Automated immunoassay analyzers

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Name of instrument/First year sold/Where designed	AxSym/AxSym Plus/1993 worldwide, 1994 U.S./U.S.	ARCHITECT i2000SR; i2000; i4000/—/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S.	U.S./U.S.
No. of units in clinical use in U.S./Outside U.S.	2,000/14,000	272/4,096
Operational type/Model type/Sample handling system	cont. random access/stat, batch floor-standing/segment	batch, random access, cont. random access/floor-standing/track & LAS
Dimensions in inches (H × W × D)/Instrument footprint in square feet	60.5 × 63 × 33.5 in/14.6 sq ft	i200SR, 48 × 61 × 49/20.3 sq ft; i2000, 48 × 68 × 44 in/22.7 sq ft per module
Tests available on instrument in U.S.	ultra hTSH II, TT3, TT4, FT3, FT4, T-uptake, total βhCG, FSH, LH, progest., estrad., prolac., testosterone, CK-MB, homocysteine, myogl., 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., anti-TPO & TG, 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	cardiac: troponin I, CK-MB, myoglobin; fertility: total beta-hCG, LH, FSH, prolactin, progesterone, estradiol, DHEA-S; cancer: total PSA, free PSA, 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)
Tests cleared but not clinically released	—	fertility: SHBG; hep/retro/congenitals: HAVAB-M
Tests not available in U.S. but submitted for clearance	—	transplant: tacrolimus, sirolimus; metabolic: PTH; hep/retro/congenitals: CORE-M, rubella IgG
Tests not available in U.S. but available in other countries	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	fertility: testosterone; transplant: tacrolimus, sirolimus; cancer: SCC, AFP; metabolic: B12, folate, intact PTH; hep/retro/congenitals: HIV Ag/Ab combo, syphilis, HBeAg, anti-HBe, HAVAB-G, anti-HBc, CMV IgG, CMV IgM, rubella IgM, rubella IgG
Research-use-only assays	n/a	n/a
Tests in development	A1c	cardiac: MPO, choline, homocysteine; thyroid: Tg; fertility: PIGF, sFLt-1; transplant: cyclosporine; cancer: pro-GRP, CYFRA 21-1, AFP; metabolic: C-peptide, vitamin D; hep/retro/congenitals US only: CORE, HAVAB-G, HIV combo; outside US: HCV Ag/Ab combo, HCV core Ag, HTLV I/II, CMV IgG avidity, toxo IgG, toxo IgM, toxo IgG avidity
User-defined methods implemented for what analytes	n/a	none
Tests not available on other manufacturers' analyzers	n/a	none
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/Separation methods	FPIA, MEIA, ion capture, REA/heterogen., bead (microparticle), fiber matrix filter	Chemiflex (enhanced chemiluminescence) w/5 flexible protocols/magnetic microparticle
No. of different measured assays onboard simultaneously	20	25
No. of different assays programmed, calibrated at once	20	25
No. of user-definable (open) channels	0	n/a
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	20/100	25/100-test & 500-test per kit
Shortest/Median onboard reagent stability/Refrigerated onboard	onboard reagent stability: 112, 224, 336/no	30 days/30 days/yes (2–12ºC)
Multiple reagent configurations supported	no	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/assay name, reag. lot No., expir. date, pack No. ID	yes/assay No., reagent serial No., lot No., tests per kit, exp. date, onboard stability time, master calibration curve
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/< 0.1 ppm	n/a/no
Walkaway capacity in minutesutes/Specimens/Tests-assays	60/90/90	300/135/12,500
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/90 reaction vessels	yes/1,200
Uses washable cuvettes/Replacement frequency	no	no/n/a
Minimum specimen vol. required	83 uL/150 uL	50 uL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 uL/73 uL for sample cup, 450 uL for aliquot, 4.5 mL for primary	150 uL/50 uL for all tube types
Supplied with UPS (backup power)/Requires floor drain	yes (soft close of files only)/optional	yes/no
Requires dedicated water system/Water consumption	no/—	no/n/a
Noise generated	52–68 decibels	48–70 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/100 & 75 mm/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	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
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	no/no	no/no
Time between initial result & reaspiration of sample for rerun	seconds	<20 seconds
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte	6 pt. or 2 pt. w/ master calib., index calib.	2–6 pt. curve
Calibrants can be stored onboard/Avg. calibration frequency	no/4 weeks	no/minimum 30 days or once per lot
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes (up to 4 curves/analyte)	yes/yes
How often QC required	shortest interval: 8 hours, longest: 24 hours	3 levels every 24 hours for quantitative, 2 levels for qualitative
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/1 minute	n/a/no/10 minutes
Stat time to completion of ß-hCG test	10 minutes	15.6 minutes
Time delay from ordering stat test to aspir. of sample	30 seconds from standby	<20 seconds
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	68–120 tests/flexible platform—load list dependent (assay dependent)	67/200 tests per hour
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/no	onboard/no
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	n/a	n/a
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	no/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	yes, AbbottLink	yes, AbbottLink
On-site response time of service engineer	12 hours	8 business hours
Mean time between failures/To repair failures	5 months/within 12 hours per customer request	10.4 weeks/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 14 minutes; weekly: 65 minutes; monthly: 11 minutes	daily: 16 minutes; weekly: <10 minutes; monthly: none (for both manual & automated procedures)
Onboard maintenance records/Maintenance training demo module	no/no	yes/yes
List price/Targeted bed size or daily volume	$124,000/up to 200 IA tests per day	$169,500/>200 immunoassays per day
Annual service contract cost (24 hours/7 days)	flexible options available	flexible options available
Training provided w/ purchase/Advanced operator training	yes/yes	yes/yes
Distinguishing features (supplied by vendor)	menu, reliability, online exception help, pressure monitoring, foam avoidance, ratio calculation, stat TAT	Chemiflex technology delivers excellent sensitivities and extended linearities while the RSH allows for priority and routine samples to be processed simultaneously without compromising stats

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Automated immunoassay analyzers

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Name of instrument/First year sold/Where designed	ARCHITECT ci8200/2003/U.S.	ChemWell/1998/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S.	U.S./open system
No. of units in clinical use in U.S./Outside U.S.	232/1,107	10/900+
Operational type/Model type/Sample handling system	batch, random access, cont. random access/floor-standing/features a patented Robotic Sample Handler that uses multi-dimensional sample handling	batch, random access/benchtop/rack
Dimensions in inches (H × W × D)/Instrument footprint in square feet	48 × 127 × 49 in/43.2 sq ft	16 × 34 × 20 in/4 sq ft
Tests available on instrument in U.S.	cardiac: troponin I, CK-MB, myoglobin; fertility: total beta-hCG, LH, FSH, prolactin, progesterone, estradiol, DHEA-S; cancer: total PSA, free PSA, 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); contact company for full test menu	unlimited—open system
Tests cleared but not clinically released	fertility: SHBG; hep/retro/congenitals: HAVAB-M	—
Tests not available in U.S. but submitted for clearance	transplant: tacrolimus, sirolimus; metabolic: PTH; hep/retro/congenitals: CORE-M, rubella IgG	—
Tests not available in U.S. but available in other countries	fertility: testosterone; transplant: tacrolimus, sirolimus; cancer: SCC, AFP; metabolic: B12, folate, intact PTH; hep/retro/congenitals: HIV Ag/Ab combo, syphilis, HBeAg, anti-HBe, HAVAB-G, anti-HBc, CMV IgG, CMV IgM, rubella IgM, rubella IgG	unlimited—open system
Research-use-only assays	n/a	unlimited—open system
Tests in development	cardiac: MPO, choline, homocysteine; thyroid: Tg; fertility: PlGF, sFLt-1; transplant: cyclosporine; cancer: pro-GRP, CYFRA 21-1, AFP; metabolic: C-peptide, vitamin D; hep/retro/congenitals US only: CORE, HAVAB-G, HIV combo; outside US: HCV Ag/Ab combo, HCV core Ag, HTLV I/II, CMV IgG avidity, toxo IgG, toxo IgM, toxo IgG avidity	—
User-defined methods implemented for what analytes	—	general biochemistries
Tests not available on other manufacturers' analyzers	n/a	n/a
Fully automated microplate system	n/a	yes
No. of each analyte performed in separate disposable unit	n/a	up to 12
No. of wells in microplate	n/a	min. strip, 8; max. full plate, 96
Methods supported/Separation methods	photometric, potentiometric, & Chemiflex (enhanced chemiluninescence)	EIA/coated microwell
No. of different measured assays onboard simultaneously	93	up to 12
No. of different assays programmed, calibrated at once	93	unlimited
No. of user-definable (open) channels	220	unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	93/50–1,700	27/assay dependent
Shortest/Median onboard reagent stability/Refrigerated onboard	3 days/28 days/yes	assay dependent/assay dependent/yes (10°C below ambient)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/assay name, reagent No., lot No., tests per kit, expiration date, others	no
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	open system/SmartWash technology	no/none
Walkaway capacity in minutesutes/Specimens/Tests-assays	300/367/>75,000	assay dependent/96/12
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	both disposable and semi-permanent glass/1,200 or 165	yes/96
Uses washable cuvettes/Replacement frequency	yes/as needed, 1-year minimum	yes/assay dependent
Minimum specimen vol. required	2 uL	2 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	50 uL	2µL/—
Supplied with UPS (backup power)/Requires floor drain	yes/yes	no/no
Requires dedicated water system/Water consumption	yes/25 L per hour	no
Noise generated	48-70 decibels	—
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5, 7, 10 mL/no	yes/12 × 100 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	no/—
Bar-code placement per NCCLS standard Auto2A	yes	—
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	no/no
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/yes	no/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	yes/yes
Time between initial result & reaspiration of sample for rerun	<20 seconds	assay dependent
Autocalibration or autocalibration alert	yes	no
No. of calibrators required for each analyte	2 or 6 pt.	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	yes/assay dependent
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	from 2 levels after calibration, to 3 per 24 hours	shortest interval: each run; longest: daily
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	n/a/no/10 minutes	yes/yes/2 minutes
Stat time to completion of ß-hCG test	<15.6 minutes	assay dependent
Time delay from ordering stat test to aspir. of sample	<20 seconds	30 seconds
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	400/1,200	assay dependent
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/no	onboard/yes (included)
Interfaces up and running in active user sites with	all major LIS vendors	—
LIS interface operates simultaneously w/ running assays	yes	no
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	n/a	n/a
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	no	no
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	yes, AbbottLink	no
On-site response time of service engineer	8 business hours	within 48 hours
Mean time between failures/To repair failures	5.8 weeks/—	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: <15 minutes; weekly: <35 minutes; monthly: 15 minutes (for both manual & automated procedures)	daily: <10 minutes; weekly: <10 minutes; monthly: <10 minutes
Onboard maintenance records/Maintenance training demo module	yes/yes	no/no
List price/Targeted bed size or daily volume	$375,000/200–500 immunoassay tests per day	$25,000/up to 500 tests per day
Annual service contract cost (24 hours/7 days)	n/a	$4,000
Training provided w/ purchase/Advanced operator training	yes/yes	3 days on site/no
Distinguishing features (supplied by vendor)	integration of CC and IA without compromising stat TAT, results, or throughput because of patented SmartWash technology, which minutesimizes carryover to <0.1 ppm; large reagent capacity of 93 assays, with sample load up to 367	ability to perform general biochemistries; optional reagent cooling module

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Automated immunoassay analyzers

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Name of instrument/First year sold/Where designed	Access/Access 2 Immunoassay System/2001/U.S.	UniCel DxI 800/2003/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S. & France	U.S./U.S., France
No. of units in clinical use in U.S./Outside U.S.	>2,400/>3,700	>400/>400
Operational type/Model type/Sample handling system	cont. random access/benchtop/rack	cont. random access/floor standing/rack, direct track sampling
Dimensions in inches (H × W × D)/Instrument footprint in square feet	18.5 × 39 × 24 in/6.5 sq ft	66.7 × 67.5 × 37.7 in/17.7 sq ft
Tests available on instrument in U.S.	CEA, T3, T4, T-uptake, 3rd-gen. TSH, FT4, FT3, βhCG, DHEA-S, prolac, FSH, LH, prog-est., estrad., unconj. estriol, B12, fol., RBC fol., ferr., intrinsic factor Ab, CK-MB, myogl., cortisol, urine cortisol, insulin, AFP-open neural tube defect, total IgE, digox., toxo IgG, rubella IgG, hybritech PSA & fPSA, testosterone, ostase, toxo IgM, antithy-roglob., hypersensitive human growth hormone, thyroglobulin, AccuTnI, OV monitor (CA 125 antigen), BR monitor (CA 15.3 antigen), GI monitor (CA 19.9 antigen), BNP, TPO Ab, iPTH, EPO	CEA, T3, T4, T-uptake, 3rd-gen. TSH, FT4, FT3, βhCG, DHEA-S, prolac, FSH, LH, prog-est., estrad., unconj. estriol, B12, fol., RBC fol., ferr., intrinsic factor Ab, CK-MB, myogl., cortisol, urine cortisol, insulin, AFP-open neural tube defect, total IgE, digox., toxo IgG, rubella IgG, hybritech PSA & fPSA, testosterone, ostase, toxo IgM, antithy-roglob., hypersensitive human growth hormone, thyroglobulin, AccuTnI, OV monitor (CA 125 antigen), BR monitor (CA 15.3 antigen), GI monitor (CA 19.9 antigen), BNP, AFP ONTD, hybritech PSA, hybritech fPSA, TPO Ab, iPTH, EPO
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 1/2, HBsAg, HBsAg confirm., HBsAB, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6	HIV 1/2, HBsAg, HBsAg confirm., HBsAB, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6
Research-use-only assays	IL-6	IL-6
Tests in development	CMV IgG & IgM, rubella IgM, soluble transferrin receptor, BPH-A, [-2]proPSA, ANA, ds-DNA Ab, PIGF, sVEGF R1 (preeclampsia), PAPP-A, SHBG, HBeAg, HBeAb, HIV combo	CMV IgG & IgM, rubella IgM, soluble transferrin receptor, BPH-A, [-2]proPSA, PAPP-A, SHBG, HBeAb, HBeAg, HIV combo, ANA, ds-DNA Ib, inhibin A, PIGF, sVEGF RI (preeclampsia)
User-defined methods implemented for what analytes	none	none
Tests not available on other manufacturers' analyzers	AFP-ONTD, hybritech PSA & fPSA, intrinsic factor Ab	intrinsic factor Ab
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	n/a	—
No. of wells in microplate	n/a	—
Methods supported/Separation methods	chemiluminescence/magnetic particle	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	24	50
No. of different assays programmed, calibrated at once	24	50
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	24/100 tests per kit, 50 tests per cartridge	50/50 tests per cartridge, 100 or 1,000 tests per kit
Shortest/Median onboard reagent stability/Refrigerated onboard	336 hours/28 days/yes (4°C)	336 hours/28 days/yes (3–10°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/assay No., lot No., expir., unique reagent pack ID No.	yes/assay No., lot No., expir., unique reagent pack ID No.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/ 10 ppm	n/a/< 10 ppm
Walkaway capacity in minutesutes/Specimens/Tests-assays	180/60/300	288 (avg.—assay mix dependent)/120/1,200 (avg.)
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/294	yes/>1,000
Uses washable cuvettes/Replacement frequency	no	no
Minimum specimen vol. required	specimen container dependent	specimen container dependent
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/100 µL	5 µL/160 µL
Supplied with UPS (backup power)/Requires floor drain	yes (when networked)/no	yes (PC only)/optional
Requires dedicated water system/Water consumption	no	no/—
Noise generated	<70 decibels	<60 decibels
Has dedicated pediatric sample cup/Dead vol.	yes/100 µL	yes/100 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13x75 & 100, 16x75 & 100, 2 µL & 3 µL cups; 13x75, 13x100 aliquot tubes/no	yes/12x75 to 16x100 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	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	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
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	no/no	no/no
Time between initial result & reaspiration of sample for rerun	36 seconds	<9 seconds (minimum)
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte	6	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	no/28 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	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/remains in ready mode	no/no/remains in ready mode
Stat time to completion of ß-hCG test	15 minutes	15 minutes
Time delay from ordering stat test to aspir. of sample	36 seconds	18 seconds
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	33/100 (36 seconds)	min. 67, max. 133/min. 200, max. 400 (9 or 18 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	onboard/yes (included or additional cost—negotiable)	onboard/yes (included or additional cost—negotiable)
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	no	yes (Beckman Coulter automation systems)
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 max., usually within 6 hours	per negotiated contract
Mean time between failures/To repair failures	not available/not available	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 15 minutes; weekly: 30 minutes; monthly: none	daily: <10 minutes; weekly: TBD; monthly: none
Onboard maintenance records/Maintenance training demo module	yes/no	yes/yes
List price/Targeted bed size or daily volume	$149,800/all volumes & hospital sizes	$325,000/300+ beds or >400 tests per day
Annual service contract cost (24 hours/7 days)	$15,800	$29,900
Training provided w/ purchase/Advanced operator training	4 days at vendor offices/yes	5 days at vendor office for 2 employees/yes
Distinguishing features (supplied by vendor)	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; state-of-the-art chemiluminescence methodology; superior assays: TSH, FT_4, UE_3, hybritech PSA, fPSA, B_{12}, fol., AccuTnI	high throughput immunoassay analyzer; uses proven 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

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Automated immunoassay analyzers

Part 4 of 25

See accompanying article on page 24

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Name of instrument/First year sold/Where designed	UniCel DxC 600i Synchron Access Clinical System/2006/U.S.	UniCel DxI 600 Access Immunoassay System/2007/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S.	U.S./U.S.
No. of units in clinical use in U.S./Outside U.S.	>115/>115	—/—
Operational type/Model type/Sample handling system	continuous random access/floor standing/rack-closed tube	continuous random access/floor standing/rack
Dimensions in inches (H × W × D)/Instrument footprint in square feet	62 × 126.5 × 48/42.16 sq ft	67 × 61.5 × 37.5 in/16.02 sq ft
Tests available on instrument in U.S.	total T3, total T4, thyroid uptake, fast hTsH, HYPER sensitive hTSH (3rd generations), free T3, free T4, total BhCG, DHEA-s, prolactin, hFSH, hLH, progesterone, estradiol, unconjugated estriol, vit. B12, folate, RBC folate, ferritin, intrinsic factor Ab, CK-MB, myoglobin, cortisol (serum & urine), ultrasensitive insulin, AFP (ONTD), total IgE, digoxin, chlam. Ag & confirm., toxo IgG, toxo IgM, rubella IgG, testosterone, thyroglobulin, thyroglobulin Ab, ultrasensitive hGH, ostase bone alkaline phosphatase, Accu TnI troponin, triage BNP, OV monitor (CA 125 antigen), BR monitor (CA 15-3 antigen), GI monitor (CA19-9 antigen), plus >100 Synchron chemistry tests, including critical care, genral esoteric, urnine & CSF chemistries, DAT, TDMs, proteins, serologies, TPO Ab, iPTH, EPO	AccuTnI, CK-MB, myoglobin, digoxin, vitamin B12, ferritin, dil-ferritin, folate, RBC folate, unconjugated estriol, total BhCG, testosterone, DHEA-S, prolactin, estradiol, progesterone, CEA, thyroglobulin, OV monitor (CA 125 antigen), BR monitor (CA 15-3 antigen), GI monitor (CA19-9 antigen), AFP, PSA, free PSA, cortisol, insulin, total IgE, TSH, fast TSH, free T4, ostase, EPO, hFSH, hLH, inhibin A, total T3/T4, thyroid uptake, free T3, thyroglobulin Ab, TPO Ab, hGH, PTH, iPTH
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	IL-6, rubella IgM	IL-6, rubella IgM
Research-use-only assays	IL-6	IL-6
Tests in development	ANA screen, ds-DNA Ab, CMV IgG, CMV IgM, rubella IgM, PIGF (preeclampsia), sVEGF RI (preeclampsia), BPH-A, [-2]proPSA, soluble transferrin receptor, PAPP-A, SHBG, HBe Ab, HBe Ag, HIV combo	PAPP-A, PIGF (preeclampsia), sVEGF RI (preeclampsia), SHBG, soluble transferrin receptor (sTfR), [-2]proPSA, BPH-A, ANA screen, dsDNA Ab, CMV IgG, CMV IgM, rubella IgM
User-defined methods implemented for what analytes	—	—
Tests not available on other manufacturers' analyzers	intrinsic factor Ab	—
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, enzyme immunoassay/magnetic particle	chemiluminescence, enzyme immunoassay/magnetic particle
No. of different measured assays onboard simultaneously	89	50
No. of different assays programmed, calibrated at once	89	50
No. of user-definable (open) channels	100	—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	89/100 tests per kit (immunoassay); 300 tests per container (gen. chem.)	50/50
Shortest/Median onboard reagent stability/Refrigerated onboard	336 hours/28 days/yes (2°-10°C)/yes	336 hours/56 days/yes (4–10°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/specific cartridge ID, No. of tests, available tests, expiration date, lot No., calibration expiration	yes/assay No., lot No., expiration date, unique reagent pack ID No.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/10 ppm	no/<10 ppm
Walkaway capacity in minutesutes/Specimens/Tests-assays	180/96/5,280	240/—/—
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	closed/liquid
Uses disposable cuvettes/Max. No. stored	yes/294	yes/1,800
Uses washable cuvettes/Replacement frequency	yes/2-year warranty (gen. chem.)	no
Minimum specimen vol. required	specimen container dependent	assay dependent, ~20 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/100 µL	5 µL/specimen container dependent
Supplied with UPS (backup power)/Requires floor drain	optional/yes	yes (PC only)/optional
Requires dedicated water system/Water consumption	yes/16 L per hour	no/—
Noise generated	—	<60 decibels
Has dedicated pediatric sample cup/Dead vol.	yes (gen. chem.)/—	yes/80 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13 × 75 & 100 to 16 × 100 mm/yes	yes/12 × 75 to 16 × 85 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	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/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	no/no
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/no	no/no
Time between initial result & reaspiration of sample for rerun	36 seconds	—
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte	assay dependent	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	no/28 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	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/remains in ready mode	no/no/remains in ready mode
Stat time to completion of ß-hCG test	17 minutes	15 minutes
Time delay from ordering stat test to aspir. of sample	36 seconds	9 seconds
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	—/100-immunoassay, 990-gen. chem. (36 seconds)	—/200 (9 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 add-on/yes (additional cost)	optional add-on onboard/yes (included or additional)
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	yes	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	no	yes, Beckman Coulter automation systems
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	no/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	—	—
Mean time between failures/To repair failures	—/per negotiated contract	per negotiated contract/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: <15 minutes; weekly: 36 minutes; monthly: 11 minutes	<10 minutes; daily: 10 minutes; weekly: n/a; monthly: none
Onboard maintenance records/Maintenance training demo module	yes/no	yes (includes audit trail/yes
List price/Targeted bed size or daily volume	$400,000/—	$199,500/200–400 beds/100–300 tests per day
Annual service contract cost (24 hours/7 days)	per negotiated contract	per negotiated contract
Training provided w/ purchase/Advanced operator training	yes/yes	—/yes
Distinguishing features (supplied by vendor)	performs parallel processing of immunoassay and chemistry tests on a single workstation; closed-tube aliquot (CTA) and closed-tube sampling (CTS) eliminate manual processes; robust test menu integrates immunoassay and chemistry product lines	powerful, flexible, and technologically advanced analyzer targeted to mid- and high-volume laboratories; proven chemiluminescent technology and the same reagents as DxI 800 and Access 2; delivers consistent results across platforms; will be integrated with other UniCel systems in 2007

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SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 5 of 25 *See accompanying article on page 24*	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	DSX Automated System/2000/Guernsey, U.K.	DS2/2006/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.K.	U.S./U.S., U.K.
No. of units in clinical use in U.S./Outside U.S.	>150/>500	—/—
Operational type/Model type/Sample handling system	batch/benchtop/rack	batch, with continuous load/benchtop/rack
Dimensions in inches (H × W × D)/Instrument footprint in square feet	32 × 42 × 36 in/7 sq ft	30 × 17 × 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, H. pylori, syphilis, chlamydia, mycoplasma, legionella IgG/IgM, legionella UA, CCP, HSV 1/2 IgG type specific, tetanus toxoid, ASCA IgG/IgA, diptheria 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, diptheria toxoid, EBV VCA IgG, IgM, EBV-EA IgG, EBV EBNA-1 IgG/IgM, toxo IgG/IgM, rubella IgG/Igm, CMV IgG/IgM & IgG capture, HSV 1/2 IgG, HSV type specific 1&2, measles IgG/IgM, mumps IgG, high avidity dsDNA, PLAC test, others
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for clearance	—	—
Tests not available in U.S. but available in other countries	open system—any ELISA	open system—ELISA
Research-use-only assays	open system	open system
Tests in development	phosphatidylinositol IgG/IgM, phosphatidylethanolamine IgG/IgM/IgA, phosphatidylglycerol IgG/IgM, phosphatidylcholine IgG/IgM, phosphatidic acid IgG/IgM, prothrombin, C3d CIC, SMA, LKM	phosphatidylinositol IgG/IgM, phosphatidylethanolamine IgG/IgA, phosphatidylglycerol IgG/IgM, phosphatidlycholine, IgG/IgA, phosphatidic Acid, IgG/IgM, prothrombin, C3d, SMA, LKM
User-defined methods implemented for what analytes	open system	open system
Tests not available on other manufacturers' analyzers	open system	open system
Fully automated microplate system	yes	yes
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	min. strip: 1 × 8; max. full plate: 96 × 4 plates	min. strip 1 × 8; max. full plate: 96 wells × 2 plates
Methods supported/Separation methods	EIA/coated microwell	enzyme immunoassay/coated microwell
No. of different measured assays onboard simultaneously	12 assays per plate	12 assays per plate
No. of different assays programmed, calibrated at once	unlimited	unlimited
No. of user-definable (open) channels	unlimited	unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	25/96 per 4 plates	8/96
Shortest/Median onboard reagent stability/Refrigerated onboard	24 hours/n/a/no	24 hours/n/a/no
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/—	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/0	—/0 with disposable tips
Walkaway capacity in minutesutes/Specimens/Tests-assays	assay dependent/92/assay dependent	assay dependent/98/assay dependent
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	no	no/—
Uses washable cuvettes/Replacement frequency	no	no/—
Minimum specimen vol. required	200 µL	5 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/200 µL (50 µL with microtubes)	5 µL/200 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/—
Requires dedicated water system/Water consumption	no	no
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	yes/50 µL	yes/50 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/various/no	yes/—/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/—	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)	no	no
Measures No. of tests remaining/Short sample detection	no/yes	no/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/no	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	n/a	—
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	assay specific	varies
Calibrants can be stored onboard/Avg. calibration frequency	yes/once per analyte per plate	yes/each assay
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/no
How often QC required	per plate	each assay
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/no	yes/no
Automatic shutdown/Startup is programmable/Startup time	yes/—/1–2 minutes	no/yes/1–2 minutes
Stat time to completion of ß-hCG test	n/a	n/a
Time delay from ordering stat test to aspir. of sample	n/a	n/a
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	assay dependent	assay dependent
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	—/yes
Data management capability/Instrument vendor supplies LIS interface	onboard/yes (additional)	onboard/yes (additional cost)
Interfaces up and running in active user sites with	Cerner Classic & Millennium, Misys, SoftComp, Live Link, Triple G, FCC, ACA, LCW, LabLink	—
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	n/a	—
Bidirectional interface capability	yes (host query)	yes (host query)
Results transmitted to LIS as soon as test time complete	yes (manual transmission available)	yes
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	no/yes/yes	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	within 24 hours	—
Mean time between failures/To repair failures	n/a/<24 hours	n/a/<24 hours
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 minutes; weekly: n/a; monthly: n/a	daily: 5 minutes; weekly: n/a; monthly: n/a
Onboard maintenance records/Maintenance training demo module	no/no	yes/no
List price/Targeted bed size or daily volume	$57,372 (dependent on modules)/200+ beds	$33,000/100–200 beds
Annual service contract cost (24 hours/7 days)	$7,950	$6,400
Training provided w/ purchase/Advanced operator training	8 days on site, 2 days at vendor offices/yes	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 wtih drag and drop icons; large sample throughput for a 2-plate microplate system with 98 samples and continuous load feature; consumable status window shows location and volume requirements during loading

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Automated immunoassay analyzers

Part 6 of 25

See accompanying article on page 24

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Name of instrument/First year sold/Where designed	VIDAS & MiniVidas/1989/U.S.	BioPlex 2200/2006/Australia
Country where manufactured/Where reagents manufactured	Italy/France	Australia/U.S.
No. of units in clinical use in U.S./Outside U.S.	2,200/>20,000	15/3
Operational type/Model type/Sample handling system	batch, random access/benchtop/n/a	continuous random access/floor standing/rack
Dimensions in inches (H × W × D)/Instrument footprint in square feet	Vidas: 16 × 32 × 21 in; MiniVidas: 21 × 21 × 17 in/Vidas 4.5, MiniVidas 4 sq ft	58 × 72 × 34 in/12 sq ft
Tests available on instrument in U.S.	same for both instruments: *C. diff.* toxin A, chlam. Ag, chlam. blocking, rotavirus, rubella IgG, measles IgG, mumps IgG, varicella IgG, Lyme (IgG/IgM), TSH, FT4, T4, T3, hCG, estradiol, FSH, LH, prolac., progest., ferr., total IgE, digoxin, *H. pylori* IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM., quant. D-dimer, tPSA, toxo competition, testosterone	ANA Screen, anti-dsDNA (quant.), anti-SS-A, anti-SS-B, anti-SmRNP, anti-Sm, anti-RNP, anti-Scl-70, anti-Jo-I, anti-centromere B, anti-chromatin, anti-ribosomal P, EBV-nuclear antigen IgG, EBV-viral capsid antigen IgG, EBV-early antigen diffuse IgG, EBV-viral capside antigen IgM, heterophile antibodies
Tests cleared but not clinically released	—	syphilis IgG
Tests not available in U.S. but submitted for clearance	trop. I, CK-MB	none
Tests not available in U.S. but available in other countries	HBsAg, anti-HBs total, anti-HBc IgM, anti-HBc total, HBeAg, anti-HBe, HAV IgM, anti-HAV total, HIV 1/2, HIV P24II, HIV DVO, tox IgG avidity, testosterone, myoglobin, trop. I, FT3, fPSA, CEA, AFP, CA 15.3, CA 19.9, CA 125, vWT, prot. C, β-2-microglobulin, stallergy	none
Research-use-only assays	none	none
Tests in development	EBV, HbA1c, procalcitonin, *C. difficile* toxin A&B	autoantibodies for vascular, phospholipid, and gastrointestinal diseases; syphilis; toxoplasma, rubella, CMV antibodies
User-defined methods implemented for what analytes	none	none
Tests not available on other manufacturers' analyzers	all assays for use on Vidas instruments only	heterophile antibodies
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	1 test per strip	—
No. of wells in microplate	n/a	—/—
Methods supported/Separation methods	fluorescence, EIA/coated solid phase receptacle (SPR)/pipetting device	bead flow cytometric (multiplex)/magnetic particle
No. of different measured assays onboard simultaneously	Vidas: 30, MiniVidas: 12	440
No. of different assays programmed, calibrated at once	total menu	440
No. of user-definable (open) channels	0	none
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	unit dose format/30 or 60	440/100
Shortest/Median onboard reagent stability/Refrigerated onboard	n/a/n/a/no	720 hours/30 days/yes (2–8°C)
Multiple reagent configurations supported	no	no
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/assay name, lot No., sequence No., expir.	yes/kit type, lot No., kit serial No.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover	no/2 ppm
Walkaway capacity in minutesutes/Specimens/Tests-assays	assay dependent/12–30/12–30	480 minutes/280/17,600
System is open (home-brew methods can be used)/Liquid or dry system	no/dry	closed/liquid
Uses disposable cuvettes/Max. No. stored	no	yes/800
Uses washable cuvettes/Replacement frequency	no	no
Minimum specimen vol. required	100 µL	5µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	100 µL/n/a	5µL/70µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/no	no/0.5 L per hour
Noise generated	—	<67 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/n/a/no	yes/10–16mm diameter and 41–100mm height/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	n/a	yes
Onboard test auto inventory (determines vol. in container)	n/a	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/yes
Auto detection of adequate reagent or specimen	no	yes
Clot detection/Reflex testing capability	no/no	yes/yes
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	—/—
Time between initial result & reaspiration of sample for rerun	n/a	—
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	1	analyte dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/14 days	no/14 days
Multipoint calib. supported/Multiple calibs. stored for same assay	no (mftr.-determined calib. curves)/yes	yes/no
How often QC required	shortest interval: 8 hours, longest: 24 hours	24 hours/24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	no/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/remains ready	no/no/10 minutes
Stat time to completion of ß-hCG test	30 minutes	n/a
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 (—)	100/300/36 seconds
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	—/yes
Data management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	onboard/no
Interfaces up and running in active user sites with	Misys, Meditech, McKesson, Advanced Lab Systems (Path Lab), Cerner, Citation, SCC, Siemens, SAIC/CHCS, CompuLab, Antrim, Dawning, Genesys (Dynamedix), 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	n/a	—
Bidirectional interface capability	yes (broadcast download)	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/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	w/in 24 hours	—
Mean time between failures/To repair failures	Vidas: 350 days, MiniVidas: 1,000 days/<2 hours	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 10–15 minutes; weekly: 10–15 minutes; monthly: 30 minutes	daily: 5 minutes; weekly: 30–40 minutes; monthly: none
Onboard maintenance records/Maintenance training demo module	yes/yes	—/—/—
List price/Targeted bed size or daily volume	Vidas: $51,800, MiniVidas: $28,100/400 beds	$305,000/200 tests per day
Annual service contract cost (24 hours/7 days)	$2,340–$4,680 (MiniVidas 30)	inquire
Training provided w/ purchase/Advanced operator training	as needed on site, 3 days at vendor offices/yes	7 days on site, 7 days at vendor offices/yes
Distinguishing features (supplied by vendor)	features make VIDAS a good choice for routine batch testing as well as emergency stat testing; gold-standard ELISA methodology; unique 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	fully automated/random access; innovative multiplex chemistry; eFlex software with bi-directional interface

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Automated immunoassay analyzers

Part 7 of 25

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	Bio-Rad Laboratories Clinical Diagnostics Group Greg Stewart greg_stewart@bio-rad.com 4000 Alfred Nobel Dr. Hercules, CA 94547 510-724-7000 www.bio-rad.com	Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Drive Hercules, CA 94547 510-724-7000 www.bio-rad.com
Name of instrument/First year sold/Where designed	PR 3100TSC Photometer/2006/Austria	PhD System/2000/Belgium
Country where manufactured/Where reagents manufactured	Austria/U.S.	France/U.S.
No. of units in clinical use in U.S./Outside U.S.	—/—	175/300
Operational type/Model type/Sample handling system	batch/benchtop/rack	batch/benchtop/rack
Dimensions in inches (H × W × D)/Instrument footprint in square feet	7 × 13 × 13 in/2 sq ft	35 × 66 × 35 in/16 sq ft
Tests available on instrument in U.S.	contact Bio-Rad representative	ANA (EIA), anti-centromere (EIA), anti-dsDNA (EIA), anti-ENA (EIA), anti-Jo-1 (EIA), anti-SS-A (EIA), 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)
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for clearance	none	—
Tests not available in U.S. but available in other countries	ANA screen, ENA Plus screen, anti-dsDNA, anti-Jo-1, anti-SS-A, anti-SS-B, anti-Scl-70, anti-Sm, anti-Sm/RNA, anti-centromere, 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	not in U.S.	—
Tests in development	blood virus panel	—
User-defined methods implemented for what analytes	none	—
Tests not available on other manufacturers' analyzers	none	—
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	—	1
No. of wells in microplate	min. strip: 1; max. full plate: 96	min. strip: 1; max. full plate: 96
Methods supported/Separation methods	enzyme immunoassay/coated microwell	EIA/coated microwell
No. of different measured assays onboard simultaneously	1	8
No. of different assays programmed, calibrated at once	1	8
No. of user-definable (open) channels	closed until 6 months post launch	no limit
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	0/n/a	8/192
Shortest/Median onboard reagent stability/Refrigerated onboard	n/a/n/a/no	4 hours/—/no
Multiple reagent configurations supported	no	yes
Reagent container placed directly on system for use	—	requires operator prehandling/preparation
Reagents bar coded/Information in bar code	no/—	no/n/a
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/n/a	yes/—
Walkaway capacity in minutesutes/Specimens/Tests-assays	1/up to 96/1	195/184/1
System is open (home-brew methods can be used)/Liquid or dry system	yes (6 months post launch)/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/n/a
Uses washable cuvettes/Replacement frequency	no/—	no/n/a
Minimum specimen vol. required	n/a	1 µL specimen
Minimum sample vol. aspirated precisely at once/Min. dead vol.	n/a/n/a	1 µL/200 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/no
Requires dedicated water system/Water consumption	no/n/a	no
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	no/—	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/—/no	no/—/no
Sample bar-code reading capability/Autodiscrimination	no/no	yes (2 of 5 interl., codabar, codes 39 & 128)/no
Bar-code placement per NCCLS standard Auto2A	no	yes
Onboard test auto inventory (determines vol. in container)	no	no
Measures No. of tests remaining/Short sample detection	no/no	no/yes
Auto detection of adequate reagent or specimen	no	yes
Clot detection/Reflex testing capability	no/no	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	no/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	—	n/a
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	1 calibration plate	1–5
Calibrants can be stored onboard/Avg. calibration frequency	no/weekly	no/each run
Multipoint calib. supported/Multiple calibs. stored for same assay	no/no	yes/no
How often QC required	shortest interval: weekly; longest interval: monthly	each run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	—/no	no/no
Automatic shutdown/Startup is programmable/Startup time	no/no/—	no/no/5 minutes
Stat time to completion of ß-hCG test	n/a	n/a
Time delay from ordering stat test to aspir. of sample	n/a	n/a
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	—/—	n/a/n/a
Can auto transfer QC results to LIS/Onboard capability to review QC	no/no	no/yes
Data management capability/Instrument vendor supplies LIS interface	no/no	onboard/yes (included)
Interfaces up and running in active user sites with	—	—
LIS interface operates simultaneously w/ running assays	no	yes
Uses LOINC to transmit orders and results	no	can be customized
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	no	no
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/yes/yes	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	units returned for service	<24 hours
Mean time between failures/To repair failures	—/—	6 months/4 hours
Onboard error codes to facilitate troubleshooting	no	yes
Avg. time to complete maintenance by lab personnel	daily: 0; weekly: 5 minutes; monthly: 5 minutes	daily: 15 minutes; weekly: 15 minutes; monthly: 30 minutes
Onboard maintenance records/Maintenance training demo module	no/—	no/no
List price/Targeted bed size or daily volume	$5,800/5-200 tests per day	$39,000/>50 tests per day
Annual service contract cost (24 hours/7 days)	inquire	inquire
Training provided w/ purchase/Advanced operator training	1 day on site	2 days on site/no
Distinguishing features (supplied by vendor)	compact, stand-alone microplate photometer; onboard computer allowing user control of instrument and data reduction; colored touchscreen with wizard interface provides streamlined operation of all assays	accurate pipetting at 1 µL; connection of 1–10 pipetting stations together through an ethernet hub, graphical user interface; added module for IFA slide processing

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Automated immunoassay analyzers

Part 8 of 25

See accompanying article on page 24

	Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Dr. Hercules, CA 94547 510-724-7000 www.bio-rad.com	Dade Behring Inc. Colleen Grier griercm@dadebehring.com 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.dadebehring.com
Name of instrument/First year sold/Where designed	Evolis/2001/Germany	Dimension Vista 1500 Intelligent Lab System/2006/U.S.
Country where manufactured/Where reagents manufactured	Germany/U.S.	U.S./U.S. and Germany
No. of units in clinical use in U.S./Outside U.S.	165/800	—/—
Operational type/Model type/Sample handling system	batch/benchtop/rack	batch, random access continuous random access/floor standing/sample rack and aliquot plate system
Dimensions in inches (H × W × D)/Instrument footprint in square feet	37 × 44 × 30 in/10 sq ft	55⅝ × 84⅛ × 43¾ in/ 26 sq ft
Tests available on instrument in U.S.	contact Bio-Rad representative	100 total (includes vendor supported applications), 35 general chemistry, 6 thyroids, 4 cardiac, 14 TDM, 17 TDM, 23 plasma proteins, βHCG
Tests cleared but not clinically released	—	cyclosporine, homocysteine, ferritin
Tests not available in U.S. but submitted for clearance	—	B12, folate
Tests not available in U.S. but available in other countries	HIV Ab, HIV Ab/Ag, HIV Ag, HBsAg, HBc Ab, HCV Ab, HTLV-1, anti-HBs, toxo IgG, toxo IgM, rubella IgG, EBV VCA IgG, EBV VCA IgM, EBV EAD, EBV EBNA, syphilis total Ab, CMV total Ab	n/a
Research-use-only assays	not in U.S.	—
Tests in development	infectious disease & autoimmune panels	CEA, AFP, CA 125, CA 15-3, CA 19-9, fertility panel, cancer markers, plasma proteins, hormones, cardiac, infectious disease
User-defined methods implemented for what analytes	none	n/a
Tests not available on other manufacturers' analyzers	none	LOCI technology
Fully automated microplate system	yes	no
No. of each analyte performed in separate disposable unit	—	—
No. of wells in microplate	min. strip, 1; max. full plate, 96	—/—
Methods supported/Separation methods	EIA/coated microwell	chemiluminescence, enzyme immunoassay, ACMIA, EMIT, LOCI, PETINIA, NEPH/none
No. of different measured assays onboard simultaneously	4	77–100
No. of different assays programmed, calibrated at once	4	>100
No. of user-definable (open) channels	closed in U.S. market	10 (in development)
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	4/96	100/20–1,200
Shortest/Median onboard reagent stability/Refrigerated onboard	30 minutes/assay dependent/n/a	72 hours/30 days/yes
Multiple reagent configurations supported	yes	no
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	no	yes/test ID, lot No., individual-sequence No.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/no (disposable tips)	yes/<1 ppm
Walkaway capacity in minutesutes/Specimens/Tests-assays	varies by assay/180/4	>45/150/—
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes (in development)/liquid
Uses disposable cuvettes/Max. No. stored	microplates	yes/>1,500 semipermanent
Uses washable cuvettes/Replacement frequency	microplates	yes/automatic, as needed
Minimum specimen vol. required	0.2 µL	2 µL analytical, 75 µL aliquot
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL/100 µL	2 µL (GLU=1.2)/20 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no	no/20 L per hour
Noise generated	60 decibels	<70 decibels
Has dedicated pediatric sample cup/Dead vol.	no	yes/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5, 7, 10 mL/no	yes/10 × 50, 10 × 65, 13 × 65, 13 × 75, 13 × 100, 15 × 92, 16 × 100, 13 × 90/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)/yes
Bar-code placement per NCCLS standard Auto2A	no	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/yes
Auto detection of adequate reagent or specimen	no	yes
Clot detection/Reflex testing capability	yes/no	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/no	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	yes/no
Time between initial result & reaspiration of sample for rerun	n/a	—
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte	assay dependent	varies, 2–6
Calibrants can be stored onboard/Avg. calibration frequency	no/with each run	yes/30–90 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/yes
How often QC required	user determined	shortest interval: 24 hours/n/a
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes (through Unity QC program)	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/—	no/no/n/a
Stat time to completion of ß-hCG test	n/a	10 minutes
Time delay from ordering stat test to aspir. of sample	n/a	<2 minutes
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	assay dependent	200/600 (3.6 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/—	yes/yes
Data management capability/Instrument vendor supplies LIS interface	onboard/yes	onboard (Dade Behring)/no
Interfaces up and running in active user sites with	in development	Mysis
LIS interface operates simultaneously w/ running assays	no	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	n/a	—
Bidirectional interface capability	yes (broadcast download)	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	yes (StreamLab in development)
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/no/no	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	24 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: 30 minutes	daily: <5 minutes; weekly: none; monthly: 10–20 minutes
Onboard maintenance records/Maintenance training demo module	yes/no	no/no/yes
List price/Targeted bed size or daily volume	$65,000/50–400 tests per day	$552,240/>4,000 tests per day
Annual service contract cost (24 hours/7 days)	inquire	$55,000
Training provided w/ purchase/Advanced operator training	3 days in Redmond, Wash./no	5 days on site, 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	fully automated microplate system that meets the highest level of safety (positive identification of samples, reagents, microplates, clot detection, no contamination), flexibility (continuous loading of samples, reagents, and microplates), and productivity (four plates, 180 samples, four different assays can be processed simultaneously)	homogeneous LOCI technology for high sensitivity IA assays; fast analytical time, 10-minute cardiac markers, 21-minute anemia methods; ultra integrates platform that eliminates sample sharing/splitting & streamlines lab workflow

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Automated immunoassay analyzers

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See accompanying article on page 24

	Dade Behring Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.dadebehring.com	Dade Behring Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.dadebehring.com
Name of instrument/First year sold/Where designed	Stratus CS Acute Care Diagnostic System/—/—	Dimension Xpand Plus Integrated Chemistry System/2004/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S.	U.S./U.S.
No. of units in clinical use in U.S./Outside U.S.	—/—	—/—
Operational type/Model type/Sample handling system	random access/benchtop/whole blood collection tube	random access, cont. random access/floor-standing/racks
Dimensions in inches (H × W × D)/Instrument footprint in square feet	18 × 27 × 22 in/4.1 sq ft	45 × 51 × 31 in (without monitor)/10.6 sq ft
Tests available on instrument in U.S.	mass CK-MB, myoglobin, β-hCG, D-dimer, NT-pro BNP, troponin I, hsCRP	alb., calc., creatinine, dir. bilir., enzy. carb., iron, magn., phosphorus, total bilir., TIBC, IBCT, total protein, urea nitr., uric acid, CO2, chlor., potas., sodium, cholesterol, glucose, AHDL, ALDL, triglyc., thyrox. uptake, total thyrox., hemoglobin A1c, acid phosphat., alanine amino-transfer., alkaline phosph., amylase, aspartate aminotransfer., CK, CK isoenzyme, glutamyl transfer., lactic dehydrogen., lipase, pseudocholinester., ferr., free thyrox., HCG, mass CK-MB, myoglob., tPSA, fPSA, TSH, trop. I, C3, C4, CRP, high-sens. CRP, IgA, IgG, IgM, transferr., ammonia, urine CSF protein, lactic acid, prealbum., carbamazep., cyclosp., digox., digitox., gentam., lith., phenobarb., phenyt., theophy., tobram., vancomycin, valp. acid, acetamin., ethyl alcohol, salicylate; urine screens: amph., barbit., benzo., cannab., cocaine metab., ecstasy, methad., opiates, phencyc., procainami., lidocaine, n-acetyl., (see Dimension RxL Max for full general chemistry menu), triiodothy., microalb., NT-proBNP, tacrolimus
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	—	system performs heterogeneous immunoassays and general assays on single platform—complete routine chemistry menu
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	—	—
No. of wells in microplate	—	—
Methods supported/Separation methods	fluorescence, EIA, dendrimer technology/fiber matrix filter	EIA, latex particle turbidimetric, direct turbidimetric/heterogeneous, magnetic particles
No. of different measured assays onboard simultaneously	up to 4	47
No. of different assays programmed, calibrated at once	1	190
No. of user-definable (open) channels	0	10
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	n/a/unit dose test packs	47/15–360
Shortest/Median onboard reagent stability/Refrigerated onboard	n/a	72 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/assay ID, lot No., expir., calib. param.	yes/lot No., unique flex ID, stability, expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover	yes/n/a due to probe washing
Walkaway capacity in minutesutes/Specimens/Tests-assays	14 minutes to 1st result, subsequent results in 4 minutes intervals/1/up to 4	can be hours/60/>1,000
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes/reconstitutes onboard, no reagent prep required by operator/liquid
Uses disposable cuvettes/Max. No. stored	no	yes/12,000
Uses washable cuvettes/Replacement frequency	no	no/n/a
Minimum specimen vol. required	2.5 mL whole blood	2 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	n/a	2 µL/primary tube capable
Supplied with UPS (backup power)/Requires floor drain	optional/no	yes/no
Requires dedicated water system/Water consumption	no/n/a	yes/up to 2 L per hours
Noise generated	<65 decibels	<70 decibels
Has dedicated pediatric sample cup/Dead vol.	no	yes/10–20 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/4 or 5 mL/yes	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)	n/a	yes
Measures No. of tests remaining/Short sample detection	n/a/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/no	no/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	not affected	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/no	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	yes/yes
Time between initial result & reaspiration of sample for rerun	n/a	<20 seconds
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	1 Calpack	varies—3 levels for most assays
Calibrants can be stored onboard/Avg. calibration frequency	no/30–90 days same lot, new lot	yes (Na, K, Cl)/up to 90 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	shortest interval: daily electronic QC, longest: every 30 days for liquid controls	24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/30 minutes to warm up	not required
Stat time to completion of ß-hCG test	14 minutes	16 minutes
Time delay from ordering stat test to aspir. of sample	immediately	24 seconds
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	3/9	up to 83/up to 250 (14.4 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data management capability/Instrument vendor supplies LIS interface	yes/yes (additional)	optional/yes (additional)
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	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	yes
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	no/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	>225 days/2.9 hours	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: none; weekly: none; monthly: 10 minutes	daily: <5 minutes; weekly: 10 minutes; monthly: 15 minutes
Onboard maintenance records/Maintenance training demo module	no/yes	yes/yes
List price/Targeted bed size or daily volume	—/any size emergency department	—/—
Annual service contract cost (24 hours/7 days)	multiple types	multiple types
Training provided w/ purchase/Advanced operator training	3 days on site/no	5 days on site; 4 days at vendor offices/no
Distinguishing features (supplied by vendor)	whole blood collection tubes (heparin) or precentrifuged plasma (heparin/sodium citrate); onboard centrifugation; unit-dose test packs; color-coded calibrators packaged on Calpaks; 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	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

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Automated immunoassay analyzers

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	Dade Behring Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.dadebehring.com	Diamedix Corp. Pat Ahmad pat_ahmad@ivaxdiagnostics.com 2140 N. Miami Ave., Miami FL 33127 305-324-2300 www.diamedix.com
Name of instrument/First year sold/Where designed	Dimension RxL Max/Max Suite Integrated Chemistry System/2003/U.S.; Dimension RxL Integrated Chemistry System/1997/U.S.	Mago Plus Automated EIA Processor/1997/Italy (MAGO 4 to be added)
Country where manufactured/Where reagents manufactured	U.S./U.S.	Italy/U.S.
No. of units in clinical use in U.S./Outside U.S.	—/—	250/—
Operational type/Model type/Sample handling system	batch, random access, cont. random access/floor-standing/racks	batch, random access/benchtop/rack
Dimensions in inches (H × W × D)/Instrument footprint in square feet	44 × 62.5 × 30.5 in./13.2 sq ft	28 × 48 × 26 in/8.7 sq ft
Tests available on instrument in U.S.	see Dimension Xpand test menu for endocrinology, enzymes, heterogeneous immunoassays, specialty, immunology, TDM & toxicology; general chemistry test menu: album., calcium, cholest., creatinine, dir. & total bili., enzymatic CO2, glucose, HDLC, automated HDL, automated LDL, iron, magnes., phosphorus, total iron-binding capacity (& no pretreat), total protein, triglyc., urea nitrogen, uric acid, carbon dioxide, chloride, potassium, sodium	autoimmune: ANA screen, ENA screen, SSA, SSB, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, β2 glycoprotein IgG/IgM, cardiolipin screen/IgA/IgG/IgM, gliadin IgA/IgG, MPO, PR3, TPO,TG, RF; infectious disease: toxoplasma IgG/IgM, rubella IgG/IgM, CMV IgG/IgM, B burgdorferi IgG/IgM, EBV VCA IgG/IgM, EBNA IgG/IgM, EBV-EA IgG/IgM, HSV 1&2 IgG/IgM, *H. pylori* IgG, measles IgG, mumps, IgG, VZV IgG, mycoplasma IgG
Tests cleared but not clinically released	—	none
Tests not available in U.S. but submitted for clearance	—	none
Tests not available in U.S. but available in other countries	—	contact company
Research-use-only assays	—	none
Tests in development	—	none
User-defined methods implemented for what analytes	—	user defined
Tests not available on other manufacturers' analyzers	system performs heterogeneous immunoassays and general assays on a single platform—complete routine chemistry menu	none
Fully automated microplate system	no	yes
No. of each analyte performed in separate disposable unit	—	1 analyte per well
No. of wells in microplate	—	min. 1 × 8 wells; max. 96 wells
Methods supported/Separation methods	EIA, latex particle turbidimetric, direct turbidimetric/heterogeneous, magnetic particles	EIA/coated microwell (MAGO 4, EIA & IFA in parallel)
No. of different measured assays onboard simultaneously	47 (91 with optional reagent management system)	9
No. of different assays programmed, calibrated at once	190	~50 currently preprogrammed assays
No. of user-definable (open) channels	10	20 per diskette, unlimited diskette capability
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	Max=47, Max Suite=91/15–360	9/96
Shortest/Median onboard reagent stability/Refrigerated onboard	72 hours/30 days/yes (2–8°C)	—/—/no
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., expir. date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/n/a due to probe washing	no/not susceptible, continuous cleaning
Walkaway capacity in minutesutes/Specimens/Tests-assays	can be hours/60/>1,000	up to 2.5 hours—assay dependent/120/384
System is open (home-brew methods can be used)/Liquid or dry system	yes/no reagent prep required by operator for liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	yes/12,000	yes/120
Uses washable cuvettes/Replacement frequency	no/—	no/n/a
Minimum specimen vol. required	2 µL	50 µL (pediatric)
Minimum sample vol. aspirated precisely at once/Min. dead vol.	2 µL/primary tube capable	4 µL/25 µL (pediatric)
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	yes/3.2 L per hour	no/n/a
Noise generated	<70 decibels	—
Has dedicated pediatric sample cup/Dead vol.	yes/10–20 µL	yes/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5, 7, 10 mL/no	yes/11–15 mm × 75–100 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	yes	—
Onboard test auto inventory (determines vol. in container)	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/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	yes/yes	no/no
Time between initial result & reaspiration of sample for rerun	<20 seconds	n/a
Autocalibration or autocalibration alert	yes	no
No. of calibrators required for each analyte	varies—3 levels for most assays	assay dependent, 2–6
Calibrants can be stored onboard/Avg. calibration frequency	yes (Na, K, Cl)/up to 90 days	yes/per run
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/no
How often QC required	24 hours	per run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	not required	n/a/n/a/<5 minutes
Stat time to completion of ß-hCG test	16 minutes	n/a
Time delay from ordering stat test to aspir. of sample	24 seconds	n/a
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	up to 166/up to 500 (7.2 seconds)	120/360 (2.5 hours—assay dependent)
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 (DBNet–Dade Behring)/yes (additional cost)	onboard/yes (included in price)
Interfaces up and running in active user sites with	all major LIS vendors	Cerner, Misys, 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	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	2–8 hours	24 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: none
Onboard maintenance records/Maintenance training demo module	yes/yes	no/no
List price/Targeted bed size or daily volume	—/—	$62,000/all bed sizes, all test volumes
Annual service contract cost (24 hours/7 days)	multiple types	service during normal business hours included in reagent rental agreement
Training provided w/ purchase/Advanced operator training	5 days on site, 4 days at vendor offices/yes	1–2 days on site/yes
Distinguishing features (supplied by vendor)	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	FDA-cleared system (instruments and reagents); moderate complexity; strip by strip timing, accommodates primary reagent packaging

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Automated immunoassay analyzers

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	Diamedix Corp.	DiaSorin Inc.
	Bob Uleski bob_uleski@ivaxdiagnostics.com	**Dawn Franzmeier** dawn.franzmeier@diasorin.com
	2140 N. Miami Ave.	**1951 Northwestern Ave.**
	Miami, FL 33127	**Stillwater, MN 55082**
	305-324-2300 www.diamedix.com	**800-328-1482/651-439-9710** www.diasorin.com
Name of instrument/First year sold/Where designed	**PARSEC* System Automated EIA Processor/2005/Italy**	**ETI-Max 3000/2002/Germany**
Country where manufactured/Where reagents manufactured	**Italy/U.S.**	**Germany/U.S., Italy**
No. of units in clinical use in U.S./Outside U.S.	***not for sale in U.S.—pending FDA 510(k) clearance**	**165/750**
Operational type/Model type/Sample handling system	**continuous random access/benchtop/racks**	**batch, random access/benchtop/rack**
Dimensions in inches (H × W × D)/Instrument footprint in square feet	**36 × 58 × 29 in/11.6 sq ft**	**40 × 45 × 30 in/10 sq ft**
Tests available on instrument in U.S.	**autoimmune: ANA Screen, ENA Screen, SSA, SSB, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, β2 glycoprotein IgG/IgM, cardiolipin screen/IgA/IgG/IgM, gliadin IgA/IgG, MPO, PR3, TPO,TG, RF; infectious disease: toxoplasma IgG/IgM, rubella IgG/IgM, CMV IgG/IgM, B burgdorferi IgG/IgM, EBV VCA IgG/IgM, EBNA IgG/IgM, EBV-EA IgG/IgM, HSV 1&2 IgG/IgM, *H. pylori* IgG, measles IgG, mumps, IgG, 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, *H. pylori* IgG, Lyme IgG & IgM combo, HSV I/II IgG, Trep-Sure syphilis IgG, 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	**none**	**none**
Tests not available in U.S. but submitted for clearance	**none**	**none**
Tests not available in U.S. but available in other countries	**contact company**	**none**
Research-use-only assays	**none**	**none**
Tests in development	**mycoplasma IgM**	**none**
User-defined methods implemented for what analytes	**user defined**	**n/a**
Tests not available on other manufacturers' analyzers	**none**	**HBeAg, anti-HBe**
Fully automated microplate system	**yes**	**yes**
No. of each analyte performed in separate disposable unit	**1 analyte per well**	**—**
No. of wells in microplate	**min. 1 × 8 wells; max. 96 wells**	**min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate up to 7 plates at a time**
Methods supported/Separation methods	**enzyme immunoassay/coated microwell**	**EIA/coated microplate**
No. of different measured assays onboard simultaneously	**unlimited**	**open**
No. of different assays programmed, calibrated at once	**unlimited**	**open**
No. of user-definable (open) channels	**unlimited**	**unlimited**
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	**unlimited/96**	**volume dependent**
Shortest/Median onboard reagent stability/Refrigerated onboard	**—/—/no**	**no/no/no**
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., component, exp. date, date of manufacture, shelf life**	**yes/—**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**no/not susceptible, disposable tips**	**yes/no**
Walkaway capacity in minutesutes/Specimens/Tests-assays	**up to 2.5 hours—assay dependent/unlimited/unlimited**	**assay dependent/180/variable**
System is open (home-brew methods can be used)/Liquid or dry system	**yes/liquid**	**yes/liquid**
Uses disposable cuvettes/Max. No. stored	**yes/unlimited**	**no**
Uses washable cuvettes/Replacement frequency	**no/n/a**	**no**
Minimum specimen vol. required	**50 µL (pediatric)**	**10 µL**
Minimum sample vol. aspirated precisely at once/Min. dead vol.	**5 µL/100 µL (pediatric)**	**10 µL/200 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes/no**	**yes/no**
Requires dedicated water system/Water consumption	**no/n/a**	**no/no**
Noise generated	**—**	**—**
Has dedicated pediatric sample cup/Dead vol.	**yes/—**	**no**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/11–15 mm × 75–100 mm/no**	**yes/multiple/no**
Sample bar-code reading capability/Autodiscrimination	**yes (2 of 5 interl., codabar, codes 39 & 128, plus others)/yes**	**yes/yes**
Bar-code placement per NCCLS standard Auto2A	**—**	**yes**
Onboard test auto inventory (determines vol. in container)	**—**	**yes**
Measures No. of tests remaining/Short sample detection	**yes/yes**	**yes/yes**
Auto detection of adequate reagent or specimen	**—**	**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	**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	**n/a**	**n/a**
Autocalibration or autocalibration alert	**no**	**no**
No. of calibrators required for each analyte	**assay dependent, 2–6**	**varies per kit**
Calibrants can be stored onboard/Avg. calibration frequency	**yes/per run**	**no/each run**
Multipoint calib. supported/Multiple calibs. stored for same assay	**yes/yes**	**yes/no**
How often QC required	**per run**	**per run**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
Automatic shutdown/Startup is programmable/Startup time	**no/n/a/<10 minutes**	**no/yes/5 minutes**
Stat time to completion of ß-hCG test	**n/a**	**n/a**
Time delay from ordering stat test to aspir. of sample	**n/a**	**n/a**
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	**assay and configuration dependent**	**assay dependent**
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 (included in price)**	**yes/yes**
Interfaces up and running in active user sites with	**n/a**	**yes**
LIS interface operates simultaneously w/ running assays	**yes**	**yes**
Uses LOINC to transmit orders and results	**no**	**—**
How labs get LOINC codes for reagent kits	**n/a**	**—**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes**
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	**yes/yes/yes**	**no/no/no**
Can order (via modem) malfunctioning part(s) w/o operator	**no**	**no**
On-site response time of service engineer	**24 hours**	**24 hours**
Mean time between failures/To repair failures	**—/—**	**n/a/n/a**
Onboard error codes to facilitate troubleshooting	**yes**	**yes**
Avg. time to complete maintenance by lab personnel	**daily: none; weekly: none; monthly: none**	**daily: 5 minutes; weekly: 30 minutes**
Onboard maintenance records/Maintenance training demo module	**n/a/n/a**	**yes/no**
List price/Targeted bed size or daily volume	**$110,000 for basic system/all bed sizes, all test volumes**	**$75,000/medium- and large-sized hospitals**
Annual service contract cost (24 hours/7 days)	**service during normal business hours included in reagent rental agreement**	**$8,500 (additional $4,500 for 24/7)**
Training provided w/ purchase/Advanced operator training	**4-5 days on site; at vendor offices as requested/yes**	**3 days/yes**
Distinguishing features (supplied by vendor)	**scalable to workload, continuous loading, needs no blank wells, remote diagnostics, accomodates 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**

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Automated immunoassay analyzers

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	DiaSorin Inc. **Julie Kordosky** julie.kordosky@diasorin.com 1951 Northwestern Ave. Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com	Grifols USA Inc. **Patricia Silver** patricia.silver@grifols.com 8784 NW 18th Terrace Miami, FL 33172 800-379-0957 www.grifolsusa.com
Name of instrument/First year sold/Where designed	Liaison/1997/Germany	Triturus/1999/Spain
Country where manufactured/Where reagents manufactured	Germany/U.S., Italy	Spain/U.S., Germany
No. of units in clinical use in U.S./Outside U.S.	100/1,700	>200/>1,500
Operational type/Model type/Sample handling system	batch, continuous random access/benchtop/rack	batch, random access & cont. random access/benchtop/universal carousel
Dimensions in inches (H × W × D)/Instrument footprint in square feet	63 × 136 × 66 cm/9.9 sq ft	28.3 × 41.3 × 34.3 in/10 sq ft
Tests available on instrument in U.S.	25 hydroxyvitamin D, intact PTH, EBV IgM, EBNA IgG, VCA IgG, EA IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM, treponema, 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, oncology markers, hepatitis, and HIV profiles
Tests cleared but not clinically released	—	n/a
Tests not available in U.S. but submitted for clearance	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, Sangtec 100, AFP, HCG, ferritin, TSH, FT3, FT4, T3, T4, 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, tTG IgA, testosterone, NSE, progesterone, estradiol, VZV IgM, calcitonin, ANA screen, ENA screen, direct renin	n/a
Tests not available in U.S. but available in other countries		n/a
Research-use-only assays	—	n/a
Tests in development	1,25 dihydroxy vitamin D, osteocalcin, BSAP, cardiolipin IgG, IgM, IgA, hGH, HSV-1 IgG	n/a
User-defined methods implemented for what analytes	n/a	n/a
Tests not available on other manufacturers' analyzers	S-100, 25 hydroxy vitamin D	n/a
Fully automated microplate system	no	yes
No. of each analyte performed in separate disposable unit	n/a	8
No. of wells in microplate	n/a/n/a	min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate 4 plates at a time
Methods supported/Separation methods	chemiluminescence/magnetic particle	EIA/coated microwell, onboard shaker, 4 individually temperature-controlled incubators
No. of different measured assays onboard simultaneously	15	1–8 tests on 1–4 plates
No. of different assays programmed, calibrated at once	15	8 assays
No. of user-definable (open) channels	0	unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	15/100	8/96
Shortest/Median onboard reagent stability/Refrigerated onboard	7/28 days/yes (12°C)	n/a/n/a/no
Multiple reagent configurations supported	no	yes
Reagent container placed directly on system for use	yes	minimal operator preparation, handling
Reagents bar coded/Information in bar code	yes/all lot information	no
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/no	yes/no
Walkaway capacity in minutesutes/Specimens/Tests-assays	75/144/1,500	180/92/8
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	yes/720	no
Uses washable cuvettes/Replacement frequency	no	no
Minimum specimen vol. required	assay dependent	200 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/200 µL	2 µL/300 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no but has external waste port to drain into sink or floor drain
Requires dedicated water system/Water consumption	no	no/n/a
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	yes/75 µL	yes/50 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/—/no	yes/12, 13, 14, 16 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	—	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/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
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/no	yes/yes
Time between initial result & reaspiration of sample for rerun	2 minutes	n/a
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte	2	1–14
Calibrants can be stored onboard/Avg. calibration frequency	yes/28 days	no/check every month
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/yes
How often QC required	24 hours	each run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	no/no
Automatic shutdown/Startup is programmable/Startup time	no/no/2 minutes	yes/yes/1–2 minutes
Stat time to completion of ß-hCG test	n/a	system is open, depends on reagent methodology
Time delay from ordering stat test to aspir. of sample	2 minutes	n/a
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	—	depends on reagent methodology
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data management capability/Instrument vendor supplies LIS interface	no/yes (additional)	yes/yes (additional)
Interfaces up and running in active user sites with	—	all major LISs
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	—	yes
How labs get LOINC codes for reagent kits	—	LIS—unidirectional or bidirectional
Bidirectional interface capability	yes (host query)	yes (host query & 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/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	24 hours	within 24 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: 10 minutes; weekly: 20 minutes; monthly: 30 minutes	daily: 5–20 minutes; weekly: n/a; monthly: n/a
Onboard maintenance records/Maintenance training demo module	no/no	yes (includes audit trail of who replaced parts)/yes
List price/Targeted bed size or daily volume	$125,000/—	$69,000/300+ or higher
Annual service contract cost (24 hours/7 days)	inquire	varies, multiple types available
Training provided w/ purchase/Advanced operator training	3 days on site/yes	yes/yes
Distinguishing features (supplied by vendor)	benchtop analyzer with high throughput; unique menu offering; up to 15 assays onboard, reagent integral ready to use	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

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	Hycor Biomedical Inc. cs@hycorbiomedical.com 7272 Chapman Ave. Garden Grove, CA 92841 714-933-30000 www.hycorbiomedical.com	Inverness Medical Professional Diagnostics David Curtis david.curtis@invmed.com 2 Research Way Princeton, NJ 08540 800-257-9525 ext. 8081 www.invernessmedicalpd.com
Name of instrument/First year sold/Where designed	HY•TEC 288 *PLUS*/outside U.S. 1998, U.S. 1999/Netherlands	AIMS/2007/Switzerland
Country where manufactured/Where reagents manufactured	Netherlands/U.S., Scotland	Switzerland/U.S.
No. of units in clinical use in U.S./Outside U.S.	47/156	—/—
Operational type/Model type/Sample handling system	random batches/benchtop/rack-robotics	batch/benchtop/rack
Dimensions in inches (H × W × D)/Instrument footprint in square feet	29.5 × 42.5 × 27.5 in/8 sq ft	35 × 67 × 40 in/—
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, cardiolipin scr.; 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
Tests cleared but not clinically released	anti-tissue transglutaminase IgA and IgG	—
Tests not available in U.S. but submitted for clearance	none	HSV (type specific HSV-1, HSV-2), celiac IgG (TTG, gliadin), celiac IgA (TTG, gliadin)
Tests not available in U.S. but available in other countries	specific IgG, cardiolipin IgA, ssDNA, total rheumatoid factor, anti-phosphatidyl serine scr., anti-phosphatidyl serine IgG, IgM, anti-tissue transglutaminase IgA and IgG	—
Research-use-only assays	none	HIV blot
Tests in development	ANCA profile, centromere, CCP	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	yes	yes
No. of each analyte performed in separate disposable unit	8 (1 analyte per well; multiple analytes per well/screens; up to 8 analytes per run)	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	EIA, tube-based & microplate-based assays/activated cellulose & coated well	enzyme immunoassay, multiflexing/bead, coated microwell
No. of different measured assays onboard simultaneously	varies by assay, up to 288 allergens or 8 autoimmune	4
No. of different assays programmed, calibrated at once	multiple	multiple
No. of user-definable (open) channels	unlimited	unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	varies by assay, up to 288 allergens or 8 autoimmune	4/96
Shortest/Median onboard reagent stability/Refrigerated onboard	8 hours/12 hours/no	—/—/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	no	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/<1 part in 10,000	yes/—
Walkaway capacity in minutesutes/Specimens/Tests-assays	assay dependent/100/288	assay dependent/240/4
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	open/liquid
Uses disposable cuvettes/Max. No. stored	no	no/—
Uses washable cuvettes/Replacement frequency	no	no/—
Minimum specimen vol. required	10 µL, 110 µL w/ dead vol.	210 µL based on 16 mm tube
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL–50 µL, assay dependent//100 µL	10 µL/200 µL based on 16 mm tube
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/—/no	yes/10 × 16 mm outer dimensions/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/n/a	yes (2 of 5 interl., codabar, codes 39 & 128)/—
Bar-code placement per NCCLS standard Auto2A	no	—
Onboard test auto inventory (determines vol. in container)	yes	yes
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	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	—/—
Time between initial result & reaspiration of sample for rerun	n/a	—
Autocalibration or autocalibration alert	yes	—
No. of calibrators required for each analyte	1–5	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/monthly	—
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	—
How often QC required	every assay	every assay
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	—/yes
Automatic shutdown/Startup is programmable/Startup time	yes/no/2–3 minutes	yes/yes/10 minutes
Stat time to completion of ß-hCG test	n/a	—
Time delay from ordering stat test to aspir. of sample	n/a	—
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	n/a	assay dependent/—/—
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	—/yes
Data management capability/Instrument vendor supplies LIS interface	onboard/optional	—/yes
Interfaces up and running in active user sites with	25	—
LIS interface operates simultaneously w/ running assays	no	no
Uses LOINC to transmit orders and results	no	—
How labs get LOINC codes for reagent kits	n/a	—
Bidirectional interface capability	yes	yes (broadcast download)
Results transmitted to LIS as soon as test time complete	optional	—
Interface available (or will be) to auto specimen handling system	no	—
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/no	no/—/—
Can order (via modem) malfunctioning part(s) w/o operator	no	—
On-site response time of service engineer	48 hours	24–48 hours
Mean time between failures/To repair failures	7 months/4 hours	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 10–15 minutes; weekly: 20–25 minutes; monthly: 20–25 minutes	daily: 15 minutes; weekly: 20 minutes; monthly: 20 minutes
Onboard maintenance records/Maintenance training demo module	yes (includes audit trail of who replaced parts)/yes	no/—
List price/Targeted bed size or daily volume	$55,000/all sites, variable test vols.	$149,900/>150 beds
Annual service contract cost (24 hours/7 days)	$5,500	$18,500
Training provided w/ purchase/Advanced operator training	3 days on site/yes	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

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Automated immunoassay analyzers

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	Olympus America Inc. Frank Bartholf frank.bartholf@olympus.com 3500 Corporate Pkwy., Center Valley, PA 18034 484-896-5000 www.olympusamerica.com	Olympus America Inc. Lorraine Damico lorraine.damico@olympus.com 3500 Corporate Pkwy., Center Valley, PA 18034 484-896-5000 www.olympusamerica.com
Name of instrument/First year sold/Where designed	AU400e/2002; AU400/1999/Japan	AU3000i Immunoassay System/2007/Japan
Country where manufactured/Where reagents manufactured	Japan/U.S., Ireland	Japan/Ireland
No. of units in clinical use in U.S./Outside U.S.	>670/>2,500	0/5
Operational type/Model type/Sample handling system	cont. random access/floor-standing/rack & turntable	continuous random access/floor standing/racks
Dimensions in inches (H × W × D)/Instrument footprint in square feet	47.6 × 57.1 × 29.9 in/11.9 sq ft	57 × 67 × 47 in/22 sq ft plus computer
Tests available on instrument in U.S.	α1-acid glycoprotein, α1-antitrypsin, anti-streptolysin O, apolipo. A1 & B, β-2-microglobulin, CRP, high-sensitivity CRP, CRP for pediatrics, C3 & C4 complement, ferr., haptoglobin, immunogl. A, G, M, microalbumin, prealb., rheum. factor, transferrin, acetamin., amikacin, caffeine, carbamaz., digoxin, disopyramide, ethosux., gentamicin, lidocaine, methotrexate, N-acetylprocain., phenobarb., phenytoin, primidone, procain., quinidine, salicylate, theoph., tobramycin, valp. acid, vancomycin, amphet., barb., benzodiazep., cannab., cocaine metab., ethanol, LSD, methadone, methaq., opiate, PCP, propoxyphene, tox barb., tox benzo., tox tricyc., T-uptake, T4 thyrox.; also, general chemistries, enzymes, direct HDL & direct LDL	TSH, T3, LH, FSH
Tests cleared but not clinically released	ceruloplasmin, HbA1c, lithium, cholinesterase, urinary protein, oxycodone, G6PD, estriol	—
Tests not available in U.S. but submitted for clearance	D-dimer	T4, fT4
Tests not available in U.S. but available in other countries	cotinine	AFP, fT3
Research-use-only assays	none	—
Tests in development	none	T-uptake, CEA, PSA, fPSA, βHCG, βHcG-stat, PROL, E2, PROG, testosterone, troponin I, TnI-stat, BNP, CKMB, CKMB-stat, ferritin, folate, B12, vit. D, PTH, IgE, OV-TC (CA125), BR-TC (CA15-3), GI-TC (CA19-9)
User-defined methods implemented for what analytes	fructosamine	—
Tests not available on other manufacturers' analyzers	none	TSH, 4th generation
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	n/a	—
No. of wells in microplate	n/a	—
Methods supported/Separation methods	EIA, photometric, potentiometric, calc. results/none (all homogeneous)	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	>40	24
No. of different assays programmed, calibrated at once	99	180
No. of user-definable (open) channels	95	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	76/100–6,160	24/assay dependent (100 or 200)
Shortest/Median onboard reagent stability/Refrigerated onboard	168 hours/60 days/yes (4–12°C)	336 hours/21 days/yes (4–12°)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	requires minimal operator prehandling/preparation
Reagents bar coded/Information in bar code	yes/reag. ID, lot No., bottle No., expir.	yes/lot specific master calibration information; calibrator set points; internal QC targets; product name, lot information, expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/n/a	no/no, disposable tips used to prevent carryover
Walkaway capacity in minutesutes/Specimens/Tests-assays	variable/up to 102/8,058	up to 240/300/1,000
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	no	yes/1,000 with on-the-fly bulk refill
Uses washable cuvettes/Replacement frequency	yes/permanent	no
Minimum specimen vol. required	2 µL per test	10–100 µL (test dependent)
Minimum sample vol. aspirated precisely at once/Min. dead vol.	2 µL/25 µL	10 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	optional/yes	yes/no
Requires dedicated water system/Water consumption	yes/20 L per hour @ peak consump.	yes/11 gallons per hour at max. throughput
Noise generated	<65 decibels	<65 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/pediatric, 5 mL, 7 mL, 10 mL/no	yes/11.5–16 mm (width) and 55–102 mm (height); microcups/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	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	yes/yes	yes/no
Time between initial result & reaspiration of sample for rerun	varies by run size	15 minutes
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	1–6	1 or 2 point master curves (test dependent)
Calibrants can be stored onboard/Avg. calibration frequency	yes/14 days	yes/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	user-defined	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/24 hour availability	yes/yes/~5 minutes
Stat time to completion of ß-hCG test	n/a	18 minutes
Time delay from ordering stat test to aspir. of sample	<1 minute	300 seconds
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	133.3/400 (9 seconds)	80/240 (15 seconds after 1st result with 300 sample tube continuous loading)
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	Cerner, Antrim, CCA, Chemware, Dawning, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Orchard, Citation	—
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	n/a	—
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	—
Mean time between failures/To repair failures	>30 weeks/<24 hours	TBD/TBD
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 12 minutes; monthly: 45 minutes	daily: <5 minutes; weekly: <30 minutes; monthly: 10 minutes
Onboard maintenance records/Maintenance training demo module	yes (incl. audit trail of who replaced parts)/yes	yes/yes
List price/Targeted bed size or daily volume	$130,000/200–2,000 tests per day (depending on menu)	$274,870 including ancillaries/>200—volume varies (contact Olympus rep)
Annual service contract cost (24 hours/7 days)	$13,990	$19,500
Training provided w/ purchase/Advanced operator training	5 days on site, 5 days at vendor offices/yes	5 days on site, 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	open reagent system; 125-test menu includes general chemistry and homogeneous immunoassay; onboard automation to repeat, reflex, or predilute samples; true random access and fast throughput; family of standardized analyzers including AU640, AU640e, AU2700, and AU5400	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

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Automated immunoassay analyzers

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	Ortho-Clinical Diagnostics, a Johnson & Johnson Company Russ Potter rpotter3@ocdus.jnj.com 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 or 908-218-1300 www.orthoclinical.com	Ortho-Clinical Diagnostics, a Johnson & Johnson Company Russ Potter rpotter3@ocdus.jnj.com 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 or 908-218-8674 www.orthoclinical.com
Name of instrument/First year sold/Where designed	VITROS ECi Immunodiagnostic System/1997/U.S.	VITROS ECiQ Immunodiagnostic System/2004/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.K.	U.S./U.K.
No. of units in clinical use in U.S./Outside U.S.	>3,000 worldwide	>3,000 worldwide
Operational type/Model type/Sample handling system	cont. random access/floor standing/universal sample trays (circular) accommodate primary & secondsondary containers without need for adapters	cont. random access/floor standing/circular universal sample trays accommodate primary & secondsondary containers without need for adapters
Dimensions in inches (H × W × D)/Instrument footprint in square feet	51 × 44 × 29 in/8.9 sq ft	51 × 44 × 29 in/8.9 sq ft
Tests available on instrument in U.S.	3rd-gen. TSH, TT3, TT4, FT3, FT4, T3-uptake, total ß-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	3rd-gen. TSH, TT3, TT4, FT3, FT4, T3-uptake, total ß-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
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for clearance	aHIV 1&2	aHIV 1&2
Tests not available in U.S. but available in other countries	fβ–hCG, a-HBe, HBeAg, a-HIV I&II, toxo IgG, rubella IgM	a-HBe, HBeAg, a-HIV I&II, free β–hCG, toxo IgG, rubella IgM
Research-use-only assays	none	none
Tests in development	toxo. IgM, CMV IgG, CMV IgM	toxo. IgM, CMV IgG, CMV IgM
User-defined methods implemented for what analytes	none	none
Tests not available on other manufacturers' analyzers	NTx	N-telopeptide
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/Separation methods	chemiluminescence (enhanced)/individual coated microwell	chemiluminescence (enhanced)/individual coated microwell
No. of different measured assays onboard simultaneously	20	20
No. of different assays programmed, calibrated at once	20 programmed & calibrated at once; up to 25 lots calibrated per assay	20; up to 25 lots calibrated per assay
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	20/100	20/100
Shortest/Median onboard reagent stability/Refrigerated onboard	56 days/56 days/yes (2°–8°C)	56 days/56 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/test ID, expir., lot No., pack ID	yes/test ID, expir., lot No., pack ID
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	—/zero carryover	yes/zero carryover
Walkaway capacity in minutesutes/Specimens/Tests-assays	360/60/400	360/60/400
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	no	no
Minimum specimen vol. required	10 µL	10 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL/80 µL	10 µL/80 µL
Supplied with UPS (backup power)/Requires floor drain	no but it is available/no	no, but it is available/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	60 decibels	60 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/mult. ped., microtainers & cups, 5mL, 7mL, 10mL on same univ. sample tray/no	yes/mult. ped., microtainers & cups, 5mL, 7mL, 10mL on same univ. sample tray/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128, & ISBT 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128, & ISBT 128)/yes
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/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
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	no/no	no/no
Time between initial result & reaspiration of sample for rerun	assay dependent	assay dependent
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	1–3	1–3
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	once per 24 hours	once per 24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/immediate upon completion of last sample metering	yes/yes/immediate upon completion of last sample metering
Stat time to completion of ß-hCG test	24 minutes	24 minutes
Time delay from ordering stat test to aspir. of sample	immediate upon completion of last sample metering	immediate upon completion of last sample metering
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	30/90 (40 seconds)	30/90 (40 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	onboard/no	onboard/no
Interfaces up and running in active user sites with	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	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
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	yes	yes
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	yes (broadcast download)	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	yes (all systems)	yes (all systems)
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes no	yes/yes/yes no
Can order (via modem) malfunctioning part(s) w/o operator		
On-site response time of service engineer	<4 hours (contract dependent)	<4 hours (contract dependent)
Mean time between failures/To repair failures	—/dependent on corrective action	dependent on corrective action/dependent on corrective action
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: <5 minutes; weekly: <30 minutes; monthly: <10 minutes	daily: <5 minutes; weekly: <30 minutes; monthly: <10 minutes
Onboard maintenance records/Maintenance training demo module	no/yes	no/yes
List price/Targeted bed size or daily volume	$140,000/flexible for majority of customer demand	$150,000/flexible for majority of customer demand
Annual service contract cost (24 hours/7 days)	varies w/ service level choices	varies w/ service level choices
Training provided w/ purchase/Advanced operator training	3.5 days at vendor offices/yes, as needed on site	as needed on site, 3.5 days at vendor offices/—
Distinguishing features (supplied by vendor)	uses proprietary Intellicheck Technology to perform, monitor, document, and verify diagnostic checks throughout sample and assay processing to significantly reduce the potential of misreported results; exclusive IntelliReport providing real-time status and traceability on the quality of reported results; uses patented Enhanced Chemiluminescence, MicroWell technology; provides simple to use, fully automated, true random access, stat testing for routine and specialty immunodiagnostic testing	uses proprietary Intellicheck Technology to perform, monitor, document, and verify diagnostic checks throughout sample and assay processing to reduce the potential of misreported results; exclusive IntelliReport providing real-time status and traceability on the quality of reported results; uses patented Enhanced Chemiluminescence, MicroWell technology; provides simple to use, fully automated, true random access, stat testing for routine and specialty immunodiagnostic testing; features enhanced ergonomics

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Automated immunoassay analyzers

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	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	ImmunoCAP 250 system/2004/Japan, Sweden	ImmunoCAP 1000 system/2003/Japan, Sweden
Country where manufactured/Where reagents manufactured	Japan, Sweden/Sweden	Japan, Sweden/Sweden
No. of units in clinical use in U.S./Outside U.S.	150/600	150/600
Operational type/Model type/Sample handling system	continuous random access/floor standing/racks	continuous random access/floor standing/racks
Dimensions in inches (H × W × D)/Instrument footprint in square feet	73 × 50 × 30 in + 26 in wide computer stand/—	83 × 71 × 40 in + 26 in wide computer stand/—
Tests available on instrument in U.S.	more than 550 ImmunoCAP specific IgE tests, ImmunoCAP total IgE, and ImmunoCAP specific IgG** tests, ELIA autoimmune products, tTg (tissue transglutaminase), IgA, IgG, gliadin IgA, IgG, CCP (cyclic citrullinated peptide)	more than 550 ImmunoCAP specific IgE tests, ImmunoCAP total IgE, and ImmunoCAP specific IgG** tests
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 is for investigational use only	**specific IgG is for investigational use only
Tests in development	—	—
User-defined methods implemented for what analytes	—	—
Tests not available on other manufacturers' analyzers	Phadia AB ImmunoCAP and ELIA assays	Phadia AB ImmunoCAP 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	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells
No. of different measured assays onboard simultaneously	3 methods	3 methods
No. of different assays programmed, calibrated at once	not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory	not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory
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	3/400 or 100 depending on the conjugate type
Shortest/Median onboard reagent stability/Refrigerated onboard	5 days/1 year/yes (2–8°C)	5 days/1 year/yes (2–8°C)
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/—	no/zero carryover (disposable sample tips)
Walkaway capacity in minutesutes/Specimens/Tests-assays	470/50 simultaneously/370 tests	460/200 simultaneously/2,400 tests
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	n/a	n/a
Minimum specimen vol. required	40 µL	40 µL per test
Minimum sample vol. aspirated precisely at once/Min. dead vol.	40 µL/40–200 µL (varies with tube type)	40 µL/40–200 µL (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/10 L
Noise generated	65 dBA	68 dBA
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/10–17 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	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	no/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	100 minutes
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/30 minutes unattended
Stat time to completion of ß-hCG test	n/a	n/a
Time delay from ordering stat test to aspir. of sample	6 minutes	6 minutes
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	20 specimens/60 (100 minutes to first result, then 1 result per 60 seconds)	80 specimens/240 (100 minutes to first result, then 1 result per 15 seconds)
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)
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	n/a	n/a
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	<24 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: 1 minutes; weekly: 10 minutes; monthly: 15 minutes	daily: 1 minutes; weekly: 10 minutes; monthly: 15 minutes
Onboard maintenance records/Maintenance training demo module	yes/—	yes/—
List price/Targeted bed size or daily volume	$75,000/>20,000–95,000 tests per year	$235,000/>95,000 tests per year
Annual service contract cost (24 hours/7 days)	—	—
Training provided w/ purchase/Advanced operator training	3.5 days at vendor offices/yes	4.5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	provides advanced and 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	provides advanced and 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

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

Automated immunoassay analyzers

Part 17 of 25

See accompanying article on page 24

	Phadia	Randox Laboratories Ltd.
	Nicole Lampas nicole.lampas@phadia.com 4169 Commercial Ave. Portage, MI 49002 800-346-4364 www.phadia.us	David Ferguson evidence.support@randox.com Diamond Road Crumlin, County Antrim, BT29 40Y +44 28 94 422413 www.randox.com
Name of instrument/First year sold/Where designed	ImmunoCAP 100E system/1995/Sweden	Evidence System/2004/United Kingdom
Country where manufactured/Where reagents manufactured	Sweden/Sweden	United Kingdom/United Kingdom
No. of units in clinical use in U.S./Outside U.S.	600/12,000	—/—
Operational type/Model type/Sample handling system	batch/benchtop/carousel	batch/floor standing/carousel
Dimensions in inches (H × W × D)/Instrument footprint in square feet	18 × 28 × 24 in + computer/—	68 × 78 × 39 in/35.75 sq ft
Tests available on instrument in U.S.	more than 550 ImmunoCAP specific IgE tests, ImmunoCAP total IgE, gliadin, ImmunoCAP specific IgG tests**, ECP**, trytase**, ELIA, autoimmune products, tTg (tissue transglutaminase) IgA, IgG, gliadin IgA, IgG, CCP (cyclic citrullinated peptide)	cocaine, methamphetamine, amphetamine, methadone, PCP, opiates, cannabinoids, barbiturates, benzodiazepine, progesterone, prolactin, LH, FSH, estradiol
Tests cleared but not clinically released	—	none
Tests not available in U.S. but submitted for clearance	—	MDMA, LSD, fentanyl, propoxyphene, methaqualone, oxycodone, oxymorphone, hydromorphone, ketamine, buprenorphine
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
Research-use-only assays	**ImmunoCAP specific IgG tests, ECP, trytase are investigational use only (IUO)	GPBB, FABP, CA III, VCAM-1, ICAM-1, E-selectin, P-selectin, L-selectin, IL-2, IL-4, IL-6, IL-8, IL-10, VEGF, TNFa, IFNg, IL-1a, IL-1b, MCP-1, EGF, GFAP, S100B, hsCRP, BDNF, D-dimer, NSE, NGAL, vWF, thrombomodulin, sIL-2Ra, sIL-6r, sTNFRI, sTNFRII, MMP-9
Tests in development	—	IL1-1Ra, IGF-1 free, RANTES, PDGF-AA, PDGF-BB, eotaxin, IP-10, IL-12p70, IL-3, IL-5, IL-7, IL-13, IL-15, Il-23, GM-CSF, MIP-1a, TNFb, maternal screening array, sepsis array, endocrine array, metabolic arrays, and additional drugs of abuse array
User-defined methods implemented for what analytes	—	none
Tests not available on other manufacturers' analyzers	Phadia AB ImmunoCAP and ELIA assays	GPBB, FABP, CA III, VCAM-1, ICAM-1, E-selectin, P-selectin, L-selectin, IL-2, IL-4, VEGF, IFNg, IL-1a, MCP-1, EGF, BDNF, NGAL, thrombomodulin, sIL-6r, sTNFRI, sTNFRII, MMP-9
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/Separation methods	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells	chemiluminescence/—
No. of different measured assays onboard simultaneously	4	8
No. of different assays programmed, calibrated at once	7	12
No. of user-definable (open) channels	0, closed system	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	48–96 depending on the conjugate type	96/360
Shortest/Median onboard reagent stability/Refrigerated onboard	n/a	assay dependent 1–14 days/yes (2–8ºC)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes (wash solution requires preparation)	yes
Reagents bar coded/Information in bar code	yes/product name, lot No., expiration date	yes/product component, size, lot No., expir. date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/—	no/—
Walkaway capacity in minutesutes/Specimens/Tests-assays	180 minutes/varies with analyte/48	100/180/540–1,980
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	no/n/a	no/n/a
Uses washable cuvettes/Replacement frequency	n/a/n/a	no/n/a
Minimum specimen vol. required	40 µL per test	7 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	40 µL/40–200 µL (varies with tube type)	7 µL/70–350 µL (varies with cup type)
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no
Requires dedicated water system/Water consumption	no/1 L per run	no/n/a
Noise generated	—	n/a
Has dedicated pediatric sample cup/Dead vol.	no	no/n/a
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10–16 mm × 50–105 mm/no	yes/12 mm, 16 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	yes
Onboard test auto inventory (determines vol. in container)	no	yes
Measures No. of tests remaining/Short sample detection	no/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/yes	no/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	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	2.5 hours–batch run	—
Autocalibration or autocalibration alert	yes	no
No. of calibrators required for each analyte	6 per analyte for calibration run, and 2 per analyte when using stored curve	9 (multi-analyte calibrators)
Calibrants can be stored onboard/Avg. calibration frequency	yes/28 days or sooner if conjugate lots change	yes/weekly (dependent on panel)
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	once per work shift (user defined)	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/20 minutes including request entry or downloading	yes/no/13 minutes
Stat time to completion of ß-hCG test	n/a	n/a
Time delay from ordering stat test to aspir. of sample	n/a	n/a
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	batch analyzer/48/180 minutes processing time for batch to finish	108/324 (5 minutes)
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 (included)	onboard/Randox, included in price
Interfaces up and running in active user sites with	Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others	yes
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 (host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	yes	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	no/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	n/a, 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: 5 minutesr; weekly: 10 minutesr; monthly: 15 minutes	daily: <5 minutes; weekly: 10 minutes; monthly: 30 minutes
Onboard maintenance records/Maintenance training demo module	yes/no	no/—
List price/Targeted bed size or daily volume	$22,000/>7,000–20,000 tests per year	$275,000/500+
Annual service contract cost (24 hours/7 days)	—	varies
Training provided w/ purchase/Advanced operator training	3.5 days at vendor offices/yes	5 days on site/—
Distinguishing features (supplied by vendor)	provides advanced and 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	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

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Automated immunoassay analyzers

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	Roche Diagnostics	Roche Diagnostics
	Todd Atkinson todd.atkinson@roche.com	**Todd Atkinson** todd.atkinson@roche.com
	9115 Hague Rd.	**9115 Hague Rd.**
	Indianapolis, IN 46250	**Indianapolis, IN 46250**
	800-428-5074 www.roche.com/labsystems/us	**800-428-5074** www.roche.com/labsystems/us
Name of instrument/First year sold/Where designed	**Elecsys 2010/1996/—**	**Cobas e411/2006/Japan**
Country where manufactured/Where reagents manufactured	**Japan/Germany**	**Japan/Germany**
No. of units in clinical use in U.S./Outside U.S.	**>800/>6,000**	**—/—**
Operational type/Model type/Sample handling system	**cont. random access/benchtop/rack or disk**	**continuous random access/benchtop/rack, disk**
Dimensions in inches (H × W × D)/Instrument footprint in square feet	**22.1 × 47.2 × 28.7 in/9.4 sq ft**	**47.2 × 28.7 × 43 in (disk); 67 × 37.4 × 43 in (rack)/—**
Tests available on instrument in U.S.	**ferritin, folate, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, free PSA, total PSA, ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone, prolactin, SHBG, testosterone, total & βCG, 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**	**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**
Tests cleared but not clinically released	**n/a**	**n/a**
Tests not available in U.S. but submitted for clearance	**P1NP**	**P1NP**
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**	**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**
Research-use-only assays	**n/a**	**n/a**
Tests in development	**25-OH vitamin D3, rubella IgG/IgM, toxo IgG/IgM, 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**	**25-OH vitamin D3, rubella IgG/IgM, toxo IgG/IgM, 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, HBsAg, HBsAg confirmatory, anti-HBs, total PSA (screening), free PSA**
User-defined methods implemented for what analytes	**n/a**	**n/a**
Tests not available on other manufacturers' analyzers	**—**	**9-minute PTH ANO cardiac assays**
Fully automated microplate system	**no**	**no**
No. of each analyte performed in separate disposable unit	**n/a**	**—**
No. of wells in microplate	**n/a**	**—**
Methods supported/Separation methods	**electrochemiluminescence/magnetic particle**	**electrochemiluminescence, magnetic particle/magnetic particle**
No. of different measured assays onboard simultaneously	**15**	**18**
No. of different assays programmed, calibrated at once	**60**	**18**
No. of user-definable (open) channels	**0**	**0**
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	**15/100–200**	**18/100–200 tests per kit**
Shortest/Median onboard reagent stability/Refrigerated onboard	**56 days/56 days/yes (20°C)**	**—/56 days/yes (20°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/calib. curve, application params., lot No., expir., reag. name**	**yes/calib. curve, application params., lot No., expir., reag. name**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**no/zero carryover (disposable sample tips)**	**no/zero carryover (disposable sample tips)**
Walkaway capacity in minutesutes/Specimens/Tests-assays	**120/disk: 30, rack: 100/180**	**disk: 120/30/180; rack: —/100/18**
System is open (home-brew methods can be used)/Liquid or dry system	**no/liquid**	**no/—**
Uses disposable cuvettes/Max. No. stored	**yes/—**	**yes/360 assay tips; 180 assay cups**
Uses washable cuvettes/Replacement frequency	**no**	**no/—**
Minimum specimen vol. required	**10 µL**	**10 µL**
Minimum sample vol. aspirated precisely at once/Min. dead vol.	**10 µL/100 µL**	**10 µL/100 µL**
Supplied with UPS (backup power)/Requires floor drain	**—/no**	**no/no**
Requires dedicated water system/Water consumption	**no/—**	**no/no**
Noise generated	**—**	**—**
Has dedicated pediatric sample cup/Dead vol.	**no**	**no**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/13–16 mm diam./no**	**yes/13–16 mm diameter/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	**—**	**—**
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	**yes/no**	**yes/no**
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	**no/no**	**no/no**
Time between initial result & reaspiration of sample for rerun	**—**	**—**
Autocalibration or autocalibration alert	**yes**	**yes**
No. of calibrators required for each analyte	**2**	**2**
Calibrants can be stored onboard/Avg. calibration frequency	**no/monthly**	**no/monthly for lot; weekly for rack**
Multipoint calib. supported/Multiple calibs. stored for same assay	**yes/yes**	**yes/yes**
How often QC required	**once per 24 hours**	**once per day**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
Automatic shutdown/Startup is programmable/Startup time	**no/no/4 minutes**	**yes/no/4 minutes**
Stat time to completion of ß-hCG test	**9 minutes (hCG intact)**	**9 minutes**
Time delay from ordering stat test to aspir. of sample	**42 seconds**	**42 seconds**
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	**30/88 (42 seconds)**	**30/86 (42 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	**onboard/yes (additional cost)**	**onboard/yes (additional cost)**
Interfaces up and running in active user sites with	**all major LISs**	**—**
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 (CLAS & Roche task targeted automation)**	**yes**
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	**no/yes/no**	**no/yes/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	**—/—**	**—/—**
Onboard error codes to facilitate troubleshooting	**yes**	**yes**
Avg. time to complete maintenance by lab personnel	**daily: 1 minutes; weekly: 5 minutes; biweekly: 25 minutes; monthly: none**	**daily: 5 minutes; weekly: 6 minutes; monthly: 10–15 minutes**
Onboard maintenance records/Maintenance training demo module	**no/no (training CD-ROM)**	**no/no**
List price/Targeted bed size or daily volume	**varies, based on contract**	**$150,000 disk; $165,000 rack/varies; primary IA system or back-up unit**
Annual service contract cost (24 hours/7 days)	**included w/ reagent rental**	**included with reagent rental**
Training provided w/ purchase/Advanced operator training	**3 days at Indianapolis offices/yes**	**4 days on site/yes**
Distinguishing features (supplied by vendor)	**liquid ready-to-use reagents; autocalib., autodil.; ECL technology for broad dynamic ranges, and fast turnaround time, stat interrupt; onboard reag. storage; minimal maintenance**	**liquid ready-to-use reagents; ECL technology for broad dynamic ranges; fast TAT; stat interrupt; minimal maintenance**

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Automated immunoassay analyzers

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Name of instrument/First year sold/Where designed	Modular Analytics E170/2001/Japan	Cobas e 601 Analyzer/2006/—
Country where manufactured/Where reagents manufactured	Japan/Germany	Japan/Germany
No. of units in clinical use in U.S./Outside U.S.	>250/>300 (combination of E and EE systems) and >25 Integrated Modular Systems (U.S. only)	—/—
Operational type/Model type/Sample handling system	continuous random access/floor-standing/rack	continuous random access/floor-standing/rack
Dimensions in inches (H × W × D)/Instrument footprint in square feet	47 × 47 × 31.5 in (Modular E configuration)/approx. 60 sq ft (one module system)	46.1 × 71.8 × 40/19.73 sq ft
Tests available on instrument in U.S.	ferritin, folate, RBC folate, vitamin B12, C-peptide, insulin, AFP, CA 125 II, CA 15-3 II, CA 19-9, CEA, free PSA, total PSA, ACTH, cortisol, DHEA-S, estradiol, FSH, LH, progesterone, prolactin, SHBG, testosterone, total and βhCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps, osteocalcin	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 βhCG, anti-TG, anti-TPO, FT3, FT4, T3, T4, TSH, T-uptake, CK-MB, digoxin, myoglobin, NT proBNP, troponin T, IgE, PTH, beta crosslaps, osteocalcin
Tests cleared but not clinically released	HBsAg, HBsAg confirmatory, anti-HBs	n/a
Tests not available in U.S. but submitted for clearance	P1NP	P1NP
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	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
Research-use-only assays	n/a	n/a
Tests in development	25-OH vitamin D3, rubella IgG/IgM, toxo IgG/IgM, 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	25-OH vitamin D3, rubella IgG/IgM, toxo IgG/IgM, 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, HBsAg, HBsAg confirmatory, anti-HBs, total PSA (screening), free PSA
User-defined methods implemented for what analytes	n/a	n/a
Tests not available on other manufacturers' analyzers	—	—
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	—	n/a
No. of wells in microplate	—	n/a
Methods supported/Separation methods	electrochemiluminescence/magnetic particle, electrochemiluminescence	electrochemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	25 per E module, maximum of 60	25 per module
No. of different assays programmed, calibrated at once	44	25 per module
No. of user-definable (open) channels	n/a	n/a
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	44	25 per module/100-200
Shortest/Median onboard reagent stability/Refrigerated onboard	14 days/35 days/yes (20° C)	56 days/56 days/yes (20° 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/calib. curve, application params., lot No., expir., reag. name	yes/calib. curve, application params., lot No., expir., reag. name
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	n/a/zero, uses disposable sample tips	n/a/zero, uses disposable sample tips
Walkaway capacity in minutesutes/Specimens/Tests-assays	360/—/1,006	360/300/1,000
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/—	yes/1,000
Uses washable cuvettes/Replacement frequency	no	no/—
Minimum specimen vol. required	10 µL	10 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	—/100 µL	10 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	—/—
Requires dedicated water system/Water consumption	yes/30 L per hour in full operation	yes/20 L per hours
Noise generated	—	<65 decibels
Has dedicated pediatric sample cup/Dead vol.	yes/100 µL	yes/100µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13 × 75 to 16 × 100/no	yes/13 × 75 to 16 × 100/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
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/—	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
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	—	—
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	2	2
Calibrants can be stored onboard/Avg. calibration frequency	no/monthly	no/every 28 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	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/11 minutes	yes/yes/11 minutes
Stat time to completion of ß-hCG test	18 minutes	18 minutes
Time delay from ordering stat test to aspir. of sample	—	42 seconds
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	56/176 (21 seconds)	56/176 (21 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	onboard/yes (addt'l cost)	onboard/yes (additional cost)
Interfaces up and running in active user sites with	all major LISs	all major laboratory information systems
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	no	yes
How labs get LOINC codes for reagent kits	—	Web site
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 (Roche Modular Pre-Analytical Systems and task targeted automation)	yes (Roche Modular Pre-Analytics)
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/no	yes/yes/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	24 hours	24 hourss
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 (includes audit trail of who replaced parts)/yes
List price/Targeted bed size or daily volume	varies, based on contract	varies, based on contract/—
Annual service contract cost (24 hours/7 days)	included with reagent rental	—
Training provided w/ purchase/Advanced operator training	5 days at vendor offices/yes	5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	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	ECL technology provides brand measuring ranges and low-end sensitivity; TnT; ready to use bar-coded reagents compatible with other Elecsys Systems; compatible with Modular Pre-Analytics for walkaway automation

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Automated immunoassay analyzers

Part 20 of 25

See accompanying article on page 24

Siemens Medical Solutions Diagnostics
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Name of instrument/First year sold/Where designed	ADVIA Centaur/1998/U.S.	ADVIA Centaur CP Immunoassay System/2005/U.S.
Country where manufactured/Where reagents manufactured	Ireland/U.S.	Germany/U.S.
No. of units in clinical use in U.S./Outside U.S.	1,435/3,641	>200/>400
Operational type/Model type/Sample handling system	cont. random access/floor standing/rack or direct track sampling	batch, random access, continuous random access/benchtop/7 × 12 position racks
Dimensions in inches (H × W × D)/Instrument footprint in square feet	51.5 × 72.5 × 41.5 in/21 sq ft	43 × 29 in/8.7 sq ft
Tests available on instrument in U.S.	T4, T3, T-up, TSH, TSH-3, FT4, FT3, aTPO, aTG, intact PTH, CEA, AFP, cPSA, PSA, CA 19-9, BR, CA 15-3, CA 125II, HER-2/neu, digoxin, digitoxin, carbamazepine, gentamicin, pheno barbital, phenytoin, theophylline 2, tobramycin, valproic acid, vancomycin, total IgE, cortisol, C-peptide, insulin, rubella G, rubella M, toxo G, toxo M, HbsAg, HBc-IgM, HBc-total, HbsAb, HCV, HAV-IgM, HAV-total, THCG, prolactin. estradiol-6/6 III, LH, FSH, progesterone, testosterone, vit. B12, folate, ferritin, CKMB II, cTnI, TnI-ultra, myoglobin, homocysteine, BNP	T4, free T4, free T3, TSH, TSH3, T-uptake, T3, intact PTH, digoxin, BNP, CKMB, homocysteine, myoglobin, TnI-ultra, E26III, FSH, LH, tHCG, progesterone, prolactin, testosterone, AFP, PSA, cPSA, CEA, BR 27.29, CA 15-3, ferritin, vit. B12, folate, RBC folate
Tests cleared but not clinically released	none	CA 125, CA 19-9, CA 15-3, HER-2/neu, HIV 1/0/2, HCV, HBsAg, HBsAg conf, anti-HBS, HBc total, MBc total, HBc IgM, HAV total, HAV IgM, anti-TPO, anti-TG, cortisol, insulin, C-peptide, rubella G, rubella M, toxoplasma G, toxoplasma M, digitoxin, theophylline, phenobarbital, phenytoin, carbamazipine, cyclosporine, valproic acid, vancomycin, gentamicin, tobramycin, HBeAg, anti-HBE, ANA, CA 15-3
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	FPSA, tacro, ANA, CMV IgG, CMV IgM, HBeAg, anti-HBe, cyclosporine, SHBG, DHEAS, UE3	CA 19-9, CA 125, rubella G/M, toxo G/M, carbamazepine, gentamicin, phenobarbital, phenytoin, theophylline, tobramycin, valproic acid, vancomycin, cortisol, anti-TPO, others
User-defined methods implemented for what analytes	n/a	—
Tests not available on other manufacturers' analyzers	comples PSA, HER-2/neu	cPSA, HER-2/*neu*
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	n/a	—
No. of wells in microplate	n/a	—
Methods supported/Separation methods	chemiluminescence/magnetic particle	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	30	15
No. of different assays programmed, calibrated at once	65	31 (65 planned for 2008)
No. of user-definable (open) channels	0	—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	30/50–100, 200	15/50–100
Shortest/Median onboard reagent stability/Refrigerated onboard	96 hours/41 days/yes (4°C)	96 hours/28 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/assay name, lot No., expir., pack ID	yes/reagent ID, lot No., expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	n/a/zero carryover	no/zero carryover
Walkaway capacity in minutesutes/Specimens/Tests-assays	230/180/840	210/400/400
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/1,000	yes/400
Uses washable cuvettes/Replacement frequency	no	no
Minimum specimen vol. required	10 µL, assay dependent	10 uL, assay dependent
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL/50 µL	10 uL/50 uL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/~2.5 L per hours	no
Noise generated	<64 decibels w/in 1 meter	up to 65 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/multiple/no	yes/multiple/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codaboar, 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	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
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	no/no	yes/yes
Time between initial result & reaspiration of sample for rerun	15 seconds	20 seconds
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte	2	2
Calibrants can be stored onboard/Avg. calibration frequency	no/varies, avg. 21 days	no/varies, avg. 21 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	24 hours	user defined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/none	yes/yes/<5 minutes
Stat time to completion of ß-hCG test	18 minutes	15.6 minutes
Time delay from ordering stat test to aspir. of sample	15 seconds	<1 minutes
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	80/240 (15 seconds)	60/180 (20 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	onboard/—	onboard/no
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLFC, DI, Triple G, and most other major vendors	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	yes	yes
Uses LOINC to transmit orders and results	—	no
How labs get LOINC codes for reagent kits	custom definable via LIS	—
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 (Advia Workcell, LabCell, & other vendors, eg Beckman)	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/—
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	4 hours, 24 hours max.	4 hours, 24 hours max.
Mean time between failures/To repair failures	n/a/n/a	not available/not available
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 3 minutes; weekly: 20 minutes; monthly: 30 minutes	daily: 15 minutes; weekly: 20 minutes; monthly; 30 minutes
Onboard maintenance records/Maintenance training demo module	yes/yes	yes/yes
List price/Targeted bed size or daily volume	$225,000/300+ beds or 400 tests per day	$150,000/community hospitals, satellite labs
Annual service contract cost (24 hours/7 days)	depends on GPO affiliation	—
Training provided w/ purchase/Advanced operator training	varies on site, 4 days at vendor offices/yes	3 days at vendor sites plus online training/yes
Distinguishing features (supplied by vendor)	HIV and comprehensive hepatitis A, B and C testing (including the acute panel); SMART algorithms for rerun and confirmatory testing for HBsAg testing; always ready, no start-up procedures required; automates routine operations, including ability to access/change solutions, waste, disposables, and reagents at any time without pausing sampling or processing; onboard automatic dilutions, repeats, stats, and cascade reflex testing; disposable tips; and process up to 240 tests per hour	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

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SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 21 of 25 *See accompanying article on page 24*	Siemens Medical Solutions Diagnostics **Denise Pastore** denise.pastore@siemens.com 511 Benedict Avenue Tarrytown, NY 10591 914-524-5102 www.siemens.com/diagnostics	Siemens Medical Solutions Diagnostics **Louise Chang** louise.chang@siemens.com 511 Benedict Avenue Tarrytown, NY 10591 310-645-8200 www.siemens.com/diagnostics
Name of instrument/First year sold/Where designed	ADVIA Centaur XP/2006/U.S.	IMMULITE/1993; IMMULITE *Turbo*/1999; IMMULITE 1000/2002/U.S.
Country where manufactured/Where reagents manufactured	Ireland/U.S.	U.S./U.S., U.K.
No. of units in clinical use in U.S./Outside U.S.	152/—	>7,000 worldwide
Operational type/Model type/Sample handling system	continuous random access/floor standing/5-position multiple size rack or puck via ADVIA	cont. random access/benchtop/loading platform
Dimensions in inches (H × W × D)/Instrument footprint in square feet	51.5 × 72.4 × 41 in/20.6 sq ft	19 × 46 × 26 in/7.98 sq ft
Tests available on instrument in U.S.	T4, T3, T-up, TSH, TSH-3, FT4, FT3, aTPO, aTG, intact PTH, CEA, AFP, cPSA, PSA, CA 19-9, BR, CA 15-3, CA 125II, HER-2/neu, digoxin, digitoxin, carbamazepine, gentamicin, phenobarbital, phenytoin, theophylline 2, tobramycin, valproic acid, vancomycin, total IgE, cortisol, C-peptide, insulin, rubella G, rubella M, toxo G, toxo M, HbsAg, HBc-IgM, HBc-total, HbsAb, HCV, HAV-IgM, HAV-total, THCG, prolactin. estradiol-6/6 III, LH, FSH, progesterone, testosterone, vit. B12, folate, ferritin, CKMB II, cTnI, TnI-ultra, myoglobin, homocysteine, BNP	ACTH, cortisol, AlaTOP allergy screen, total IgE, EPO, ferr., folate, B12, calcitonin, i-PTH, Pyrilinks-D, CK-MB, hs CRP, homocys., myogl., trop. I, albumin, C-peptide, insulin, hGH, IGF-I, IGFBP-3, CMV IgG, *H. pylori* 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* menu: CK-MB, HCG, myogl., i-PTH, free PSA, trop. I, iPTH, vancomycin; free PSA; contact company for full menu
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for clearance	—	—
Tests not available in U.S. but available in other countries	—	GI-MA (CA 19-9), nicotine metabolite, free β-hCG, IL-6, IL-8, IL-10, LBP, PAPP-A, osteocalcin, NT-proBNP, CMV IgM
Research-use-only assays	—	ECP, TPS, IL-1beta, IL2R, TNF-alpha
Tests in development	FPSA, tacro, ANA, CMV IgG, CMV IgM, HBeAg, anti-HBe, cyclosporine, SHBG, DHEAS, UE3	*Turbo:* D-dimer
User-defined methods implemented for what analytes	n/a	none
Tests not available on other manufacturers' analyzers	complex PSA, HER-2/neu	IGF-I, IGFBP-3, androst., 3rd-gen PSA, AlaTOP allergy screen, EPO, TBG, ACTH, calcitonin, Pyrilinks-D, gastrin, *H. pylori* IgG, canine TLI, canine TSH; *Turbo* i-PTH
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a/n/a	n/a
Methods supported/Separation methods	chemiluminescence/magnetic particle	chemiluminescence/bead, centrifugation
No. of different measured assays onboard simultaneously	30 primary reagents	12
No. of different assays programmed, calibrated at once	65	unlimited
No. of user-definable (open) channels	n/a	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	30/50, 100, 200 tests per pack	12; 5 for *Turbo*/100; 50 for *Turbo* i-PTH
Shortest/Median onboard reagent stability/Refrigerated onboard	96 hours/28 days/yes (4°C)	n/a/30 days/yes (15°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/assay name, lot No., expiration date, pack ID, No. of tests	yes/test, lot No., expir.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	n/a/none—uses zero carrryover	no/<10 ppm
Walkaway capacity in minutesutes/Specimens/Tests-assays	280/180/840	100/—/70
System is open (home-brew methods can be used)/Liquid or dry system	closed/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/1,000	yes/n/a
Uses washable cuvettes/Replacement frequency	no	no
Minimum specimen vol. required	10 µL—assay	5 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL/50µL	5 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/2.5 L per hour	no/0.5 L per h
Noise generated	61.3 decibels	55-68 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/—/no	no/n/a/n/a
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes
Bar-code placement per NCCLS standard Auto2A	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/yes	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no (does have autodilution)/no (does have autodilution)	no/no
Time between initial result & reaspiration of sample for rerun	15 seconds	n/a
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	2	2-level adjustors, supplied in kit
Calibrants can be stored onboard/Avg. calibration frequency	no/average 28 days	no/1–4 weeks (assay dependent); 2 weeks for *Turbo*
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	no/yes
How often QC required	22 hours/24 hours	customer determined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	no/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/none, always ready	no/no/5 minutes
Stat time to completion of ß-hCG test	18 minutes	42 minutes; 15 minutes for *Turbo* (total hCG)
Time delay from ordering stat test to aspir. of sample	15 seconds	2.5 minutes
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	80/240/15 seconds yes	120/120 (—)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	no/yes
Data management capability/Instrument vendor supplies LIS interface	onboard/yes (LIS allowance)	onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, McKesson, Citation, Antrin, Soft, CCA, Triple G, others	CIS, CPSI, CCA, Mysis, McKesson, Cerner, Antek, CSS, others
LIS interface operates simultaneously w/ running assays		yes
Uses LOINC to transmit orders and results	yes	no
How labs get LOINC codes for reagent kits	no	—
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/ADVIA WorkCell, ADVIA LabCell, others	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	<41 hours, 24 hours max.	4 hours
Mean time between failures/To repair failures	n/a/n/a	10 months/4 hours
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 3 minutes; weekly: 20 minutes; monthly: 30 minutes	daily: 5 minutes; weekly: 10 minutes; monthly: 20 minutes
Onboard maintenance records/Maintenance training demo module	yes/yes	—/yes
List price/Targeted bed size or daily volume	$225,000/300+ beds or 400 tests per day	$75,000; *Turbo*: $77,500/>1,000 tests per month
Annual service contract cost (24 hours/7 days)	varies, GPO dependent	$8,000
Training provided w/ purchase/Advanced operator training	—/4.5 days on site/yes	3.5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	HIV & comprehensive hepatitis A, B, and C testing (including the acute panel); SMART algorithms for rerun and confirmatory testing for HBsAg testing; always ready, no start-up procedures required; automates routine operations including ability to access/change solutions, waste, disposables, and reagents at any time without pausing sampling or processing; onboard automatic dilutions, repeats, stats, and cascade reflex testing; disposable tips; processes up to 240 tests per hour	worldwide customer satisfaction; system reliability & performance; one of the largest menus available on any immunoassay analyzer

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Automated immunoassay analyzers

Part 22 of 25

See accompanying article on page 24

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Name of instrument/First year sold/Where designed	IMMULITE 2000/1998/U.S.	IMMULITE 2500 SMS/2004/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S., U.K.	U.S./U.S., U.K.
No. of units in clinical use in U.S./Outside U.S.	>4,200 worldwide	>600 worldwide
Operational type/Model type/Sample handling system	Cont. random access/floor-standing/rack	continuous random access/floor standing/rack
Dimensions in inches (H × W × D)/Instrument footprint in square feet	47 × 60 × 30 in/12.5 sq ft	79 × 112 × 40 in/30.69 sq ft
Tests available on instrument in U.S.	AlaTOP allergy scr., 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, *H. pylori* IgG, rubella IgG, rubella IgM, toxo IgG, toxo IgM, herpes I & II IgG, Pyrilinks-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, stat PTH, vancomycin; contact company for full menu	B12, folate, AlaTOP allergy scr., 3gAllergy (IgE specific allergens & allergy panels), total IgE, Pyrilinks-D, homocys., hsCRP, IGF-I, IGFBP-3, hGH, AFP, androst., DHEA SO4, estrad., unconj. estriol, FSH, LH, prolac., progest., testost., SHBG, carbamazep., digit., digoxin, phenyt., phenob., theoph., valp. acid, iPTH, ACTH, β2-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, *H. pylori* IgG, CMV IgG, rubella IgG, rubella IgM, toxo IgG, toxo IgM, gastrin, insulin, C-pep., alb., cort., ferr., calcit., EPO; stat menu: CK-MB, HCG, myogl., trop. I stat PTH, vancomycin; contact company for full menu
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for clearance	—	free PSA
Tests not available in U.S. but available in other countries	GI-MA (CA 19-9), fβHCG, IL-6, nicotine metab., PAPP-A, fPSA, IL2R, NT-pro BNP, CMV IgM, D-dimer	GI-MA (CA19-9), fβHCG, 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	ECP, allergen specific IgGs, IL-2R, IL-6	IL-6
Tests in development	ANA scr., celiac markers, dsDNA Ab, EBV-EBNA IgG, EBV-VCA IgG/IgM, anti-HAV total & IgM, HBeAg, anti-HBe, HSV I/II IgG, allergen-specific IgG4, LBP, Lyme screen, TPS, osteocalcin, syphilis, vit. D, anti-CCP	ANA scr., celiac markers, dsDNA Ab, EBV-EBNA IgG, EBC-VCA IgG, EBV-VCA IgM, gentamicin, anti-HAV IgM, anti-HAV total, HBeAg, anti-HBe, Lyme screen, osteocalcin, stat PTH, syphilis scr., tobramycin, vit D, TPS, anti-CCP
User-defined methods implemented for what analytes	none	none
Tests not available on other manufacturers' analyzers	TBG, 3rd-gen PSA, 3gAllergy, AlaTOP, androst., ACTH, calcitonin, EPO, gastrin, *H. pylori* IgG, IGF-I, IGFBP-3, canine TSH & TLI, Pyrilinks-D	TBG, 3rd-gen PSA, AlaTOP, 3gAllergy, androst., ACTH, calcitonin, EPO, gastrin, *H. pylori* IgG, IGF-I, IGFBP-3, canine TSH & TLI, Pyrilinks-D
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/Separation methods	chemiluminescence/bead, centrifugation	chemiluminescence/bead, centrifugation
No. of different measured assays onboard simultaneously	24	24
No. of different assays programmed, calibrated at once	unlimited	unlimited
No. of user-definable (open) channels	n/a	n/a
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	24/200	24/200
Shortest/Median onboard reagent stability/Refrigerated onboard	n/a/90 days/yes (4°C)	n/a/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., expir.	yes/test, lot No., expiration
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/<3 ppm	no/<3 ppm
Walkaway capacity in minutesutes/Specimens/Tests-assays	300/90/1,300	300/275/1,300
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	yes/1,300
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum specimen vol. required	5 µL to 100 µL sample	5 µL to 100 µL sample
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/50 µL	5 µL/50 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	52 decibels	52 decibels
Has dedicated pediatric sample cup/Dead vol.	yes/50 µL	yes/50 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/75–100 mm height; 12–16 mm width/no	yes/75–100 mm height; 12–16 mm width/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 or 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	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	n/a/n/a	n/a/n/a
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	no/no	no/no
Time between initial result & reaspiration of sample for rerun	min. 18 seconds	min. 18 seconds
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	2 level adjustors, supplied in kit	2 level adjustors, supplied in kit
Calibrants can be stored onboard/Avg. calibration frequency	no/1–4 weeks (assay dependent)	no/1–4 weeks (assay dependent)
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	cutomer determined	customer determined
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	yes/no/4 minutes
Stat time to completion of ß-hCG test	35 minutes (total HCG)	15 minutes (total HCG)
Time delay from ordering stat test to aspir. of sample	18 seconds	18 seconds
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	200/200 (18 seconds)	200/200 (18 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	onboard/yes (additional cost)	onboard/yes (additional cost)
Interfaces up and running in active user sites with	Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, others	Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, 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 (universal interface)	yes (universal interface)
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	4 hours	4 hours
Mean time between failures/To repair failures	3 months/5 hours	3 months/5 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: 5–10 minutes; weekly: 20 minutes; monthly: 20–30 minutes
Onboard maintenance records/Maintenance training demo module	no/yes	no/yes
List price/Targeted bed size or daily volume	$124,500/>6,000 tests per month	$200,000 includes SMS & RealTime Solutions/200+ beds
Annual service contract cost (24 hours/7 days)	$16,500 (RealTime Solutions)	$21,500 (RealTime Solutions with SMS)
Training provided w/ purchase/Advanced operator training	varies on site, 5 days at vendor offices/yes	varies on site, 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	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	large automated IA test menu available; 15-min 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

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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 23 of 25	**Siemens Medical Solutions Diagnostics**	**TOSOH Bioscience Inc.**
	Louise Chang louise.chang@siemens.com	**Shanti Narayanan** shanti.narayanan@tosoh.com
	511 Benedict Avenue	**6000 Shoreline Court, Ste. 101**
	Tarrytown, NY 10591	**South San Francisco, CA 94080**
See accompanying article on page 24	**310-645-8200** www.siemens.com/diagnostics	**800-248-6764** www.tosoh.com
Name of instrument/First year sold/Where designed	**IMMUNOASSAY WORKCELL/2005/U.S.**	**AIA-360/2004/Japan**
Country where manufactured/Where reagents manufactured	**U.S./U.S., U.K.**	**Japan/Japan**
No. of units in clinical use in U.S./Outside U.S.	**—/—**	**320/100+**
Operational type/Model type/Sample handling system	**continuous random access/floor standing/rack**	**continuous random access/benchtop/carousel**
Dimensions in inches (H × W × D)/Instrument footprint in square feet	**75 × 136 × 136 in/121 sq ft**	**21 × 19 × 16/2.1 sq ft**
Tests available on instrument in U.S.	**configuration dependent; please see IMMULITE 2000/2500 menus**	**10 minutes short time (ST) assays: TSH, FT4, T3, T4, T-uptake, FT3, 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, testosterone, CA 19-9**
Tests cleared but not clinically released	**none**	**—**
Tests not available in U.S. but submitted for clearance	**configuration dependent; see IMMULITE 2000/2500 menus**	**intact PTH**
Tests not available in U.S. but available in other countries	**configuration dependent; see IMMULITE 2000/2500 menus**	**BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg**
Research-use-only assays	**none**	**—**
Tests in development	**configuration dependent; see IMMULITE 2000/2500 menus**	**PTH, HbA1c, RBC folate**
User-defined methods implemented for what analytes	**none**	**—**
Tests not available on other manufacturers' analyzers	**configuration dependent; see IMMULITE 2000/2005 menus**	**—**
Fully automated microplate system	**no**	**n/a**
No. of each analyte performed in separate disposable unit	**n/a**	**n/a**
No. of wells in microplate	**n/a**	**n/a**
Methods supported/Separation methods	**chemiluminescence/bead, centrifugation**	**flourescence, EIA/bead**
No. of different measured assays onboard simultaneously	**48**	**25**
No. of different assays programmed, calibrated at once	**unlimited**	**entire menu**
No. of user-definable (open) channels	**n/a**	**0**
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	**48/200**	**n/a/unitized test cup**
Shortest/Median onboard reagent stability/Refrigerated onboard	**n/a/90 days/yes (4°C)**	**72hours/72hours/n/a**
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/lot No., test code**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**no/<3 ppm**	**no/zero carryover**
Walkaway capacity in minutesutes/Specimens/Tests-assays	**300/350/9,600**	**58/25/25**
System is open (home-brew methods can be used)/Liquid or dry system	**no/liquid**	**no/dry**
Uses disposable cuvettes/Max. No. stored	**yes/2,600**	**no**
Uses washable cuvettes/Replacement frequency	**no/—**	**no**
Minimum specimen vol. required	**5 µL to 100 µL sample**	**500 µL tube, 100 µL cup**
Minimum sample vol. aspirated precisely at once/Min. dead vol.	**5 µL/50 µL**	**10–100 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes/no**	**no/no**
Requires dedicated water system/Water consumption	**no/—**	**no/n/a**
Noise generated	**52 decibels**	**—**
Has dedicated pediatric sample cup/Dead vol.	**yes/50 µL**	**no**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/75–100 mm height; 12–16 mm width/no**	**yes/primary draw tubes: 13 × 75 & 100; 16 × 75 & 100/no**
Sample bar-code reading capability/Autodiscrimination	**yes (2 or 5 interl., codabar, codes 39 & 128)/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/yes**	**yes/no**
Hemolysis detection-quantitation/Turbidity detection-quantitation	**n/a/n/a**	**no/no**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**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**	**no/no**
Time between initial result & reaspiration of sample for rerun	**min. 18 seconds**	**n/a**
Autocalibration or autocalibration alert	**yes**	**no**
No. of calibrators required for each analyte	**2 level adjustors, supplied in kit**	**2 or 6-analyte dependent**
Calibrants can be stored onboard/Avg. calibration frequency	**no/1–4 weeks (assay dependent)**	**no/30–90 days**
Multipoint calib. supported/Multiple calibs. stored for same assay	**yes/yes**	**yes/yes**
How often QC required	**customer determined**	**24 hours**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**no/no**
Automatic shutdown/Startup is programmable/Startup time	**yes/no/4 minutes**	**yes/no/5 minutes**
Stat time to completion of ß-hCG test	**15 minutes (total HCG)**	**~18 minutes**
Time delay from ordering stat test to aspir. of sample	**18 second minimum**	**60 seconds**
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	**400/400 (18 seconds)**	**12/36 (1 minutes)**
Can auto transfer QC results to LIS/Onboard capability to review QC	**yes/yes onboard/yes (additional cost)**	**yes/no**
Data management capability/Instrument vendor supplies LIS interface	**Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, others**	**Antek. Schuyler House, more**
Interfaces up and running in active user sites with	**yes**	**n/a**
LIS interface operates simultaneously w/ running assays	**no**	**—**
Uses LOINC to transmit orders and results	**—**	**yes**
How labs get LOINC codes for reagent kits	**yes (broadcast download & host query)**	**package insert**
Bidirectional interface capability	**yes**	**no**
Results transmitted to LIS as soon as test time complete	**yes (universal interface)**	**yes**
Interface available (or will be) to auto specimen handling system	**yes/yes/yes**	**no**
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	**no**	**no/no/no**
Can order (via modem) malfunctioning part(s) w/o operator	**4 hours**	**no**
On-site response time of service engineer	**4 months/5 hours**	**n/a**
Mean time between failures/To repair failures	**yes**	**>6 months/24 hours**
Onboard error codes to facilitate troubleshooting	**daily: 5–10 minutes; weekly: 20 minutes; monthly: 20–30 minutes**	**yes**
Avg. time to complete maintenance by lab personnel	**no/yes**	**daily: 5 minutes**
Onboard maintenance records/Maintenance training demo module		**no/no**
List price/Targeted bed size or daily volume	**configuration dependent: $314,000-$355,000/6,000 tests per month**	**$25,000/200–1,000 tests per month**
Annual service contract cost (24 hours/7 days)	**$29,500 (with RTS)**	**$2,050-$3,500**
Training provided w/ purchase/Advanced operator training	**varies on site, 5 days at vendor offices/yes**	**training DVD; on-site install**
Distinguishing features (supplied by vendor)	**one of the largest automated immunoassay test menus available; 15-minute stat assays, flexible sample handling, user-definable testing; runs specific allergen testing alongside routine immunoassays; flexible connectivity to automation via the SMS; autoreflex, autodilute, RealTime Solutions (RTS) Internet-based service and support systems with OnLine Reports and remote diagnostics autodilution and autoreflex testing; remote diagnostics; RealTime Solutions (RTS) Internet-based service, OnLine Reports; quality management & logistics management reports**	**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**

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Automated immunoassay analyzers

Part 24 of 25

See accompanying article on page 24

	TOSOH Bioscience Inc. Susan Kolarik susan.kolarik@tosoh.com 6000 Shoreline Court, Ste. 101 South San Francisco, CA 94080 800-248-6764 www.tosoh.com	TOSOH Bioscience Inc. Susan Kolarik susan.kolarik@tosoh.com 6000 Shoreline Court, Ste. 101 South San Francisco, CA 94080 800-248-6764 www.tosoh.com
Name of instrument/First year sold/Where designed	AIA-600 II/2000/Japan	AIA-1800/2003/Japan
Country where manufactured/Where reagents manufactured	Japan/Japan	Japan/Japan
No. of units in clinical use in U.S./Outside U.S.	400/600	24/300+
Operational type/Model type/Sample handling system	cont. random access/benchtop/chain	continuous random access/floor standing/rack, sort drawer, standard and LA
Dimensions in inches (H × W × D)/Instrument footprint in square feet	19.8 × 31.6 × 29.1 in/2.5 sq ft	65 × 50 × 37 in/6.3 sq ft
Tests available on instrument in U.S.	TSH, 3rd-gen. TSH, FT4, T3, T4, T-uptake, FT3, TPO Ab, Tg Ab, βhCG, 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	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
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for clearance	intact PTH	intact PTH
Tests not available in U.S. but available in other countries	HBsAg, HBsAb, HBeAg, HbcAb, HbeAb, BNP	BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg
Research-use-only assays	—	—
Tests in development	RBC folate, PTH, HbA1c	PTH, HbA1c, RBC folate
User-defined methods implemented for what analytes	none	—
Tests not available on other manufacturers' analyzers	none	—
Fully automated microplate system	no	n/a
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/Separation methods	fluorescence, EIA/bead	flourescence, EIA/bead
No. of different measured assays onboard simultaneously	26	31 trays
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	n/a/unitized test cup	n/a/unitized test cup
Shortest/Median onboard reagent stability/Refrigerated onboard	72 hours/72 hours/n/a	72 hours/72 hours/n/a
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 minutesutes/Specimens/Tests-assays	52/26/26	58/170/640
System is open (home-brew methods can be used)/Liquid or dry system	no/dry	no/dry
Uses disposable cuvettes/Max. No. stored	n/a/unitized test cup	n/a/unitized test cup
Uses washable cuvettes/Replacement frequency	n/a	n/a
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 µL/100 µL	10 µL/50 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/n/a	no/n/a
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: 7 mL & 10 mL or 15 × 75 & 100, 13 × 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/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	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/yes	no/no
Time between initial result & reaspiration of sample for rerun	n/a	varies
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/60–90 days	no/30–90 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	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/5 minutes	yes/no/5–8 minutes
Stat time to completion of ß-hCG test	~18 minutes	~18 minutes
Time delay from ordering stat test to aspir. of sample	60 seconds	40 seconds
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	20/60 (1 minute)	60/180 (20 seconds)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/no	yes/yes
Data management capability/Instrument vendor supplies LIS interface	optional add-on (all major LIS vendors—Schuyler House, Misys, LabForce, McKesson, Antrim, Data Innovations)/yes (addt'l cost)	yes/no
Interfaces up and running in active user sites with	Schuyler House, Fletcher Flora	yes
LIS interface operates simultaneously w/ running assays	yes	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	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	no	yes (Hitachi, Lab Interlink, A&T)
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	24 hours
Mean time between failures/To repair failures	98% uptime/—	5 months/24 hours
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 5 minutes; monthly: none	daily: 5–8 minutes; weekly: 5 minutes; monthly: none
Onboard maintenance records/Maintenance training demo module	no/no	yes (includes audit trail of who replaced parts)/no
List price/Targeted bed size or daily volume	$70,000/500–2,500 tests per month	$175,000/65+ beds, 1,500–2,000 tests
Annual service contract cost (24 hours/7 days)	$5,941	$11,458
Training provided w/ purchase/Advanced operator training	3 days at vendor offices/no	4 days at vendor offices/no
Distinguishing features (supplied by vendor)	unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use	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

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Automated immunoassay analyzers

Part 25 of 25

See accompanying article on page 24

	Trinity Biotech **Marlene Jinks** marlene.jinks@trinityusa.com **4 Connell Drive, Ste. 7100** **Berkeley Heights, NJ 07922** **800-325-3424** www.trinitybiotech.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	**PersonalLab/1998/Italy**	**Nexgen Four/2003/Italy**
Country where manufactured/Where reagents manufactured	**Italy/n/a (open system)**	**Italy/U.S., Italy, Ireland, Germany**
No. of units in clinical use in U.S./Outside U.S.	**200/>400 worldwide**	**—/—**
Operational type/Model type/Sample handling system	**batch/benchtop/rack**	**batch, random access, continuous random access/benchtop/ring (carousel)**
Dimensions in inches (H × W × D)/Instrument footprint in square feet	**24 × 26 × 25.6 in/4.6 sq ft**	**28 × 53.2 × 29.5 in (includes carousel)/—**
Tests available on instrument in U.S.	**open system—any microplate assay**	**open system—any microplate assay**
Tests cleared but not clinically released	**open system**	**open system—any microplate assay**
Tests not available in U.S. but submitted for clearance	**open system**	**open system—any microplate assay**
Tests not available in U.S. but available in other countries	**open system**	**open system—any microplate assay**
Research-use-only assays	**open system**	**open system—any microplate assay**
Tests in development	**open system**	**open system—any microplate assay**
User-defined methods implemented for what analytes	**open platform**	**open system—any microplate assay**
Tests not available on other manufacturers' analyzers	**n/a (open platform)**	**open system—any microplate assay**
Fully automated microplate system	**yes**	**yes**
No. of each analyte performed in separate disposable unit	**n/a**	**n/a**
No. of wells in microplate	**min. strip: 8; max. full plate: 96**	**min. strip: 1; max. full plate: 96 × 4 plates**
Methods supported/Separation methods	**EIA/coated microplate, varies acc. to kit mftr.**	**EIA/coated microwell**
No. of different measured assays onboard simultaneously	**6 (2 plates)**	**500+**
No. of different assays programmed, calibrated at once	**500**	**500+**
No. of user-definable (open) channels	**500**	**500+**
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	**6/96 (2 plates)**	**16/manufacturer defined**
Shortest/Median onboard reagent stability/Refrigerated onboard	**mftr. dependent/no**	**—/—/no**
Multiple reagent configurations supported	**yes**	**yes**
Reagent container placed directly on system for use	**no, requires operator prehandling/preparation**	**requires operator prehandling, preparation**
Reagents bar coded/Information in bar code	**no**	**yes/—**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**yes/zero carryover option**	**yes/zero carryover with plastic tips**
Walkaway capacity in minutesutes/Specimens/Tests-assays	**—/96-6/6**	**varies/varies/varies**
System is open (home-brew methods can be used)/Liquid or dry system	**yes/—**	**yes/liquid**
Uses disposable cuvettes/Max. No. stored	**yes/192-2 plates**	**yes/—**
Uses washable cuvettes/Replacement frequency	**no/—**	**yes/—**
Minimum specimen vol. required	**200 µL plus amount required by mftr.**	**200 µL dead vol. plus amount required by test**
Minimum sample vol. aspirated precisely at once/Min. dead vol.	**10 µL/200 µL**	**10 µL/200 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes/no**	**yes/no**
Requires dedicated water system/Water consumption	**no/n/a**	**no/—**
Noise generated	**—**	**—**
Has dedicated pediatric sample cup/Dead vol.	**no**	**no/—**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/16 × 100–11 × 55 mm/no**	**yes/—/no**
Sample bar-code reading capability/Autodiscrimination	**yes (2 of 5 interl., codabar, codes 39 & 128)/—**	**yes (2 or 5 interl., codabar, codes 39 & 128)/—**
Bar-code placement per NCCLS standard Auto2A	**—**	**yes**
Onboard test auto inventory (determines vol. in container)	**yes**	**yes**
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	**no/yes**	**yes/yes**
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	**yes/yes (mftr. & assay dependent)**	**no/no**
Time between initial result & reaspiration of sample for rerun	**n/a**	**—**
Autocalibration or autocalibration alert	**n/a**	**n/a**
No. of calibrators required for each analyte	**mftr. & assay dependent**	**manufacturer dependent**
Calibrants can be stored onboard/Avg. calibration frequency	**—/mftr. & assay dependent**	**manufacturer dependent/manufacturer dependent**
Multipoint calib. supported/Multiple calibs. stored for same assay	**yes/—**	**yes/manufacturer dependent**
How often QC required	**mftr. & assay dependent**	**manufacturer dependent**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**no/n/a**	**—/—**
Automatic shutdown/Startup is programmable/Startup time	**no/no/5 minutes**	**no/no/10 minutes**
Stat time to completion of ß-hCG test	**n/a**	**manufacturer dependent**
Time delay from ordering stat test to aspir. of sample	**n/a**	**n/a**
Throughput per hours for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	**n/a**	**—/open system—depends on kit**
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 (included in price)**	**onboard/yes**
Interfaces up and running in active user sites with	**—**	**—**
LIS interface operates simultaneously w/ running assays	**yes**	**—**
Uses LOINC to transmit orders and results	**—**	**—**
How labs get LOINC codes for reagent kits	**—**	**—**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes**
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	**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	**within 24 hours**	**by contract**
Mean time between failures/To repair failures	**—/<24 hours**	**—/—**
Onboard error codes to facilitate troubleshooting	**yes**	**yes**
Avg. time to complete maintenance by lab personnel	**daily: 6–10 minutes; weekly: 10 minutes; monthly: 15 minutes**	**daily: 5 minutes; weekly: 5–10 minutes; monthly: 10–15 minutes**
Onboard maintenance records/Maintenance training demo module	**yes/no**	**—/no**
List price/Targeted bed size or daily volume	**$38,000/>100 beds**	**$72,900/>100**
Annual service contract cost (24 hours/7 days)	**depends on acquisition option**	**varies**
Training provided w/ purchase/Advanced operator training	**3–5 days on site/yes**	**3–4 days on site/no**
Distinguishing features (supplied by vendor)	**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**	**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**

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