology
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	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 closed/liquid yes/1,000 no 10 µL—assay 10 µL/50 µL yes/no no/2.5 L per hour 61.3 decibels no yes/—/no yes (2 of 5 interl., 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	chemiluminescence, enzyme immunoassay, ACMA, EMIT, LOCI, PETINIA, NEPH/none >100 >100 10 >100 72 hours/30 days/yes no yes yes/test ID, lot No., individual-sequence No. yes/<1 ppm >45/150/— yes/liquid yes/>1,500 semipermanent yes/automatic, as needed 2 µL analytical, 50 µL aliquot 2 µL (GLU=1.2)/20 µL yes/no no/20 L per hour <70 decibels yes/— yes/10 x 50, 10 x 65, 13 x 65, 13 x 75, 13 x 100, 15 x 92, 16 x 100, 13 x 90/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes yes/no — yes varies, 2-6 yes/30-90 days yes/yes shortest interval: 24 hours/— yes/yes no/no/—
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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 15 seconds 80/240/15 seconds yes yes/yes onboard/yes (LIS allowance) Cerner, Misys, Meditech, McKesson, Citation, Antrin, 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	10 minutes <2 minutes 200/600 (3.6 seconds) yes/yes onboard (Dade Behring)/no 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
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$225,000/300+ beds or 400 tests per day varies, GPO dependent —/4.5 days on site/yes	\$552,240/>4,000 tests per day inquire 5 days on site, 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	HIV & comprehensive hepatitis A, B, and C testing (includ. the acute panel); SMART algorithms for rerun and confirmatory testing for HBsAg testing; always ready, no start-up procedures; 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; processes 240 tests/hr	homogeneous LOCI technology for high sensitivity IA assays; fast analytical time, 10-minute cardiac markers, 21-minute anemia methods; ultra-integrated platform that eliminates sample sharing/splitting & streamlines lab workflow; can be configured as a Dimension Vista 3000T twin system

Automated immunoassay analyzers

Part 21 of 27	Siemens Healthcare Diagnostics Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics
Name of instrument/First year sold/Where designed	Dimension Xpand Plus Integrated Chemistry System/2004/U.S.	Dimension RxL Max/Max Suite Integrated Chemistry System/2003/U.S.; Dimension RxL Integrated Chemistry System/1997/U.S.
Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S.	U.S./U.S. —/—	U.S./U.S. —/—
Operational type/Model type/Sample handling system	random access, cont. random access/floor-standing/racks	batch, random access, cont. random access/floor-standing/racks
Dimensions in inches (H × W × D)/Instrument footprint in sq. feet	45 × 51 × 31 (without monitor)/10.6	44 × 62.5 × 30.5/13.2
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, others	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, others
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, sirolimus	mycophenolic acid, sirolimus
User-defined methods implemented for what analytes	—	—
Tests not available on other manufacturers' analyzers	system performs heterogeneous immunoassays and general assays on single platform—fully automated ISD assays	system performs heterogeneous immunoassays and general assays on a single platform—fully automated 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	ACMIA, EMIT, PETINIA, Photometry, Potentiometry/heterogeneous, magnetic particle
No. of different measured assays onboard simultaneously	91	91 (with optional reagent management system)
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	47/15–360	Max=47, Max Suite=91/15–360
Shortest/Median onboard reagent stability/Refrigerated onboard	48 hours/30 days/yes (2°–8°C)	48 hours/30 days/yes (2°–8°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/lot No., unique flex ID, stability, expiration date	yes/lot No., unique flex ID, stability, expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/— due to probe washing	yes/— due to probe washing
Walkaway capacity in minutes/Specimens/Tests-assays	can be hours/60/>2,000	can be hours/60/>2,000/>5,000
System is open (home-brew methods can be used)/Liquid or dry system	yes/reconstitutes onboard, no reagent prep required by operator/liquid	yes/no reagent prep required by operator for liquid
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/up to 2 L per hours	yes/3 L per hour/up to 5 L per hour
Noise generated	<70 decibels	<70 decibels
Has dedicated pediatric sample cup/Dead vol.	yes/10–20 µL	yes/10–20 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 interl., Codabar, codes 39 & 128)/yes	yes (2 of 5 interl., Codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS 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/yes
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
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	no/yes
Automatic shutdown/Startup is programmable/Startup time	not required	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 hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	up to 83/up to 250 (14.4 seconds)	up to 166/up to 500 (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)	optional (DBNet–Dade Behring)/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: 15 minutes
Onboard maintenance records/Maintenance training demo module	yes/yes	yes/yes
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/no	5 days on site, 4 days at vendor offices/yes
Distinguishing features (supplied by vendor)	consolidated low-volume workstation that integrates immunoassays onboard with other chemistries; allows single platform to meet over 95 percent of testing needs; eliminates sample splitting, aliquotting	analyzer integrates heterogeneous immunoassays onboard with other chemistries; allows single platform for over 95 percent of most requested tests; eliminates sample splitting between general tests and immunoassays

Automated immunoassay analyzers

Part 22 of 27	Siemens Healthcare Diagnostics Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Inc. 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	Dimension EXL Integrated Chemistry System (upgradeable w/LOCI Module)/2007/U.S. U.S./U.S. —/— batch, random access, continuous random access/floor standing/racks 49 x 82 x 34 (without monitor)/19.4	Dimension EXL with LM Integrated Chemistry System/—/U.S. U.S./U.S. —/— batch, random access, continuous random access/floor standing/racks 49 x 82 x 44 (without monitor)/25.1
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	cardiac troponin I, LV cardiac troponin I, CardioPhase hsCRP, ferritin, free PSA, free T4/ thyroxine, HCG, LV HCG, mass CK-MB, LV mass CK-MB, myoglobin, T-pro BNP, LV NT-pro BNP, thyroid stimulating hormone, total PSA, 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/thyroxine, triiodothyronine, acetamino- phen, ethyl alcohol, salicylate, urine ecstasy, urine amphetamine screen, others — — — — MPA, sirolimus	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, total T3, acetaminophen, ethyl alcohol, salicylate, urine ecstasy, urine amphetamine screen, urine barbiturates screen, urine benzodiazepines screen, urine cannabinoids screen, urine, others LOCI free T4 LOCI TSH — — LOCI NT-proBNP, LOCI troponin I, LOCI free T3, LOCI B12, LOCI folate, MPA, sirolimus
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— system performs heterogeneous immunoassays and complete routine general chemistry menu on a single platform; only fully automated, no-pretreatment ISD assays	— system performs homogeneous LOCI and heterogeneous immunoassays plus a complete routine general chemistry menu on a single platform; Only fully automated, no-pretreatment 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 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	enzyme immunoassay, ACMA, EMIT, PETINIA, photometry, potentiometry/ magnetic particle 91 190 10 91/15-360 72 hours/30 days/yes (2°-8° C) yes placed directly on system yes/lot No., unique flex ID, stability, expiration date yes/none (due to probe washing) can be hours/60/>2,000 yes/liquid, reconstitutes on board (no reagent prep required by the operator) yes/12,000 no/— 2 µL 2 µL/primary tube capable yes/no yes/up to 5 L <75 decibels yes/30 µL yes/5, 7, 10 mL/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes no/yes yes/yes yes/yes yes/no <20 seconds yes varies (3 levels for most assays) yes (NA, K, Cl)/most 90 days yes/yes 24 hours or with lot change no/yes no/no/not required	chemiluminescence, enzyme immunoassay, LOCI, ACMA, EMIT, PETINIA, photometry, potentiometry/magnetic particle, all LOCI and EMIT methods are homogenous 91 190 10 91/15-360 72 hours/30 days/yes (2°-8° C) yes placed directly on system yes/lot No., unique flex ID, stability, expiration date yes/none (due to probe washing) can be hours/60/>2,000 yes/liquid, reconstitutes on board (no reagent prep required by the operator) yes/12,000 no/— 2 µL 2 µL/primary tube capable yes/no yes/up to 5 L <75 decibels yes/30 µL yes/5, 7, 10 mL/no yes (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes/yes yes no/yes yes/yes yes/yes yes/no <20 seconds yes varies (3 levels for most assays) yes (NA, K, Cl)/most 90 days yes/yes 24 hours or with lot change no/yes no/no/not required
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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	16 minutes 24 seconds up to 146/437 (7.2 seconds) yes/yes onboard, optional add-on (EasyLink Informatics System)/yes (additional cost) all major LIS vendors	16 minutes 24 seconds up to 146/437 (7.2 seconds) yes/yes onboard, optional add-on (EasyLink Informatics System)/yes (additional cost) all major LIS vendors
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 yes/yes/yes no 2-8 hours —/— yes daily: <5 minutes; weekly: 10 minutes; monthly: 15 minutes no/no	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 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	— multiple types yes (5 days on site, 4 days at vendor offices)/no	— multiple types yes (5 days on site, 4 days at vendor offices)/no
Distinguishing features (supplied by vendor)	analyzer integrates heterogeneous immunoassays onboard with other chemistries; upgradeable with LOCI module; allows a single platform for over 95 percent of most requested tests; eliminates sample splitting between general chemistry tests and immunoassays; fully automated onboard ISD assays	analyzer integrates homogeneous LOCI and heterogeneous immunoassays onboard with other chemistries; allows a single platform for over 95 percent of most requested tests; eliminates sample splitting between general chemistry tests and immunoassays; fully automated onboard ISD assays

Automated immunoassay analyzers

Part 23 of 27	Siemens Healthcare Diagnostics Inc. Martu Richards martu.richards@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 914-524-3828 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Inc. 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 × W × D)/Instrument footprint in sq. feet	IMMULITE/1993; IMMULITE Turbo/1999; IMMULITE 1000/2002/U.S. U.S./U.S., U.K. >7,000 worldwide cont. random access/benchtop/loading platform 19 × 46 × 26/7.98	IMMULITE 2000/1998/U.S. U.S./U.S., U.K. >4,200 worldwide Cont. random access/floor-standing/rack 47 × 60 × 30/12.5
Tests available on instrument in U.S.	ACTH, cortisol, AlaTOP allergy screen, total IgE, EPO, ferr., folate, B12, calcitonin, i-PTH, Pylilinks-D, CK-MB, hs CRP, homocys., myogl., trop. I, albumin, C-peptide, insulin, hGH, IGF-I, IGFBP-3, CMV IgG, <i>H. pylori</i> IgG, anti-HBc, anti-HBc IgM, HBsAg, HBsAg confirm., anti-HBs, herpes I & II IgG, rub. quant. IgG, rub. IgM, toxo. quant. IgG, toxo. IgM, AFP, androst., DHEA-SO4, estradiol, unconj. estriol, FSH, HCG, LH, progesterone, prolactin, SHBG, testo., carbamaz., digit., digox., phenob., phenyt., theoph., valp. acid, THCA, FT3, TT3, FT4, TT4, TBG, thyrogl., anti-TG Ab, anti-TPO Ab, T-uptake, rapid TSH, 3rd-gen TSH, 3rd-gen PSA, PSA, AFP, BR-MA (CA15-3), CEA, OM-MA (CA125), PAP, beta-2 microgl., gastrin, canine TT4 + TLI + TSH; TURBO STAT MENU: CK-MB, HCG, myogl., i-PTH, trop. I	3gAllergy (IgE specific allergens & allergy panels), total IgE, AFP, CEA, OM-MA (CA125), BR-MA (CA15-3), PAP, PSA, 3rd-gen. PSA, IFG-I, IGFBP-3, hGH, FT3, TT3, TT4, FT4, TBG, thyrogl., anti-TG Ab, anti-TPO Ab, T-uptake, rapid TSH, 3rd-gen. TSH, iPTH, estrad., unconj. estriol, FSH, androst., HCG, LH, progest., prolac., testost., DHEA-SO4, β2-microgl., C-pep., folate, B12, hsCRP, homocysteine, troponin I, CK-MB, myoglobin, ACTH, digox., digit., phenob., carbamazep., phenyt., theoph., tobra., valp. acid, CMV IgG, <i>H. pylori</i> IgG, rubella IgG, rubella IgM, toxo IgG, toxo IgM, herpes I & II IgG, Pylilinks-D, anti-HBs, HBsAg, HBsAg confirm., anti-HBc, anti-HBc IgM, cortisol, ferr., calcit., gastrin, EPO, SHBG, insulin, albumin, canine TSH+T4+TLI free PSA, vancomycin; contact company for full 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	none — GI-MA (CA 19-9), nicotine metabolite, free β-hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, osteocalcin, NT-proBNP, CMV IgM	none — GI-MA (CA 19-9), fβHCG, IL-6, nicotine metab., PAPP-A, fPSA, IL2R, NT-pro BNP, CMV IgM, D-dimer
Research-use-only assays Tests in development	HBsAb quant, CMV IgM, toxo IgM ii, EBV (3), HBs confirmatory II	lyme screen, syphilis, TOXO IgM ii, CMV IgM, HBsAb quant, EBV (3), UE3 II, BHs confirmatory II, PCT, anit-CCP, anti-gliadins
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none IGF-I, IGFBP-3, androst., 3rd-gen PSA, AlaTOP allergy screen, gastrin, canine TLI, canine TSH	none 3rd-gen PSA, 3gAllergy, androst., gastrin, <i>H. pylori</i> IgG, IGF-I, IGFBP-3, canine TSH & TLI
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	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 μL 5 μL/100 μL 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 μL to 100 μL sample 5 μL/50 μL yes/no no/— 52 decibels yes/50 μL yes/75-100 mm height; 12-16 mm width/no yes (2 of 5 interl., 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 β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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 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: 5-10 minutes; weekly: 20 minutes; monthly: 20-30 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 24 of 27	Siemens Healthcare Diagnostics Inc. Martu Richards martu.richards@siemens.com 1717 Deerfield Road, Deerfield, IL 60015 914-524-3828 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Inc. 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/—/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.	B12, folate, 3gAllergy (IgE specific allergens & allergy panels), total IgE, Pylilinks-D, homocys., hsCRP, IGF-I, IGFBP-3, hGH, AFP, androst., DHEA S04, estrad., unconj. estriol, FSH, LH, prolac., progest., testost., SHBG, carbamazep., digit., digoxin, phenylt., phenob., theoph., valp. acid, iPTH, ACTH, β 2-microgl., herpes I & II IgG, anti-TG Ab, anti-TPO Ab, rapid TSH, 3rd gen TSH, FT3, TT3, FT4, TT4, T-uptake, thyrogl., CEA, BR-MA (CA15-3), OM-MA (CA125), PAP, PSA, 3rd gen PSA, <i>H. pylori</i> IgG, CMV IgG, rubella IgG, rubella IgM, toxo IgG, toxo IgM, gastrin, insulin, C-pep., alb., cort., ferr., calcit., EPO, vancomycin; TURBO STAT MENU: CK-MB, HCG, myogl., trop. I stat PTH	mass CK-MB, myoglobin, β -hCG, D-dimer, NT-proBNP, high sensitivity troponin I, <i>CardioPhase</i> hsCRP
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	GI-MA (CA19-9), f β HCG, IL-6, PAPP-A, fPSA, anti-HBc, anti-HBc IgM, HBsAg & confirm., anti-HBs, NT-proBNP, CMV IgM, nicotine metabolite, D-dimer	—
Research-use-only assays	—	—
Tests in development	lyme screen, syphilis, TOXO IgM, CMV IgM, EBV (3), PCT, anti-CCP, anti-gliadins	—
User-defined methods implemented for what analytes	none	—
Tests not available on other manufacturers' analyzers	3rd-gen PSA, 3gAllergy, androst., ACTH, gastrin, IGF-I, IGFBP-3, canine TSH & TLI	—
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	—	—
No. of wells in microplate	—	—
Methods supported/Separation methods	chemiluminescence/bead, centrifugation	fluorescence, EIA, dendrimer technology/fiber matrix filter
No. of different measured assays onboard simultaneously	24	up to 4
No. of different assays programmed, calibrated at once	unlimited	1
No. of user-definable (open) channels	—	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	24/200	up to 4 TestPaks/unit dose TestPak
Shortest/Median onboard reagent stability/Refrigerated onboard	—/90 days/yes (4°C)	—
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/test, lot No., expiration	yes/assay ID, lot No., expir., calib. param.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/<3 ppm	no/zero carryover
Walkaway capacity in minutes/Specimens/Tests-assays	300/275/1,300	14 minutes to 1st result, subsequent results in 4 minutes intervals/1/up to 4
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/1,300	no
Uses washable cuvettes/Replacement frequency	no/—	no
Minimum specimen vol. required	5 μ L to 100 μ L sample	2.5 mL whole blood
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 μ L/50 μ L	50-90 μ L/—
Supplied with UPS (backup power)/Requires floor drain	yes/no	optional/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	52 decibels	<65 decibels
Has dedicated pediatric sample cup/Dead vol.	yes/50 μ L	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/75-100 mm height; 12-16 mm width/no	yes/4 or 5 mL/yes
Sample bar-code reading capability/Autodiscrimination	yes (2 or 5 interl., Codabar, codes 39 & 128)/yes	yes (2 of 5 interl., Codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	yes	—
Measures No. of tests remaining/Short sample detection	yes/yes	—/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	—/—	not affected
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	min. 18 seconds	—
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	2-level adjustors, supplied in kit	1 Calpak
Calibrants can be stored onboard/Avg. calibration frequency	no/1-4 weeks (assay dependent)	no/30-90 days same lot, new lot
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	customer determined	shortest interval: daily electronic QC, longest: every 30 days for liquid controls
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/no/4 minutes	no/no/30 minutes to warm up
Stat time to completion of β -hCG test	15 minutes (total HCG)	14 minutes
Time delay from ordering stat test to aspir. of sample	18 seconds	immediately
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	200/200 (18 seconds)	3/9
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data-management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	yes/yes (additional cost)
Interfaces up and running in active user sites with LIS interface operates simultaneously w/running assays	Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, others	all major LIS vendors
Uses LOINC to transmit orders and results	yes	yes
How labs get LOINC codes for reagent kits	—	no
Bidirectional interface capability	yes (broadcast download & host query)	—
Results transmitted to LIS as soon as test time complete	yes	no
Interface available (or will be) to auto specimen handling system	yes (universal interface)	yes
Modem servicing/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	no/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	4 hours	2-8 hours
Mean time between failures/To repair failures	3 months/5 hours	>225 days/2.9 hours
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5-10 minutes; weekly: 20 minutes; monthly: 20-30 minutes	daily: none; weekly: none; monthly: 10 minutes
Onboard maintenance records/Maintenance training demo module	no/yes	no/yes
List price/Targeted bed size or daily volume	\$200,000 includes SMS & RealTime Solutions/200+ beds	—/any size emergency department
Annual service contract cost (24 hours/7 days)	\$21,500 (RealTime Solutions with SMS)	multiple types
Training provided w/purchase/Advanced operator training	varies on site, 5 days at vendor offices/yes	3 days on site/no
Distinguishing features (supplied by vendor)	large automated IA test menu available; 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 & logistics reports	whole blood collection tubes (heparin) or precentrifuged plasma (heparin/sodium citrate); onboard centrifugation; unit-dose test packs; color-coded calibrators packaged on Calpacks; diluent packs for dilutions; self-contained system (no waste lines, water, etc.); 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 system providing a stand-alone workstation featuring its own cart, refrigerator, & uninterruptible power supply

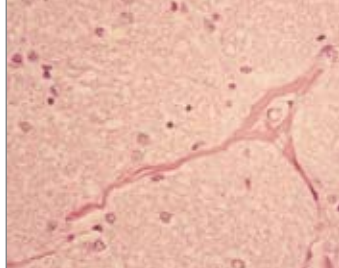
Automated immunoassay analyzers

Part 25 of 27	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 × W × D)/Instrument footprint in sq. feet	AIA-360/2004/Japan Japan/Japan 320/100+ continuous random access/benchtop/carousel 21 × 19 × 16/2.1	AIA-600 II/2000/Japan Japan/Japan 400/600 cont. random access/benchtop/chain 19.8 × 31.6 × 29.1/2.5
Tests available on instrument in U.S.	10 minutes short time (ST) assays: TSH, FT4, T3, T4, T-uptake, FT3, β-hCG, estradiol, FSH, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, β-2-microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen., ferritin, testosterone, CA 19-9, intact PTH	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
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	BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg	HBsAg, HBsAb, HBeAg, HbcAb, HbeAb, BNP
Research-use-only assays	—	—
Tests in development	HbA1c, RBC folate, cTnl 3rd gen.	RBC folate, HbA1c, cTnl 3rd gen.
User-defined methods implemented for what analytes	—	none
Tests not available on other manufacturers' analyzers	—	none
Fully automated microplate system	—	no
No. of each analyte performed in separate disposable unit	—	—
No. of wells in microplate	—	—
Methods supported/Separation methods	fluorescence, EIA/beam	fluorescence, EIA/beam
No. of different measured assays onboard simultaneously	25	26
No. of different assays programmed, calibrated at once	entire menu	entire menu
No. of user-definable (open) channels	0	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	—/unitized test cup	—/unitized test cup
Shortest/Median onboard reagent stability/Refrigerated onboard	72hours/72hours/—	72 hours/72 hours/—
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/lot No., test code	yes/lot No., test code
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover	no/zero carryover
Walkaway capacity in minutes/Specimens/Tests-assays	58/25/25	52/26/26
System is open (home-brew methods can be used)/Liquid or dry system	no/dry	no/dry
Uses disposable cuvettes/Max. No. stored	no	—/unitized test cup
Uses washable cuvettes/Replacement frequency	no	—
Minimum specimen vol. required	500 μL tube, 100 μL cup	500 μL tube, 100 μL cup
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10–100 μL	10 μL/100 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	yes/primary draw tubes: 13 × 75 & 100; 16 × 75 & 100/no	yes/primary draw tubes: 7 mL & 10 mL or 15 × 75 & 100, 13 × 75 & 100/no
Sample bar-code reading capability/Autodiscrimination	yes/yes	yes/yes
Bar-code placement per NCCLS 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	yes/no	yes/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/yes
Time between initial result & reaspiration of sample for rerun	—	—
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	2 or 6-analyte dependent	2 or 6—analyte dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/30–90 days	no/60–90 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	24 hours	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/no	no/no
Automatic shutdown/Startup is programmable/Startup time	yes/no/5 minutes	no/no/5 minutes
Stat time to completion of β-hCG test	~18 minutes	~18 minutes
Time delay from ordering stat test to aspir. of sample	60 seconds	60 seconds
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	12/36 (1 minutes)	20/60 (1 minute)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/no	yes/no
Data-management capability/Instrument vendor supplies LIS interface	Antek, Schuyler House, more	optional add-on (all major LIS vendors—Schuyler House, Misys, LabForce, McKesson, Antrim, Data Innovations)/yes (additional cost) Schuyler House, Fletcher Flora
Interfaces up and running in active user sites with	—	yes
LIS interface operates simultaneously w/running assays	—	yes
Uses LOINC to transmit orders and results	yes	yes
How labs get LOINC codes for reagent kits	package insert	package insert
Bidirectional interface capability	no	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/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	>6 months/24 hours	98% uptime/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 minutes	daily: 5 minutes; weekly: 5 minutes; monthly: none
Onboard maintenance records/Maintenance training demo module	no/no	no/no
List price/Targeted bed size or daily volume	\$25,000/200–1,000 tests per month	\$70,000/500–2,500 tests per month
Annual service contract cost (24 hours/7 days)	\$2,050–\$3,500	\$5,941
Training provided w/purchase/Advanced operator training	training DVD; on-site install	3 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	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 26 of 27	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-1800/2003/Japan Japan/Japan 24/300+ continuous random access/floor standing/rack, sort drawer, standard and LA 65 × 50 × 37/6.3	PersonalLab/1998/Italy Italy/— (open system) 200/>400 worldwide batch/benchtop/rack 24 × 26 × 25.6/4.6
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	TSH, 3rd-gen. TSH, FT4, T3, T4, T-uptake, FT3, TPO Ab, Tg Ab, βhCG, estradiol, FSH, LH, progesterone, prolactin, AFP, CEA, PSA, CA 125, 27.29, β-2-microglobulin, C-peptide, cortisol, hGH, IgE II, insulin, PAP, CK-MB, myoglobin, troponin I 2nd gen., ferritin, folate, B12, testosterone, CA 19-9, intact PTH — — BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg — HbA1c, RBC folate, cTnl 3rd gen. — —	open system—any microplate assay open system open system open system open system open platform — (open platform)
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	— — —	yes — min. strip: 8; max. full plate: 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 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	fluorescence, EIA/beam 31 trays entire menu 0 —/unitized test cup 72 hours/72 hours/— yes yes yes/lot No., test code no/zero carryover 58/170/640 no/dry —/unitized test cup — 500 μL tube, 100 μL cup 10 μL/50 μL yes/no no/— — no yes/primary draw tubes: 7 mL & 10 mL or 15 × 75 & 100; 13 × 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/30–90 days yes/yes 24 hours yes/yes yes/no/5–8 minutes	EIA/coated microplate, varies acc. to kit mfrt. 6 (2 plates) 500 500 6/96 (2 plates) mfrt. dependent/no yes no, requires operator prehandling/preparation no yes/zero carryover option —/96-6/6 yes/— yes/192-2 plates no/— 200 μL plus amount required by mfrt. 10 μL/200 μL yes/no no/— — no yes/16 × 100–11 × 55 mm/no yes (2 of 5 interl., Codabar, codes 39 & 128)/— — yes yes/yes yes no/yes no/no yes/no yes/yes (mfrt. & assay dependent) — — mfrt. & assay dependent —/mfrt. & assay dependent yes/— mfrt. & assay dependent no/— no/no/5 minutes
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hours 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 40 seconds 60/180 (20 seconds) yes/yes yes/no	— — — yes/yes onboard/yes (included in price)
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 yes package insert yes (broadcast download & host query) yes yes (Hitachi, Lab Interlink, A&T) no/no/no no 24 hours 5 months/24 hours yes daily: 5–8 minutes; weekly: 5 minutes; monthly: none yes (includes audit trail of who replaced parts)/no	— yes — — yes (broadcast download & host query) yes no yes/yes/yes no within 24 hours —/<24 hours yes daily: 6–10 minutes; weekly: 10 minutes; monthly: 15 minutes yes/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/purchase/Advanced operator training	\$175,000/65+ beds, 1,500–2,000 tests \$11,458 4 days at vendor offices/no	\$38,000/>100 beds depends on acquisition option 3–5 days on site/yes
Distinguishing features (supplied by vendor)	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	open platform; two sample aspiration options: metal needle or disposable plastic tips; proven performance and reliability; accommodates various sample tube sizes including primary tubes within same run

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	Nexgen Four/2003/Italy Italy/U.S., Italy, Ireland, Germany —/— batch, random access, continuous random access/benchtop/ring (carousel) 28 x 53.2 x 29.5 (includes carousel)/—
Tests available on instrument in U.S.	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	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 open system—any microplate assay
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 x 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 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	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 interl., 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 hours 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	manufacturer dependent — —/open system—depends on kit yes/yes onboard/yes
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 no yes/yes/yes no by contract —/— yes daily: 5 minutes; weekly: 5–10 minutes; monthly: 10–15 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	\$72,900/>100 varies 3–4 days on site/no
Distinguishing features (supplied by vendor)	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