Move to integrated analyzers well underway

Anne Ford

Ever since Gregor Mendel, father of modern genetics, started tinkering in his garden with different kinds of peas, humankind has followed its urge to cross-breed two entities, amplifying the strengths of both while minimizing their individual weaknesses. While some experiments in hybridization have only novelty value—if you've seen one "liger" (the offspring of a lion and a tiger), you've seen them all—others have achieved great success, such as so-called hybrid analyzers that perform both immunoassay and chemistry testing.

Just ask Abbott Diagnostics spokesperson Jim Schwartz: "Integrated immunoassay/chemistry solutions allow for consolidation of assays and increased productivity." Beckman Coulter vice president Mike Renard agrees: "We believe that one of the big trends is the move to integrated systems. And we also believe that people don't want to compromise analytical capabilities just to be able to integrate their chemistry and immunoassay testing processes." Many of the products in this month's instrumentation survey demonstrate this trend toward combined testing, even while the demand for immunoassay-only analyzers continues.

Take Roche. The company expects to release in July its Cobas 6000 analyzer series, which, product manager Adam Sterle says, "offers our customers the flexibility of customizing an integrated system with both chemistry and immunodiagnostics menu capability based on test mix and volume." The Cobas 6000 series can, he adds, "consolidate into one integrated platform up to 95 percent of a customer's routine workload of clinical chemistry and immunoassay testing." Roche received FDA clearance for the series, which will eventually be available to laboratories in seven different configurations, in April. Three of the configurations—the Cobas C 501 clinical chemistry analyzer, the Cobas E 601 immunoassay analyzer, and the integrated Cobas 6000 analyzer series (C 501/E 601 analyzers)—will be available upon the series' launch this summer. Potential customers in 14 cities can check out the series during a six-month road show, Connections '06, that ends in October.

Another integrated system that will be made available later this year: Diagnostic Products Corp.'s DPC Integrated Workcell. Mark R. Smith, associate director of clinical diagnostic systems, says that the workcell combines the company's Immulite 2000 or Immulite 2500 immunoassay system with its T60 chemistry system via the DPC Sample Management System, the better to "provide the laboratory access to a menu of over 160 immunochemistry assays and more than 385 specific allergens and allergy panels." The DPC Integrated Workcell is a followup of sorts to the DPC Immunoassay Workcell, which the company introduced in 2005. Smith calls the latter "a powerhouse system" for high-volume testing; operated by a single user, it can run up to 48 different assays and has a 9,600-test onboard capacity with a 350-sample maximum.

In late October, Dade Behring will bring to market the high-volume Dimension Vista system, an integrated analyzer that received FDA clearance last year. The Dimension Vista will incorporate the company's new Loci homogeneous chemiluminescent technology for immunoassay testing. "This revolutionary technology," says scientific specialist Nancy Haley, PhD, "utilizes a homogeneous two-bead chemiluminescence principle for assays that typically require a heterogeneous methodology. This technology will be utilized for tests such as cardiac markers, thyroids, and anemia tests like B_{12} and folate," as well as cancer, fertility, and infectious disease. Haley says the Loci technology's sensitivity rivals what she terms "today's best-in-class heterogeneous immunoassay format," adding, "The homogeneous format reduces both sample sizes and reaction steps for improved turnaround times."

Abbott, meanwhile, anticipates launching its i1000sr immunoassay analyzer early next year. The i1000sr will be the newest member of Abbott's Architect family of analyzers, which includes the ci8200 immunochemistry platform, a combination of the company's c8000 chemistry analyzer and i2000sr immunoassay analyzer. Of the i1000sr, Schwartz says, "This new addition to the Architect family is designed to be the most productive immunoassay analyzer in the low- to mid-volume laboratory because of innovative sample management with continuous access to reagents and supplies. The i1000sr will offer best-in-class assay performance, ease of use, user-friendly operating software, high reliability, and future physical integration with chemistry."

Abbott also intends to launch the Architect c16000 system for high-volume and high-throughput chemistry testing and the Architect ci16200 high-volume and high-throughput integrated immunochemistry system in early 2007. "Abbott's goal is to offer the Architect immunoassay, clinical chemistry, and integrated immunochemistry systems to meet various customer testing environment needs," Schwartz adds.

At Olympus America, the newest immunoassay analyzer on the horizon is the AU3000i; at press time, the company expected to launch it in Europe this month and in the United States in the last quarter of this year (pending FDA clearance). "The AU3000i will be initially available as a separate workstation," says Lorraine Damico, director of immunoassay marketing. "It will be offered as part of a workcell with AU chemistry systems during the second launch phase, which will follow." The AU3000i will offer a throughput of up to 240 tests per hour, random-access processing, a stat interrupt feature, magnetic particle capture, and chemiluminescent detection. Olympus America customers can also look forward to the introduction of the company's AU-Connector, which, Damico says, "will integrate specimen movement between Olympus AU chemistry and AU3000i systems."

This summer, says Gary Tremain, marketing

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SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

manager for The Binding Site, will bring the DS2, a two-plate immunoassay processor that represents a smaller version of the company's DSX system. "Our commitment to support these instruments as open systems has differentiated us in the marketplace from other suppliers," Tremain says. "Offering laboratories a way to automate and consolidate their testing requirements without being forced into a sole-sourced proprietary menu has proved to be a very popular and successful marketing strategy." The company creates user-required protocols specific to each laboratory, which, Tremain adds, "provides flexibility unmatched by closed systems."

At DiaSorin, meanwhile, the newest offerings are the Epstein-Barr virus early antigen IgG, *Treponema* screen, and *Borrelia* assays that will soon be available in the United States on the company's Liaison instrument. "All of these assays utilize recombinant proteins," says marketing manager Brian Lauber. "ACTH, cortisol, dsDNA, and direct renin will also be available in the U.S. market before the end of this year." The Liaison, a benchtop, random-access, chemiluminescent instrument, already offers to the U.S. market Epstein-Barr virus viral capsid antigen IgG, Epstein-Barr virus IgM, Epstein-Barr virus nuclear antigen IgG, cytomegalovirus IgG, cytomegalovirus IgM, *Toxoplasma gondii* IgG, *Toxoplasma gondii* IgM, and intact parathyroid hormone assays, along with what Lauber calls "the only fully automated, antibody-based, 25 hydroxyvitamin D assay on the market."

Just a few months ago, Beckman Coulter swelled the ranks of its UniCel family of instruments with the addition of the UniCel DxC 600i, an integrated workstation with a 150-analyte menu and a per-hour throughput of 990 chemistry and 100 immunoassay tests. It is the first in a planned line of UniCel integrated analyzers, which, Renard says, will allow the company to "tailor solutions to fit the test mix and throughput needs of many different types of laboratories across the broad spectrum of the chemistry/immunoassay menu." He calls the DxC 600i a demonstration of the company's commitment to immunoassay testing. "Several years ago, we listed two instruments in the CAP TODAY survey of immunoassay analyzers," he points out. "This year, we're listing five analyzers capable of delivering immunoassay results."

CAP TODAY's survey of immunoassay analyzers includes systems from the aforementioned manufacturers and from Awareness Technology, Bayer Health Care Diagnostics, BioMérieux, Bio-Rad Laboratories, Diamedix, Grifols USA, Hycor Biomedical, Ortho-Clinical Diagnostics, Pharmacia Diagnostics, Randox Laboratories, Tosoh Bioscience, and Trinity Biotech. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities. □

Anne Ford is a writer in Chicago.

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	Abbott Diagnostics **Nathaniel Pritchett** nat.pritchett@abbott.com **100 Abbott Park Rd., Dept. ZZ2, AP6C-5** **Abbott Park, IL 60064-3500** **847-937-3335** www.abbott.com
Name of instrument/First year sold/Where designed	**AxSym Plus/1993 worldwide, 1994 U.S./U.S.**
Country where manufactured/Where reagents manufactured	**U.S./U.S.**
No. of units in clinical use in U.S./Outside U.S.	**2,400/10,000**
Operational type/Model type/Sample handling system	**cont. random access/stat, batch floor-standing/segment**
Dimensions in inches (H x W x D)/Instrument footprint in square feet	**60.5 x 63 x 33.5 in/14.6 sq ft**
Tests available on instrument in U.S.	**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**
Tests cleared but not clinically released	**—**
Tests not available in U.S. but submitted for clearance	**AUSAB, CORE, CORE-M, HBsAg/confirmatory**
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**
Research-use-only assays	**n/a**
Tests in development	**CA 19-9, β-2-microglobulin, insulin, 3rd gen TSH, digitoxin, PTH, holoTc, anti-CCP, D-dimer**
User-defined methods implemented for what analytes	**n/a**
Tests not available on other manufacturers' analyzers	**n/a**
Fully automated microplate system	**no**
No. of each analyte performed in separate disposable unit	**n/a**
No. of wells in microplate	**n/a**
Methods supported/Separation methods	**FPIA, MEIA, ion capture, REA/heterogeneous, bead (microparticle), fiber matrix filter**
No. of different measured assays onboard simultaneously	**20**
No. of different assays programmed, calibrated at once	**20**
No. of user-definable (open) channels	**0**
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	**20/100**
Shortest/Median onboard reagent stability/Refrigerated onboard	**onboard reagent stability: 112, 224, 336/no**
Multiple reagent configurations supported	**no**
Reagent container placed directly on system for use	**yes**
Reagents bar coded/Information in bar code	**yes/assay name, reag. lot No., expir. date, pack No. ID**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**no/< 0.1 ppm**
Walkaway capacity in minutes/Specimens/Tests-assays	**60/90/90**
System is open (home-brew methods can be used)/Liquid or dry system	**no/liquid**
Uses disposable cuvettes/Max. No. stored	**yes/90 reaction vessels**
Uses washable cuvettes/Replacement frequency	**no**
Minimum specimen vol. required	**83 uL/150 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**
Supplied with UPS (backup power)/Requires floor drain	**yes (soft close of files only)/optional**
Requires dedicated water system/Water consumption	**no/—**
Noise generated	**52–68 decibels**
Has dedicated pediatric sample cup/Dead vol.	**no**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/100 & 75 mm/no**
Sample bar-code reading capability/Autodiscrimination	**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**
Auto detection of adequate reagent or specimen	**yes**
Clot detection/Reflex testing capability	**yes/yes**
Hemolysis detection-quantitation/Turbidity detection-quantitation	**no/no**
Dilution of patient samples onboard/Automatic rerun capability	**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**
Time between initial result & reaspiration of sample for rerun	**seconds**
Autocalibration or autocalibration alert	**no**
No. of calibrators required for each analyte	**6 pt. or 2 pt. w/ master calib., index calib.**
Calibrants can be stored onboard/Avg. calibration frequency	**no/4 weeks**
Multipoint calib. supported/Multiple calibs. stored for same assay	**yes/yes (up to 4 curves/analyte)**
How often QC required	**shortest interval: 8 hr, longest: 24 hr**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**
Automatic shutdown/Startup is programmable/Startup time	**no/no/1 min**
Stat time to completion of ß-hCG test	**10 min**
Time delay from ordering stat test to aspir. of sample	**30 sec from standby**
Throughput per hr 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)**
Can auto transfer QC results to LIS/Onboard capability to review QC	**yes/yes**
Data management capability/Instrument vendor supplies LIS interface	**onboard/no**
Interfaces up and running in active user sites with	**all major LIS vendors**
LIS interface operates simultaneously w/ running assays	**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)**
Results transmitted to LIS as soon as test time complete	**yes**
Interface available (or will be) to auto specimen handling system	**yes**
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	**no/yes/yes**
Can order (via modem) malfunctioning part(s) w/o operator	**yes, Abbott Link**
On-site response time of service engineer	**12 hr**
Mean time between failures/To repair failures	**5 months/within 12 hr per customer request**
Onboard error codes to facilitate troubleshooting	**yes**
Avg. time to complete maintenance by lab personnel	**daily: 14 min; weekly: 65 min; monthly: 11 min**
Onboard maintenance records/Maintenance training demo module	**no/no**
List price/Targeted bed size or daily volume	**$124,000/200 IA tests per day**
Annual service contract cost (24 hours/7 days)	**$16,800 extended hours coverage**
Training provided w/ purchase/Advanced operator training	**yes/yes**
Distinguishing features (supplied by vendor)	**menu, reliability, online exception help, pressure monitoring, clot detection, ratio calculation, stat TAT**

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Survey editor: Raymond Aller, MD

Automated immunoassay analyzers

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Name of instrument/First year sold/Where designed	Architect i2000SR; i2000; i4000/—/U.S.	Architect ci8200/2003/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.	175/3,183	140/3,500
Operational type/Model type/Sample handling system	batch, random access, cont. random access/floor-standing/track & LAS	batch, random access, cont. random access/floor-standing/features a patented Retest Sample Handler that uses multi-dimensional sample handling
Dimensions in inches (H x W x D)/Instrument footprint in square feet	i200SR, 48 x 61 x 49/20.3 sq ft; i2000, 48 x 68 x 44 in/22.7 sq ft per module	48 x 127 x 49 in/43.2 sq ft
Tests available on instrument in U.S.	Troponin I, CK-MB, myoglobin, TSH, free T3 & T4, total T3 & T4, T-uptake, β-HCG, estradiol, FSH, LH, progesterone, prolactin, CA 125, CA 15-3, CEA, free & total PSA, BNP, CA 19-9 xr, DHEA-S, anti-Tg	Troponin I, CK-MB, myoglobin, TSH, free T3 & T4, total T3 & T4, T-uptake, β-HCG, estradiol, FSH, LH, progesterone, prolactin, CA 125, CA 15-3, CEA, free & total PSA, BNP, CA 19-9 xr, DHEA-S, anti-Tg, acid phosphatase, albumin BCG & BCP, alkaline phosphatase, ALT, ALT – Act, amylase, AST, AST – Act, bilirubin (direct, total & neonatal), calcium, cholesterol, CK, CO2, creatinine, (contact company for full test menu of 105 assays)
Tests cleared but not clinically released	AFP, B12, ferritin, insulin, anti-HCV	AFP, B12, ferritin, insulin, anti-HCV
Tests not available in U.S. but submitted for clearance	HBsAg, HBsAg confirmatory, SHBG, AUSAB, anti-TPo	vanco., gent., HBsAg, HBsAg confirm., AUSAB, anti-TPo
Tests not available in U.S. but available in other countries	folate, RBC folate, ferritin, AFP, pepsinogen I & II, SCC, HAVAB-IgM, HAVAB-IgG, anti-HBs anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, HIV Ag/Ab combo	folate, RBC folate, ferritin, AFP, pepsinogen I & II, SCC, HAVAB-IgM, HAVAB-IgG, anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, HIV Ag/Ab combo, CORE, CORE-M, (contact company for full test menu)
Research-use-only assays	n/a	n/a
Tests in development	cyclosporine, sirolimus, tacrolimus, C-peptide, cortisol, homocysteine, vitamin D, CMV IgG, CMV IgM, Rubella IgG & IgM, TOXO IgG & IgM, estriol, PTH, RBC folate, pepsinogen I & II, SCC, HAVAB-IgM, HAVAB-IgG, anti-HBc, CORE-M, CORE, HBeAg, HIV Ag/Ab combo, Tg	cyclosporine, sirolimus, tacrolimus, C-peptide, cortisol, homocyst., vit. D, CMV IgG/IgM, rubella IgG/IgM, toxo IgG/IgM, estriol, PTH, B-12, folate, ferritin, AFP, lithium, D-dimer, tobramycin, lith., enzymatic creant., testosterone, acetaminophin, salicylate
User-defined methods implemented for what analytes	none	—
Tests not available on other manufacturers' analyzers	none	n/a
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	Chemiflex (enhanced chemiluminescence) w/5 flexible protocols/magnetic microparticle	photometric, potentiometric, & Chemiflex (enhanced chemiluninescence)
No. of different measured assays onboard simultaneously	25	93
No. of different assays programmed, calibrated at once	25	93
No. of user-definable (open) channels	n/a	220
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	25/100-test & 500-test per kit	93/50–1,700
Shortest/Median onboard reagent stability/Refrigerated onboard	30 days/30 days/yes (2–12ºC)	3 days/28 days/yes
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., reagent serial No., lot No., tests per kit, exp. date, onboard stability time, master calibration curve	yes/assay name, reagent No., lot No., tests per kit, expiration date, others
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	n/a/no	open system/SmartWash technology
Walkaway capacity in minutes/Specimens/Tests-assays	300/135/12,500	300/367/>75,000
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	yes/1,200	both disposable and semi-permanent glass/1,200 or 165
Uses washable cuvettes/Replacement frequency	no/n/a	yes/as needed, 1-yr minimum
Minimum specimen vol. required	50 uL	2 uL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	150 uL/50 uL for all tube types	50 uL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/yes
Requires dedicated water system/Water consumption	no/n/a	yes/30 L per hr
Noise generated	48–70 decibels	48-70 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10–16 mm diameter, up to 75–100 mm height/no	yes/10–16 mm diameter, up to 75–100 mm 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	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	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	<20 seconds	<20 sec
Autocalibration or autocalibration alert	yes	no (to be available in next SW revision)
No. of calibrators required for each analyte	2–6 pt. curve	2 or 6 pt.
Calibrants can be stored onboard/Avg. calibration frequency	no/minimum 30 days or once per lot	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	3 levels every 24 h for quantitative, 2 levels for qualitative	from 2 levels after calibration, to 3 per 24 hr
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 min	n/a/no/10 min
Stat time to completion of ß-hCG test	15.6 min	<15.6 min
Time delay from ordering stat test to aspir. of sample	<20 sec	<20 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	67/200 tests per hour	400/1,200
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	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, Abbott Link	yes, Abbott Link
On-site response time of service engineer	8 business hr	8 business hr
Mean time between failures/To repair failures	10.4 weeks/—	7.3 weeks/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 23 min; weekly: <10 min; monthly: none	daily: <10 min; weekly: <10 min
Onboard maintenance records/Maintenance training demo module	yes/yes	yes/yes
List price/Targeted bed size or daily volume	$169,500/>200 immunoassays per day	$375,000/200–500 immunoassay tests per day
Annual service contract cost (24 hours/7 days)	flexible options available	n/a
Training provided w/ purchase/Advanced operator training	yes/yes	yes/yes
Distinguishing features (supplied by vendor)	Chemiflex technology delivers excellent sensitivities and extended linearities while the RSH allows for priority and routine samples to be processed simultaneously without compromising stats	integration of CC and IA without compromising stat TAT, results, or throughput because of patented SmartWash technology, which minimizes carryover to <0.1 ppm; large reagent capacity of 93 assays, with sample load up to 367

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SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 3 of 23 *See accompanying article on page 14*	**Awareness Technology Inc.** **Chris Schneider** info@awaretech.com **1935 SW Martin Hwy.** **Palm City, FL 34990** **772-283-6540** www.awaretech.com	**Bayer Health Care Diagnostics Division** **Denise Pastore** denise.pastore.b@bayer.com **511 Benedict Ave.** **Tarrytown, NY 10591** **914-333-6162** www.bayerdiag.com
Name of instrument/First year sold/Where designed	**ChemWell/1998/U.S.**	**ADVIA Centaur/1998/U.S.**
Country where manufactured/Where reagents manufactured	**U.S./open system**	**Ireland/U.S.**
No. of units in clinical use in U.S./Outside U.S.	**8/800+**	**>1,300/>3,100**
Operational type/Model type/Sample handling system	**batch, random access/benchtop/rack**	**cont. random access/floor standing/rack or direct track sampling**
Dimensions in inches (H x W x D)/Instrument footprint in square feet	**16 x 34 x 20 in/4 sq ft**	**51.5 x 72.5 x 41.5 in/21 sq ft**
Tests available on instrument in U.S.	**unlimited—open system**	**TSH, 3rd-gen. TSH, T4, FT4, T-uptake, T3, FT3, B12, fol., RBC fol., ferr., LH, FSH, prolac., progest., testost., estradiol, hCG, CK-MB, myogl., trop. I, digoxin, digitoxin, urine & serum cortisol, IgE, equimolar PSA, CEA, AFP, BR 27.29, tobramycin, carbamazep., phenobarb., cPSA, phenytoin, aTPO, gentamicin, theophylline, vancomycin, anti-TG, rubella IgG & IgM, toxo IgG & IgM, valporic acid, CA 15-3, iPTH, homocys., CA 125 II, C-peptide, insulin, BNP, CA-19-9, HER-2/*neu***
Tests cleared but not clinically released	**—**	**—**
Tests not available in U.S. but submitted for clearance	**—**	**HBsAg, HBsAg conf., HIV1/0/2**
Tests not available in U.S. but available in other countries	**unlimited—open system**	**specific allergens, mixes, allergy screen, HBsAg conf., HBsAg, HIVI/0/2**
Research-use-only assays	**unlimited—open system**	**—**
Tests in development	**—**	**HBeAg, anti-HBe, cyclosporine, high-sensitivity troponin I, ANA, CMV IgG, CMV IgM**
User-defined methods implemented for what analytes	**general biochemistries**	**none**
Tests not available on other manufacturers' analyzers	**n/a**	**cPSA, HER-2/*neu***
Fully automated microplate system	**yes**	**no**
No. of each analyte performed in separate disposable unit	**up to 12**	**n/a**
No. of wells in microplate	**min. strip, 8; max. full plate, 96**	**n/a**
Methods supported/Separation methods	**EIA/coated microwell**	**chemiluminescence/magnetic particle**
No. of different measured assays onboard simultaneously	**up to 12**	**30**
No. of different assays programmed, calibrated at once	**unlimited**	**30**
No. of user-definable (open) channels	**unlimited**	**0**
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	**27/assay dependent**	**30/50–100**
Shortest/Median onboard reagent stability/Refrigerated onboard	**assay dependent/assay dependent/yes (10°C below ambient)**	**96 hr/28 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	**no**	**yes/assay name, lot No., expir., pack ID**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**no/none**	**n/a/zero carryover**
Walkaway capacity in minutes/Specimens/Tests-assays	**assay dependent/96/12**	**230/180/840**
System is open (home-brew methods can be used)/Liquid or dry system	**yes/liquid**	**no/liquid**
Uses disposable cuvettes/Max. No. stored	**yes/96**	**yes/1,000**
Uses washable cuvettes/Replacement frequency	**yes/assay dependent**	**no**
Minimum specimen vol. required	**2 µL**	**10 µL, assay dependent**
Minimum sample vol. aspirated precisely at once/Min. dead vol.	**2µL/—**	**10 µL/50 µL**
Supplied with UPS (backup power)/Requires floor drain	**no/no**	**yes/no**
Requires dedicated water system/Water consumption	**no**	**no/~2.5 L per hr**
Noise generated	**—**	**<64 decibels w/in 1 meter**
Has dedicated pediatric sample cup/Dead vol.	**no**	**no**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/12 x 100 mm/no**	**yes/multiple/no**
Sample bar-code reading capability/Autodiscrimination	**no/—**	**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	**no/no**	**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/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	**yes/yes**	**no/no**
Time between initial result & reaspiration of sample for rerun	**assay dependent**	**15 sec minimum**
Autocalibration or autocalibration alert	**no**	**no**
No. of calibrators required for each analyte	**assay dependent**	**2**
Calibrants can be stored onboard/Avg. calibration frequency	**yes/assay dependent**	**no/varies, avg. 21 days**
Multipoint calib. supported/Multiple calibs. stored for same assay	**yes/yes**	**yes/yes**
How often QC required	**shortest interval: each run; longest: daily**	**24 hr**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
Automatic shutdown/Startup is programmable/Startup time	**yes/yes/2 min**	**no/no/none**
Stat time to completion of ß-hCG test	**assay dependent**	**18 min**
Time delay from ordering stat test to aspir. of sample	**30 sec**	**15 sec**
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	**assay dependent**	**80/240 (15 sec)**
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)**	**onboard/—**
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**
LIS interface operates simultaneously w/ running assays	**no**	**yes**
Uses LOINC to transmit orders and results	**no**	**—**
How labs get LOINC codes for reagent kits	**n/a**	**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	**no**	**yes (IDS, Lab InterLink, Labotix, CLIDS, PSS, Hitachi CLAS, A&T)**
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 48 hr**	**4 hr, 24 hr max.**
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: <10 min; weekly: <10 min; monthly: <10 min**	**daily: 3 min; weekly: 20 min; monthly: 30 min**
Onboard maintenance records/Maintenance training demo module	**no/no**	**yes/yes**
List price/Targeted bed size or daily volume	**$25,000/up to 500 tests per day**	**$225,000/300+ beds or 400 tests per day**
Annual service contract cost (24 hours/7 days)	**$4,000**	**$21,500**
Training provided w/ purchase/Advanced operator training	**3 days on site/no**	**varies on site, 4 days at vendor offices/yes**
Distinguishing features (supplied by vendor)	**ability to perform general biochemistries; optional reagent cooling module**	**ability to access/change solutions, waste, disposables and reagents at any time without pausing sampling or processing; onboard automatic dilutions, repeats, and cascade reflex testing; disposable tips; 240 results per hour, compatible with Hitachi racks; dedicated stat entry, smart algorithm**

Automated immunoassay analyzers

Part 4 of 23

See accompanying article on page 14

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Name of instrument/First year sold/Where designed	ADVIA Centaur CP Immunoassay System/2005/U.S.	Access Immunoassay System/1993/U.S., France
Country where manufactured/Where reagents manufactured	Germany/U.S.	U.S./U.S., France
No. of units in clinical use in U.S./Outside U.S.	—/—	>1,000/>2,000
Operational type/Model type/Sample handling system	batch, random access, continuous random access/benchtop/7 x 12 position racks	Cont. random access/benchtop/rack
Dimensions in inches (H x W x D)/Instrument footprint in square feet	43 x 29 in/8.7 sq ft	18.5 x 39 x 24 in/6.5 sq ft
Tests available on instrument in U.S.	AFP, CEA, cPSA, PSA, digoxin, BNP, CK-MB, C troponin I, homocysteine, myoglobin, E26III, FSH, LH, progesterone, prolactin, ThCG, FT4, FT3, T3, T4, TSM, TSM-3, T-uptake, ferritin, folate, RBC folate, VB12	CEA, T3, T4, T-uptake, 3rd-gen. TSH, FT4, FT3, βhCG, DHEA-S, prolac, FSH, LH, progest., 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., theoph., chlam. Ag, urine chlam. Ag, chlam. Ag confirm., toxo IgG, rubella IgG, hybritech PSA & fPSA, testosterone, ostase, toxo IgM, antithyroglob., hyp e r-sensitive human growth hormone, thyroglobulin, AccuTnI, OV monitor (CA 125 antigen), BR monitor (CA 15.3 antigen), GI monitor (CA 19.9 antigen), BNP
Tests cleared but not clinically released	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	—
Tests not available in U.S. but submitted for clearance	—	TPO Ab, iPTH
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, EPO, IL-6
Research-use-only assays	—	IL-6
Tests in development	—	CMV IgG & IgM, rubella IgM, soluble transferrin receptor, BPH-A, [-2]proPSA, β2-glycoprotein 1 Ab, ANA, ds-DNA Ab, Inhibin A, PIGF, sVEGF RI (preeclampsia)
User-defined methods implemented for what analytes	—	none
Tests not available on other manufacturers' analyzers	cPSA, HER-2/*neu*	chlam. Ag & confirm., AFP-ONTD, hybritech PSA & fPSA, 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	15	24
No. of different assays programmed, calibrated at once	100	24
No. of user-definable (open) channels	—	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	15/50–100	24/50 tests per cartridge, 100 tests per kit
Shortest/Median onboard reagent stability/Refrigerated onboard	96 hr/28 days/yes (2–8°C)	336 hr/28 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/reagent ID, lot No., expiration date	yes/assay No., lot No., expir., unique reag. pack ID No.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover	no/ 10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	210/400/400	180/60/300-31
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/400	yes/294
Uses washable cuvettes/Replacement frequency	no	no
Minimum specimen vol. required	100 uL	specimen container dependent
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 uL/50 uL	5 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	no/no
Requires dedicated water system/Water consumption	no	no/n/a
Noise generated	up to 65 decibels	<70 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/multiple/no	yes/13 x 75 & 100, 16 x 75 & 100, 2 mL & 3 mL sample cups/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codaboar, 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	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	yes/yes	no/no
Time between initial result & reaspiration of sample for rerun	20 sec	n/a
Autocalibration or autocalibration alert	yes	no
No. of calibrators required for each analyte	2	6
Calibrants can be stored onboard/Avg. calibration frequency	no	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	user defined	24 hr
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/yes/<5 min	no/no/remains in ready mode
Stat time to completion of ß-hCG test	15.6 min	15 min
Time delay from ordering stat test to aspir. of sample	<1 min	36 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	60/180 (20 sec)	33/100 (36 sec)
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 or addt'l cost—negotiable)
Interfaces up and running in active user sites with	ADVIA Centaur CP is compatible with ADVIA Centralink Networking Solution	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 (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/—	no/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	4 hr, 24 hr max.	24 hr max., usually w/in 6 hr
Mean time between failures/To repair failures	not available/not available	not available/not available
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 3 min; weekly: 20 min; monthly; 30 min	daily: 15 min; weekly: 30 min; monthly: none
Onboard maintenance records/Maintenance training demo module	yes/yes	yes/no
List price/Targeted bed size or daily volume	$150,000/community hospitals, satellite labs	$129,800/all vols. & hospital sizes
Annual service contract cost (24 hours/7 days)	—	$14, 800
Training provided w/ purchase/Advanced operator training	4 days at vendor offices/yes	4 days at vendor offices/yes
Distinguishing features (supplied by vendor)	add reagents, consumables, samples without interruption; uses same reagents/consumables as ADVIA Centaur; throughput 180 tests/hour	continuous random access benchtop analyzer; state-of-the-art chemiluminescence methodology; ease of use: any test, any tech, any time; superior assays: TSH, FT_4, UE_3, hybritech PSA, fPSA, B_{12}, fol., AccuTnI

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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 5 of 23 *See accompanying article on page 14*	**Beckman Coulter Inc.** **Joel Greiner** jcgreiner@beckman.com **200 S. Kraemer Blvd.** **Brea, CA 92821** **714-993-8329** www.beckmancoulter.com	**Beckman Coulter Inc.** **Katie Blount** kjblount@beckman.com **200 S. Kraemer Blvd.** **Brea, CA 92821** **714-993-8749** www.beckmancoulter.com
Name of instrument/First year sold/Where designed	**Access 2 Immunoassay System/2001/U.S.**	**Synchron LXi 725/2002/U.S.**
Country where manufactured/Where reagents manufactured	**U.S./U.S. & France**	**U.S./U.S.**
No. of units in clinical use in U.S./Outside U.S.	**>1,300/>1,000**	**—/—**
Operational type/Model type/Sample handling system	**cont. random access/benchtop/rack**	**cont. random access/floor standing/rack-closed tube**
Dimensions in inches (H x W x D)/Instrument footprint in square feet	**18.5 x 39 x 24 in/6.5 sq ft**	**60 x 134.5 x 48 in/44.8 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, progest., 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., theoph., chlam. Ag, urine chlam. Ag, chlam. Ag confirm., toxo IgG, rubella IgG, hybritech PSA & fPSA, testosterone, ostase, toxo IgM, antithyroglob., hypersensitive human growth hormone, thyroglobulin, AccuTnI, OV monitor (CA 125 antigen), BR monitor (CA 15.3 antigen), GI monitor (CA 19.9 antigen), BNP**	**CEA, T3, T4, TU, 3rd gen TSH, FT4, FT3, βhCG, DHEA-S, prolac, FSH, LH, progest, estrad., unconj. estriol, B12, fol., ferr., intrinsic factor Ab, CK-MB, myogl., cortisol, urine cortisol, insulin, AFP-open neural tube defect, total IgE, digox., theoph., chlam. Ag, urine chlam. Ag, chlam. Ag confirm, toxo IgG, toxo IgM, rubella IgG, hybritech PSA, hybritech fPSA, testosterone, thyroglob., anti-thyroglob., human growth hormone, ostase, AccuTnI, C3, C4, haptoglobin, BNP, OV monitor (CA 125 antigen), BR monitor (CA 15.3 antigen), GI monitor (CA 19.9 antigen), plus >100 Synchron chem tests, including critical care, general, esoteric, urine & CSF chemistries, all current Synchron DATs, TDMs, proteins, serologies**
Tests cleared but not clinically released	**—**	**—**
Tests not available in U.S. but submitted for clearance	**TPO Ab, iPTH**	**TPO Ab, iPTH**
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, EPO, IL-6**	**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, β2-glycoprotein 1 Ab, ANA, ds-DNA Ab, Inhibin A, PlGF, sVEGF R1 (preeclampsia)**	**CMV IgG & IgM, rubella IgM, EPO, soluble transferrin receptor, β2-glycoprotein 1 Ab, ANA, ds-DNA Ab, Inhibin A, PlGF (preeclampsia), BPH-A, [-2]proPSA, sVEGF R1 (preeclampsia)**
User-defined methods implemented for what analytes	**none**	**—**
Tests not available on other manufacturers' analyzers	**chlam. Ag & confirm., 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**	**65**
No. of different assays programmed, calibrated at once	**24**	**65**
No. of user-definable (open) channels	**0**	**100**
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**	**100 tests per kit (immuno), 300 tests per container set (general)**
Shortest/Median onboard reagent stability/Refrigerated onboard	**336 hr/28 days/yes (4°C)**	**336 hr/28 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/assay No., lot No., expir., unique reagent pack ID No.**	**yes/assay No., lot No., expir., unique reagent pack ID**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**no/ 10 ppm**	**no/ 10 ppm**
Walkaway capacity in minutes/Specimens/Tests-assays	**180/60/300**	**180/132/5,280**
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/294**
Uses washable cuvettes/Replacement frequency	**no**	**yes, 2 yr warranty (general chem.)**
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/100 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes (when networked)/no**	**yes/yes**
Requires dedicated water system/Water consumption	**no**	**yes/16 L per hr**
Noise generated	**<70 decibels**	**—**
Has dedicated pediatric sample cup/Dead vol.	**yes/100 µL**	**yes/—**
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/13x75 & 100, 16x75 & 100 mm/yes**
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**	**yes for general chemistry/yes for general chemistry**
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/no**
Time between initial result & reaspiration of sample for rerun	**36 sec**	**36 sec**
Autocalibration or autocalibration alert	**no**	**no**
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 hr**	**24 hr**
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 min**	**17 min**
Time delay from ordering stat test to aspir. of sample	**36 sec**	**36 sec**
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	**33/100 (36 sec)**	**33/100 (immuno), 1,440 (chem) (36 sec)**
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)**	**optional add-on/yes (included or additional cost is 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**	**yes**
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**	**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	**24 hr max., usually within 6 hr**	**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 min; weekly: 30 min; monthly: none**	**—**
Onboard maintenance records/Maintenance training demo module	**yes/no**	**yes/no**
List price/Targeted bed size or daily volume	**$149,800/all volumes & hospital sizes**	**—/—**
Annual service contract cost (24 hours/7 days)	**$15,800**	**per negotiated contract**
Training provided w/ purchase/Advanced operator training	**4 days at vendor offices/yes**	**yes/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**	**workstation consolidation without compromise through the use of innovative automation; single point-of-sample entry using closed tube sampling, dual scheduling, and parallel processing**

Automated immunoassay analyzers

Part 6 of 23

See accompanying article on page 14

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Name of instrument/First year sold/Where designed	UniCel DxI 800/2003/U.S.	UniCel DxC 600i Synchron Access Clinical System/2006/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S., France	U.S./U.S.
No. of units in clinical use in U.S./Outside U.S.	>350/>350	—/—
Operational type/Model type/Sample handling system	cont. random access/floor standing/rack, direct track sampling	continuous random access/floor standing/rack-closed tube
Dimensions in inches (H x W x D)/Instrument footprint in square feet	66.7 x 67.5 x 37.7 in/17.7 sq ft	62 x 126.5 x 48/42.16 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, progest., 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., theoph., chlam. Ag, urine chlam. Ag, chlam. Ag confirm., toxo IgG, rubella IgG, hybritech PSA & fPSA, testosterone, ostase, toxo IgM, antithyroglob., hyper-sensitive 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	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, theophylline, chlamydia Ag, chlamydia Ag, Confirmatory, 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
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for clearance	TPO Ab, iPTH	TPO Ab, iPTH
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, EPO, IL-6	IL-6, EPO, rubella IgM
Research-use-only assays	IL-6	IL-6
Tests in development	CMV IgG & IgM, rubella IgM, EPO, soluble transferrin receptor, BPH-A, [-2]proPSA, β2-glycoprotein 1 Ab, ANA, ds-DNA Ib, Inhibin A, PIGF, sVEGF RI (preeclampsia)	EPO, ANA screen, ds-DNA Ab, B2-glycoprotein I Ab, CMV IgG, CMV IgM, rubella IgM, Inhibin A, PIGF (preeclampsia), sVEGF RI (preeclampsia), BPH-A, [-2]proPSA, soluble transferrin receptor
User-defined methods implemented for what analytes	none	—
Tests not available on other manufacturers' analyzers	intrinsic factor Ab	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/magnetic particle	chemiluminescence, enzyme immunoassay/magnetic particle
No. of different measured assays onboard simultaneously	50	89
No. of different assays programmed, calibrated at once	50	89
No. of user-definable (open) channels	0	100
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	50/50 tests per cartridge, 100 or 1,000 tests per kit	89/100 tests per kit (immunoassay); 300 tests per container (gen. chem.)
Shortest/Median onboard reagent stability/Refrigerated onboard	336 hr/28 days/yes (3–10°C)	336 hr/28 days/yes (2°-10°C)/yes
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/specific cartridge ID, No. of tests, available tests, expiration date, lot No., calibration expiration
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	n/a/< 10 ppm	no/10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	288 (avg.—assay mix dependent)/120/1,200 (avg.)	180/96/5,280
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/294
Uses washable cuvettes/Replacement frequency	no	yes/2-year warranty (gen. chem.)
Minimum specimen vol. required	specimen container dependent	specimen container dependent
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/160 µL	5 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	yes (PC only)/optional	optional/yes
Requires dedicated water system/Water consumption	no/—	yes/16 L per hr
Noise generated	<60 decibels	—
Has dedicated pediatric sample cup/Dead vol.	yes/100 µL	yes (gen. chem.)/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/12x75 to 16x100 mm/no	yes/13 x 75 & 100 to 16 x 100 mm/yes
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	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	yes/no
Time between initial result & reaspiration of sample for rerun	<9 sec (min.)	36 sec
Autocalibration or autocalibration alert	yes	no
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 h	24 hr
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 min	17 min
Time delay from ordering stat test to aspir. of sample	18 sec	36 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	min. 67, max. 133/min. 200, max. 400 (9 or 18 sec)	—/100-immunoassay, 990-gen. chem. (36 sec)
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 is negotiable)	optional add-on/yes (additional cost)
Interfaces up and running in active user sites with	all major LIS vendors	all major LIS vendors
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	no	yes
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 (Beckman Coulter automation systems)	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	per negotiated contract	—
Mean time between failures/To repair failures	—/—	—/per negotiated contract
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: <10 min; weekly: TBD; monthly: none	daily: <15 min; weekly: 36 min; monthly: 11 min
Onboard maintenance records/Maintenance training demo module	yes/yes	yes/no
List price/Targeted bed size or daily volume	$325,000/300+ beds or >400 tests per day	—/—
Annual service contract cost (24 hours/7 days)	$29,900	per negotiated contract
Training provided w/ purchase/Advanced operator training	5 days at vendor office for 2 employees/yes	yes/yes
Distinguishing features (supplied by vendor)	highest 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	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

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Automated immunoassay analyzers

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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 x W x D)/Instrument footprint in square feet	32 x 42 x 36 in/7 sq ft	30 x 17 x 26/3.07
Tests available on instrument in U.S.	ANA screen, ENA scr., SS-A, SS-B, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, GBM, MPO, PR3, TG, TPO, cardiolipin IgG/IgM/IgA & scr, B2GP1 IgG/IgM/IgA & scr, phosphatidylserine IgG/IgM/IgA, C1q CIC, gliadin IgG/IgA & scr, tTG IgA, tTG IgG, RF, anti-CCP, histone, EBV VCA IgG/IgM, EBV EA-D IgG, EBV EBNA-1 IgG/IgM, toxo IgG/IgM, rubella IgG/IgM. CMV IgG/IgM.IgM capture, HSV 1/2 IgG, measles IgG/IgM, mumps IgG, VZV IgG, IgM, lyme IgM/IgG & scr, H. pylori, syphilis, chlamydia, mycoplasma, legionella IgG/IgM, legionella UA, CCP, HSV 1/2 IgG type specific, tetanus toxoid, ASCA IgG/IgA, diptheria toxoid	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, phosphatidly serine 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, 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 ELISA system
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, phosphatidyl ethanolamine IgG, IgA, phosphatidyl lycerol 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 x 8; max. full plate 96 x 4 plates	min. strip 1 x 8; max. full plate: 96 wells x 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 hr/n/a/no	24 hr/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 minutes/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 min	no/yes/1–2 min
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 hr 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 hr	—
Mean time between failures/To repair failures	n/a/<24 hr	n/a/<24 hr
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 min; weekly: n/a; monthly: n/a	daily: 5 min; 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	$52,635 (dependent on modules)/200+ beds	$30,000/100–200 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; sw 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 8 of 23

See accompanying article on page 14

	bioMérieux Inc. **Marcum Bell** marcum.bell@na.biomerieux.com 100 Rodolphe St. Durham, NC 27712 919-620-2000 www.biomerieux-usa.com	Bio-Rad Laboratories Clinical Diagnostics Group **Greg Stewart** greg_stewart@bio-rad.com 4000 Alfred Nobel Dr. Hercules, CA 94547 510-724-7000 www.bio-rad.com
Name of instrument/First year sold/Where designed	VIDAS & MiniVIDAS/1989/U.S.	PR 3100TSC Photometer/2006/Austria
Country where manufactured/Where reagents manufactured	Italy/France	Austria/U.S.
No. of units in clinical use in U.S./Outside U.S.	2,200/>20,000	0/0
Operational type/Model type/Sample handling system	batch, random access/benchtop/n/a	batch/benchtop/rack
Dimensions in inches (H x W x D)/Instrument footprint in square feet	Vidas: 16 x 32 x 21 in; MiniVidas: 21 x 21 x 17 in/Vidas 4.5, MiniVidas 4 sq ft	7 x 13 x 13/2
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	contact Bio-Rad representative
Tests cleared but not clinically released	—	none
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	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	none	not in U.S.
Tests in development	EBV, HbA1c, procalcitonin, *C. difficile* toxin A&B	blood virus panel
User-defined methods implemented for what analytes	none	none
Tests not available on other manufacturers' analyzers	all assays for use on Vidas instruments only	none
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	min. strip: 1; max. full plate: 96
Methods supported/Separation methods	fluorescence, EIA/coated solid phase receptacle (SPR)/pipetting device	enzyme immunoassay/coated microwell
No. of different measured assays onboard simultaneously	Vidas: 30, MiniVidas: 12	1
No. of different assays programmed, calibrated at once	total menu	1
No. of user-definable (open) channels	0	closed until 6 months post launch
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	unit dose format/30 or 60	0/n/a
Shortest/Median onboard reagent stability/Refrigerated onboard	n/a/n/a/no	n/a/n/a/no
Multiple reagent configurations supported	no	no
Reagent container placed directly on system for use	yes	—
Reagents bar coded/Information in bar code	yes/assay name, lot No., sequence No., expir.	no/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover	no/n/a
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/12–30/12–30	1/up to 96/1
System is open (home-brew methods can be used)/Liquid or dry system	no/dry	yes (6 months post launch)/liquid
Uses disposable cuvettes/Max. No. stored	no	no/—
Uses washable cuvettes/Replacement frequency	no	no/—
Minimum specimen vol. required	100 µL	n/a
Minimum sample vol. aspirated precisely at once/Min. dead vol.	100 µL/n/a	n/a/n/a
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no
Requires dedicated water system/Water consumption	no/no	no/n/a
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	no	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/n/a/no	no/—/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	no/no
Bar-code placement per NCCLS standard Auto2A	n/a	no
Onboard test auto inventory (determines vol. in container)	n/a	no
Measures No. of tests remaining/Short sample detection	no/no	no/no
Auto detection of adequate reagent or specimen	no	no
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	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	n/a	—
Autocalibration or autocalibration alert	yes	no
No. of calibrators required for each analyte	1	1 calibration plate
Calibrants can be stored onboard/Avg. calibration frequency	no/14 days	no/weekly
Multipoint calib. supported/Multiple calibs. stored for same assay	no (mftr.-determined calib. curves)/yes	no/no
How often QC required	shortest interval: 8 hr, longest: 24 hr	shortest interval: weekly; longest interval: monthly
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	—/no
Automatic shutdown/Startup is programmable/Startup time	no/no/remains ready	no/no/—
Stat time to completion of ß-hCG test	30 min	n/a
Time delay from ordering stat test to aspir. of sample	no delay	n/a
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	Vidas: 20, MiniVidas: 8/Vidas: 60, MiniVidas: 24 (—)	—/—
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	no/no
Data management capability/Instrument vendor supplies LIS interface	onboard/yes (additional cost)	no/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	no
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)	no
Results transmitted to LIS as soon as test time complete	yes	no
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	no/yes/yes	no/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	w/in 24 hr	units returned for service
Mean time between failures/To repair failures	Vidas: 350 days, MiniVidas: 1,000 days/<2 hr	—/—
Onboard error codes to facilitate troubleshooting	yes	no
Avg. time to complete maintenance by lab personnel	daily: 10–15 min;, weekly: 10–15 min; monthly: 30 min	daily: 0; weekly: 5 min; monthly: 5 min
Onboard maintenance records/Maintenance training demo module	yes/yes	no/—
List price/Targeted bed size or daily volume	Vidas: $51,800, MiniVidas: $28,100/400 beds	$5,800/5-200 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	1 day on site
Distinguishing features (supplied by vendor)	features make VIDAS the ideal instrument 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	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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 9 of 23 *See accompanying article on page 14*	Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Drive Hercules, CA 94547 510-724-7000 www.bio-rad.com	Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Dr. Hercules, CA 94547 510-724-7000 www.bio-rad.com
Name of instrument/First year sold/Where designed	PhD System/2000/Belgium	Evolis/2001/Germany
Country where manufactured/Where reagents manufactured	Belgium/U.S.	Germany/U.S.
No. of units in clinical use in U.S./Outside U.S.	150/250	100/250
Operational type/Model type/Sample handling system	batch/benchtop/rack	batch/benchtop/rack
Dimensions in inches (H x W x D)/Instrument footprint in square feet	35 x 66 x 35 in/16 sq ft	37 x 44 x 30 in/10 sq ft
Tests available on instrument in U.S.	ANA (EIA), anti-centromere (EIA), anti-dsDNA (EIA), anti-ENA (EIA), anti-Jo-1 (EIA), anti-SS-A (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	contact Bio-Rad representative
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for clearance	—	—
Tests not available in U.S. but available in other countries	—	HIV Ab, HIV Ab/Ag, HIV Ag, HBsAg, 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
Research-use-only assays	—	not in U.S.
Tests in development	—	infectious disease & autoimmune panels
User-defined methods implemented for what analytes	—	none
Tests not available on other manufacturers' analyzers	—	none
Fully automated microplate system	no	yes
No. of each analyte performed in separate disposable unit	1	—
No. of wells in microplate	min. strip: 1; max. full plate: 96	min. strip, 1; max. full plate, 96
Methods supported/Separation methods	EIA/coated microwell	EIA/coated microwell
No. of different measured assays onboard simultaneously	8	4
No. of different assays programmed, calibrated at once	8	4
No. of user-definable (open) channels	no limit	closed in U.S. market
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	8/192	4/96
Shortest/Median onboard reagent stability/Refrigerated onboard	4 hr/—/no	30 min/assay dependent/n/a
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/n/a	no
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/—	no/no (disposable tips)
Walkaway capacity in minutes/Specimens/Tests-assays	195/184/1	varies by assay/180/4
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	no/n/a	microplates
Uses washable cuvettes/Replacement frequency	no/n/a	microplates
Minimum specimen vol. required	1 µL specimen	0.2 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	1 µL/200 µL	10 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no	no
Noise generated	—	60 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/—/no	yes/5, 7, 10 mL/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/no	yes (2 of 5 interl., codabar, codes 39 & 128)/no
Bar-code placement per NCCLS standard Auto2A	yes	no
Onboard test auto inventory (determines vol. in container)	no	yes
Measures No. of tests remaining/Short sample detection	no/yes	no/no
Auto detection of adequate reagent or specimen	yes	no
Clot detection/Reflex testing capability	no/no	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	n/a	n/a
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	1–5	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/each run	no/with each run
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/no
How often QC required	each run	user determined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/no	yes/yes (through Unity QC program)
Automatic shutdown/Startup is programmable/Startup time	no/no/5 min	no/no
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 hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	n/a/n/a	assay dependent
Can auto transfer QC results to LIS/Onboard capability to review QC	no/yes	yes/—
Data management capability/Instrument vendor supplies LIS interface	onboard/yes (included)	onboard/yes
Interfaces up and running in active user sites with	—	in development
LIS interface operates simultaneously w/ running assays	yes	no
Uses LOINC to transmit orders and results	can be customized	no
How labs get LOINC codes for reagent kits	—	n/a
Bidirectional interface capability	no	yes (broadcast download)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	no/no/no	yes/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	<24 hr	24 hr
Mean time between failures/To repair failures	6 months/4 hr	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 15 min; weekly: 15 min; monthly: 30 min	daily: 5 min; weekly: 10 min; monthly: 30 min
Onboard maintenance records/Maintenance training demo module	no/no	yes/no
List price/Targeted bed size or daily volume	$38,000/>50 tests per day	$65,000/50–400 tests per day
Annual service contract cost (24 hours/7 days)	$6,000	inquire
Training provided w/ purchase/Advanced operator training	2 days on site/no	3 days in Redmond, Wash./no
Distinguishing features (supplied by vendor)	accurate pipetting at 1 µL; connection of 1–10 pipetting stations together through an ethernet hub, graphical user interface; added module for IFA slide processing	fully automated microplate system that meets the highest level of safety (positive identification of samples, reagents, microplates, clot detection, no contamination), flexibility (continuous loading of samples, reagents, and microplates), and productivity (four plates, 180 samples, four different assays can be processed simultaneously)

Automated immunoassay analyzers

Part 10 of 23

See accompanying article on page 14

	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 Stat Fluorometric Analyzer/1998/U.S.	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.	700/700	1,200/800
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 x W x D)/Instrument footprint in square feet	18 x 27 x 22 in./4.1 sq. ft.	45 x 51 x 31 in (without monitor)/10.6 sq ft
Tests available on instrument in U.S.	mass CK-MB, trop. I, myoglobin, β-hCG, D-dimer, NT-pro BNP	thyrox. uptake, total thyrox., hemoglobin A1c, acid phosphat., alanine aminotransferase, alkaline phosphatase, amylase, aspartate aminotransferase, CK, CK isoenzyme, glutamyl transferase, lactic dehydrogenase, lipase, pseudocholinesterase, 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., cyclosporine, digox., digitox., gentamicin, lithium, phenobarbital, phenytoin, theophy., tobramycin, vancomycin, valp. acid, acetaminophen, ethyl alcohol, salicylate; urine screens: amph., barbit., benzo., cannab., cocaine metab., methad., opiates, phencyc., procainamide, lidocaine, n-acetylprocainamide (see Dimension RxL Max for full general chemistry menu), quinidine, triiodothyronine, microalbumin, NT-proBNP
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 hr/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 minutes/Specimens/Tests-assays	14 min to 1st result, subsequent results in 4 min 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 for liquid
Uses disposable cuvettes/Max. No. stored	no	yes/12,000
Uses washable cuvettes/Replacement frequency	no	no/—
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 hr
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 sec
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	1 cal pack	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 hr
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 min. to warm up	not required
Stat time to completion of ß-hCG test	14 min	16 min
Time delay from ordering stat test to aspir. of sample	immediately	24 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	3/9	83/250 (14.4 sec)
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 hr	2–8 hr
Mean time between failures/To repair failures	>225 days/2.9 hr	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: none; weekly: none; monthly: 10 min	daily: <5 min; weekly: 10 min; monthly: 15 min
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); 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	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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 11 of 23 *See accompanying article on page 14*	Dade Behring Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.dadebehring.com	Diagnostic Products Corp. info@dpconline.com 5210 Pacific Concourse Dr., Los Angeles, CA 90045-6900 310-645-8200 www.dpcweb.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.	IMMULITE/1993; IMMULITE *Turbo*/1999; IMMULITE 1000/2002/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S.	U.S./U.S., U.K.
No. of units in clinical use in U.S./Outside U.S.	combined: 2,500/2,000	>6,500 worldwide
Operational type/Model type/Sample handling system	batch, random access, cont. random access/floor-standing/racks	cont. random access/benchtop/loading platform
Dimensions in inches (H x W x D)/Instrument footprint in square feet	44 x 62.5 x 30.5 in./13.2 sq ft	19 x 46 x 26 in/7.98 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	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, trop. I; contact company for full menu
Tests cleared but not clinically released	—	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), free PSA, 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	—	*Turbo:* D-dimer
User-defined methods implemented for what analytes	—	none
Tests not available on other manufacturers' analyzers	system performs heterogeneous immunoassays and general assays on a single platform—complete routine chemistry menu	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
No. of wells in microplate	—	n/a
Methods supported/Separation methods	EIA, latex particle turbidimetric, direct turbidimetric/heterogeneous, magnetic particles	chemiluminescence/bead, centrifugation
No. of different measured assays onboard simultaneously	47 (91 with optional reagent management system)	12
No. of different assays programmed, calibrated at once	190	unlimited
No. of user-definable (open) channels	10	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	Max=47, Max Suite=91/15–360	12; 5 for *Turbo*/100; 50 for *Turbo* i-PTH
Shortest/Median onboard reagent stability/Refrigerated onboard	72 hr/30 days/yes (2–8°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/lot No., unique flex ID, stability, expiration date	yes/test, lot No., expir.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/n/a due to probe washing	no/<10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	can be hours/60/>1,000	100/—/70
System is open (home-brew methods can be used)/Liquid or dry system	yes/no reagent prep required by operator for liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/12,000	yes/n/a
Uses washable cuvettes/Replacement frequency	no/—	no
Minimum specimen vol. required	2 µL	5 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	2 µL/primary tube capable	5 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	yes/3.2 L per hr	no/0.5 L per h
Noise generated	<70 decibels	55-68 decibels
Has dedicated pediatric sample cup/Dead vol.	yes/10–20 µL	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5, 7, 10 mL/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	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 sec	n/a
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	varies—3 levels for most assays	2-level adjustors, supplied in kit
Calibrants can be stored onboard/Avg. calibration frequency	yes (Na, K, Cl)/up to 90 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	24 hr	customer determined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	no/yes
Automatic shutdown/Startup is programmable/Startup time	not required	no/no/5 min
Stat time to completion of ß-hCG test	16 min	42 min; 15 min for *Turbo* (total hCG)
Time delay from ordering stat test to aspir. of sample	24 sec	2.5 min
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	55–166/167–500 (7.2 sec.)	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	optional (DBNet–Dade Behring)/yes (addt'l cost)	onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	all major LIS vendors	CIS, CPSI, CCA, Mysis, McKesson, Cerner, Antek, CSS, 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	yes/yes/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	2–8 hr	4 hr
Mean time between failures/To repair failures	—/—	10 months/4 hr
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 min, weekly: 10 min, monthly: 15 min	daily: 5 min; weekly: 10 min; monthly: 20 min
Onboard maintenance records/Maintenance training demo module	yes/yes	—/yes
List price/Targeted bed size or daily volume	—/—	$75,000; *Turbo*: $77,500/>1,000 tests per month
Annual service contract cost (24 hours/7 days)	multiple types	$8,000
Training provided w/ purchase/Advanced operator training	5 days on site, 4 days at vendor offices/yes	3.5 days at vendor offices/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	worldwide customer satisfaction; system reliability and performance; one of the largest menus available on any immunoassay analyzer

Automated immunoassay analyzers

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	Diagnostic Products Corp. info@dpconline.com 5210 Pacific Concourse Dr., Los Angeles, CA 90045-6900 310-645-8200 www.dpcweb.com	**Diagnostic Products Corp.** info@dpconline.com 5210 Pacific Concourse Dr., Los Angeles, CA 90045-6900 310-645-8200 www.dpcweb.com
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.	>3,600 worldwide	—
Operational type/Model type/Sample handling system	Cont. random access/floor-standing/rack	continuous random access/floor standing/rack
Dimensions in inches (H x W x D)/Instrument footprint in square feet	47 x 60 x 30 in/12.5 sq ft	79 x 112 x 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-S04, 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; 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; 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	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, vancomycin, 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, vancomycin, 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	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
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 minutes/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 sec	min. 18 sec
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 min	yes/no/4 min
Stat time to completion of ß-hCG test	35 min (total HCG)	15 min (total HCG)
Time delay from ordering stat test to aspir. of sample	18 sec	18 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	200/200 (18 sec)	200/200 (18 sec)
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 hr	4 hr
Mean time between failures/To repair failures	3 months/5 hr	3 months/5 hr
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5–10 min; weekly: 20 min; monthly: 20–30 min	daily: 5–10 min; weekly: 20 min; monthly: 20–30 min
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)	$14,500 (RealTime Solutions)	$19,500 (RealTime Solutions)
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 and routine esoteric testing on one platform; clot detection; sample/reagent level detection; autodilution and autoreflex testing; remote diagnostics; RealTime Solutions (RTS) Internet-based service, OnLine Reports	largest 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, RTS Internet-based service & support

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

Automated immunoassay analyzers

Part 13 of 23

See accompanying article on page 14

	Diagnostic Products Corp. info@dpconline.com 5210 Pacific Concourse Dr., Los Angeles, CA 90045-6900 310-645-8200 www.dpcweb.com	Diamedix Corp. Sandra Yeager sandra_yeager@ivaxdiagnostics.com 2140 N. Miami Ave., Miami, FL 33127 305-324-2300 www.diamedix.com
Name of instrument/First year sold/Where designed	IMMUNOASSAY WORKCELL/2005/U.S.	Mago Plus Automated EIA Processor/1997/Italy
Country where manufactured/Where reagents manufactured	U.S./U.S., U.K.	Italy/U.S.
No. of units in clinical use in U.S./Outside U.S.	—/—	250/—
Operational type/Model type/Sample handling system	continuous random access/floor standing/rack	Batch, random access/benchtop/rack
Dimensions in inches (H x W x D)/Instrument footprint in square feet	75 x 136 x 136 in/121 sq ft	28 x 48 x 26 in/8.7 sq ft
Tests available on instrument in U.S.	configuration dependent; please see IMMULITE 2000/2500 menus	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	none
Tests not available in U.S. but submitted for clearance	configuration dependent; see IMMULITE 2000/2500 menus	none
Tests not available in U.S. but available in other countries	configuration dependent; see IMMULITE 2000/2500 menus	contact company
Research-use-only assays	none	none
Tests in development	configuration dependent; see IMMULITE 2000/2500 menus	mycoplasma IgM
User-defined methods implemented for what analytes	none	user defined
Tests not available on other manufacturers' analyzers	configuration dependent; see IMMULITE 2000/2005 menus	none
Fully automated microplate system	no	yes
No. of each analyte performed in separate disposable unit	n/a	1 analyte per well
No. of wells in microplate	n/a	min. 1 x 8 wells; max. 96 wells
Methods supported/Separation methods	chemiluminescence/bead, centrifugation	EIA/coated microwell
No. of different measured assays onboard simultaneously	48	9
No. of different assays programmed, calibrated at once	unlimited	~50 currently preprogrammed assays
No. of user-definable (open) channels	n/a	20 per diskette, unlimited diskette capability
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	48/200	9/96
Shortest/Median onboard reagent stability/Refrigerated onboard	n/a/90 days/yes (4°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/test, lot No., expiration	yes/ lot No., expir. date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/<3 ppm	no/not susceptible, continuous cleaning
Walkaway capacity in minutes/Specimens/Tests-assays	300/350/9,600	up to 2.5 hr—assay dependent/120/384
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	yes/2,600	yes/120
Uses washable cuvettes/Replacement frequency	no/—	no/n/a
Minimum specimen vol. required	5 µL to 100 µL sample	50 µL (pediatric)
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/50 µL	4 µL/25 µL (pediatric)
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/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	yes/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/75–100 mm height; 12–16 mm width/no	yes/11–15 mm x 75–100 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 or 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	yes	—
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	yes/yes	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	n/a/n/a	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	min. 18 sec	n/a
Autocalibration or autocalibration alert	yes	no
No. of calibrators required for each analyte	2 level adjustors, supplied in kit	assay dependent, 2–6
Calibrants can be stored onboard/Avg. calibration frequency	no/1–4 weeks (assay dependent)	yes/per run
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/no
How often QC required	customer determined	per run
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 min	n/a/n/a/<5 min
Stat time to completion of ß-hCG test	15 min (total HCG)	n/a
Time delay from ordering stat test to aspir. of sample	18 sec	n/a
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	400/400 (18 sec)	120/360 (2.5 h—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 (additional cost)	onboard/yes (included in price)
Interfaces up and running in active user sites with	Antek, Cerner, CIS, CPSI, CSS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, others	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 (universal interface)	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	4 hr	24 hr
Mean time between failures/To repair failures	4 months/5 hr	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5–10 min; weekly: 20 min; monthly: 20–30 min	daily: <5 min; weekly: <10 min; monthly: none
Onboard maintenance records/Maintenance training demo module	no/yes	no/no
List price/Targeted bed size or daily volume	configuration dependent: $314,000-$355,000/6,000 tests per month	$62,000/all bed sizes, all test volumes
Annual service contract cost (24 hours/7 days)	$29,500 (with RTS)	service during normal business hours included in reagent rental agreement
Training provided w/ purchase/Advanced operator training	varies on site, 5 days at vendor offices/yes	1–2 days on site/yes
Distinguishing features (supplied by vendor)	one of the largest automated immunoassay test menu 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	FDA-cleared system (instruments and reagents); moderate complexity; strip by strip timing, accommodates primary reagent packaging

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

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See accompanying article on page 14

	Diamedix Corp.	DiaSorin Inc.
	Sandra Yeager sandra_yeager@ivaxdiagnostics.com	Dawn Franzmeier dawn.franzmeier@diasorin.com
	2140 N. Miami Ave.	1951 Northwestern Ave.
	Miami, FL 33127	Stillwater, MN 55082
	305-324-2300	800-328-1482/651-439-9710
	www.diamedix.com	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	>150/>625
Operational type/Model type/Sample handling system	continuous random access/benchtop/racks	batch, random access/benchtop/rack
Dimensions in inches (H x W x D)/Instrument footprint in square feet	36 x 58 x 29 in/11.6 sq ft	40 x 45 x 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, HTLV I/II, Trep-Chek 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-mitochrondrial, anti-cardiolipin IgA, IgM, IgG & total, anti-β-2 glycoprotein 1, anti-thyroglobulin, anti-thyroid perixidase, anti-CCP, anti-centromere
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	n/a
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 x 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 minutes/Specimens/Tests-assays	up to 2.5 hr—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.	4 µL/25 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 x 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 min	no/yes/5 min
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 hr 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 hr	24 hr
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 min; weekly: 30 min
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, acccomodates 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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www.diasorin.com

Grifols USA Inc.
Patricia Silver patricia.silver@grifols.com
8880 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.	60/>1,500	>130/>1,200
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 x W x D)/Instrument footprint in square feet	63 x 136 x 66 cm/9.9 sq ft	28.3 x 41.3 x 34.3 in/10 sq ft
Tests available on instrument in U.S.	25 hydroxyvitamin D, intact PTH, EBV IgM, EBNA IgG, VCA IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM	system is completely open, any U.S. clinically cleared and research-use-only EIA procedure can be programmed; infectious diseases, autoimmune diseases, 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	Borrelia burgdorferi, treponema, VZV IgG, cortisol, ACTH, dsDNA, EA IgG	n/a
Tests not available in U.S. but available in other countries	CEA, PSA, fPSA, CA 15-3, CA-125, CA 19-9, TPA-M, EA IgG, 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	n/a
Research-use-only assays	—	n/a
Tests in development	1,25 dihydroxy vitamin D, osteocalcin, BSAP, cardiolipin IgG, IgM, IgA, rubella IgG, hGH, HSV-1 IgG	n/a
User-defined methods implemented for what analytes	n/a	n/a
Tests not available on other manufacturers' analyzers	autoimmune, S-100, avidity tests, 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 minutes/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 min	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 hr	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 min	yes/yes/1–2 min
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 min	n/a
Throughput per hr 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)	onboard/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 hr	within 24 hr
Mean time between failures/To repair failures	—/—	within 24 hr
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 10 min; weekly: 20 min; monthly: 30 min	daily: 5–20 min; 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	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

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

Automated immunoassay analyzers

Part 16 of 23

See accompanying article on page 14

	Hycor Biomedical Inc.	Olympus America Inc.
	cs@hycorbiomedical.com	Susan Watanabe susan.watanabe@olympus.com
	7272 Chapman Ave.	Two Corporate Center Dr.
	Garden Grove, CA 92841	Melville, NY 11747
	714-933-30000	800-223-0125
	www.hycorbiomedical.com	www.olympus.com
Name of instrument/First year sold/Where designed	Hy•Tec 288/outside U.S. 1998, U.S. 1999/Netherlands	AU400e/2002; AU400/1999/Japan
Country where manufactured/Where reagents manufactured	Netherlands/U.S., Scotland	Japan/U.S., Ireland
No. of units in clinical use in U.S./Outside U.S.	51/102	>500/>1,500
Operational type/Model type/Sample handling system	random batches/benchtop/rack-robotics	cont. random access/floor-standing/rack & turntable
Dimensions in inches (H x W x D)/Instrument footprint in square feet	29.5 x 42.5 x 27.5 in/8 sq ft	47.6 x 57.1 x 29.9 in/70 x 129 in
Tests available on instrument in U.S.	specific IgE, total IgE, >1,000 allergens; 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	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
Tests cleared but not clinically released	anti-tissue transglutaminase IgA and IgG	ceruloplasmin, HbA1c, lithium, cholinesterase, urinary protein
Tests not available in U.S. but submitted for clearance	none	none
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	cotinine
Research-use-only assays	none	none
Tests in development	ANCA profile, centromere	none
User-defined methods implemented for what analytes	—	fructosamine
Tests not available on other manufacturers' analyzers	allergy & autoimmune testing on fully automated system	none
Fully automated microplate system	yes	no
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)	n/a
No. of wells in microplate	96–min. strip: 1 strip/8 wells; max. full plate: 12 strips/96 wells	n/a
Methods supported/Separation methods	EIA, tube-based & microplate-based assays/activated cellulose & coated well	EIA, photometric, potentiometric, calc. results/none (all homogeneous)
No. of different measured assays onboard simultaneously	varies by assay, up to 288 allergens or 8 autoimmune	>40
No. of different assays programmed, calibrated at once	multiple	99
No. of user-definable (open) channels	unlimited	95
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	76/100–6,160
Shortest/Median onboard reagent stability/Refrigerated onboard	8 hr/12 hr/no	168 h/60 days/yes (4–12°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	no	yes/reag. ID, lot No., bottle No., expir.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/<1 part in 10,000	yes/n/a
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/100/288	variable/up to 102/8,058
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	yes/permanent
Minimum specimen vol. required	10 µL, 110 µL w/ dead vol.	2 µL per test
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL–50 µL, assay dependent//100 µL	2 µL/25 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	optional/yes
Requires dedicated water system/Water consumption	no/—	yes/20 L per h @ peak consump.
Noise generated	—	<65 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/—/no	yes/pediatric, 5 mL, 7 mL, 10 mL/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)/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	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	no/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/yes
Time between initial result & reaspiration of sample for rerun	n/a	varies by run size
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	1–5	1–6
Calibrants can be stored onboard/Avg. calibration frequency	no/monthly	yes/14 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	every assay	lab-defined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/no/2–3 min	yes/yes/24 h availability
Stat time to completion of ß-hCG test	n/a	n/a
Time delay from ordering stat test to aspir. of sample	n/a	<1 min
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	n/a	133.3/400 (9 sec)
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/optional	onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	25	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	no	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	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	optional	yes
Interface available (or will be) to auto specimen handling system	no	yes
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/no	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	48 hr	<24 hr
Mean time between failures/To repair failures	7 months/4 hr	>30 weeks/<24 hr
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 10–15 min; weekly: 20–25 min; monthly: 20–25 min	daily: 3 min; weekly: 7 min; monthly: 45 min
Onboard maintenance records/Maintenance training demo module	yes (includes audit trail of who replaced parts)/yes	yes (incl. audit trail of who replaced parts)/yes
List price/Targeted bed size or daily volume	$55,000/all sites, variable test vols.	$130,000/200–2,000 tests per day (depending on menu)
Annual service contract cost (24 hours/7 days)	$5,500	inquire
Training provided w/ purchase/Advanced operator training	3 days on site/yes	5 days on site, 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	fully automated allergy and autoimmune testing; >1,000 allergens; user-definable software	open reagent system; 122-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

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Automated immunoassay analyzers

Part 17 of 23 *See accompanying article on page 14*	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.	>2,000 worldwide	n/a/n/a
Operational type/Model type/Sample handling system	cont. random access/floor standing/universal sample trays (circular) accommodate primary & secondary containers without need for adapters	cont. random access/floor standing/circular universal sample trays accommodate primary & secondary containers without need for adapters
Dimensions in inches (H x W x D)/Instrument footprint in square feet	51 x 44 x 29 in/8.9 sq ft	51 x 44 x 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	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
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for clearance	aHIV 1&2, aHAV total, aHAV IgM, rubella IgG	aHIV 1&2, aHAV total, aHAV IgM, rubella IgG
Tests not available in U.S. but available in other countries	CA 19-9, fβ–hCG, a-HAV IgM, a-HBe, HBeAg, a-HIV I&II, aHAV total, toxo IgG, rubella IgG	a-HAV IgM, a-HBe, HBeAg, a-HIV I&II, CA 19-9, free β–hCG, aHAV total, toxo IgG, rubella IgG
Research-use-only assays	none	none
Tests in development	rubella IgM, toxo. IgM, CMV IgG, CMV IgM	rubella 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 minutes/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 hr	once per 24 hr
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 min	24 min
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 hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	30/90 (40 sec)	30/90 (40 sec)
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	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	<4 hr (contract dependent)	<4 hr (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 min; weekly: <30 min; monthly: <10 min	daily: <5 min; weekly: <30 min; monthly: <10 min
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

Part 18 of 23 *See accompanying article on page 14*	Pharmacia Diagnostics* AB Nicole Lampas nicole.lampas@diagnostics.com 4169 Commercial Ave. Portage, MI 49002 800-346-4364 www.us.diagnostics.com	Pharmacia Diagnostics* AB Nicole Lampas nicole.lampas@diagnostics.com 4169 Commercial Ave. Portage, MI 49002 800-346-4364 www.us.diagnostics.com
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.	100/500	100/500
Operational type/Model type/Sample handling system	continuous random access/floor standing/racks	continuous random access/floor standing/racks
Dimensions in inches (H x W x D)/Instrument footprint in square feet	73 x 50 x 30 in + 26 in wide computer stand/—	83 x 71 x 40 in + 26 in wide computer stand/—
Tests available on instrument in U.S.	greater than 550 ImmunoCAP specific IgE tests, ImmunoCAP total IgE, and ImmunoCAP specific IgG** tests	greater 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	Pharmacia Diagnostics AB ImmunoCAP assays	Pharmacia Diagnostics 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 yr/yes (2–8°C)	5 days/1 yr/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 minutes/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 x 50–105 mm/no	yes/10–17 mm x 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 min	100 min
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 min	6 min
Throughput per hr 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 hr	<24 hr
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 min; weekly: 10 min; monthly: 15 min	daily: 1 min; weekly: 10 min; monthly: 15 min
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; 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 *Pharmacia Diagnostics is becoming Phadia	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 *Pharmacia Diagnostics is becoming Phadia

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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 19 of 23 *See accompanying article on page 14*	**Pharmacia Diagnostics* AB** **Nicole Lampas** nicole.lampas@diagnostics.com **4169 Commercial Ave.** **Portage, MI 49002** **800-346-4364** www.us.diagnostics.com	**Randox Laboratories Ltd.** **Julie Thomson** evidence.support@randox.com **Diamond Rd.** **Crumlin, C.o Antrim, BT29 4QY** **+44 28 94 422413** www.randox.com
Name of instrument/First year sold/Where designed	ImmunoCAP 100^{E} system/1995/Sweden	Evidence/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.	500/10,000	—/—
Operational type/Model type/Sample handling system	batch/benchtop/carousel	batch/floor standing/carousel
Dimensions in inches (H x W x D)/Instrument footprint in square feet	18 x 28 x 24 in + computer/—	68 x 78 x 39 in/35.75 sq ft
Tests available on instrument in U.S.	greater than 550 ImmunoCAP specific IgE tests, ImmunoCAP total IgE, gliadin IgA, gliadin IgG are FDA-cleared; and ImmunoCAP specific IgG tests**, ECP**, trytase** are IUO	cocaine, methamphetamine, amphetamine, methadone, PCP, opiates, cannabinoids, barbiturates, benzodiazepine, progesterone, prolactin, LH, FSH, estradiol
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	ELIA, autoimmune products (available in U.S. through Scimedx); Celikey tTg (tissue transglutinase) IgA, IgG	TT4, TT3, TSH, FT3, FT4, AFP, CA 125, CA 19-9, CA 15-3, fPSA, tPSA, hCG, CK-MB, CA III, FABP, GPBB, myoglobin, troponin, testosterone
Research-use-only assays	**ImmunoCAP specific IgG tests, ECP, trytase are investigational use only (IUO)	cell adhesion molecule array, cerebral array, further cytokines and growth factors array, maternal screen array, additional tumor markers, breast cancer diagnosis and classification, bone markers, drugs of abuse array II
Tests in development	—	many tests in development
User-defined methods implemented for what analytes	—	—
Tests not available on other manufacturers' analyzers	Pharmacia Diagnostics AB ImmunoCAP assays	IL-1β, IL-4, VEGF, EGF, MCP-1, IFN, FABP, GPBB, CA 111
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	fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulose polymer matrix reaction wells	chemiluminescence/biochip array technology
No. of different measured assays onboard simultaneously	4	22
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/—
Shortest/Median onboard reagent stability/Refrigerated onboard	n/a	3/7 days/yes (4ºC)
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 name, lot No., expir. date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/—	—/—
Walkaway capacity in minutes/Specimens/Tests-assays	180 min/varies with analyte/48	—/180/—
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	no
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)	3 µL/70 µL (varies with cup type)
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/1 L per run	no
Noise generated	—	60 decibels
Has dedicated pediatric sample cup/Dead vol.	no	yes
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10–16 mm x 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	no/no
Time between initial result & reaspiration of sample for rerun	2.5 hr–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
Calibrants can be stored onboard/Avg. calibration frequency	yes/28 days or sooner if conjugate lots change	no/weekly
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 min including request entry or downloading	yes/no/12 min
Stat time to completion of ß-hCG test	n/a	—
Time delay from ordering stat test to aspir. of sample	n/a	—
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	batch analyzer/48/180 min processing time for batch to finish	108/324/—
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/no (additional)
Interfaces up and running in active user sites with	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	—
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	yes/yes/no
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 minr; weekly: 10 minr; monthly: 15 min	daily: <5 min; weekly: 10 min; monthly: 30 min
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+ beds
Annual service contract cost (24 hours/7 days)	—	—
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; innovative products, comprehensive clinical and technical research, and extensive medical information and education, makes 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	biochip enables simultaneous analysis of multiple parameters in a single patient sample; max throughput of 1,188 test results per hour; tests not reported can be retrieved restrospectively; arrays contain multiple tests applicable to clinical and research applications; many new tests in development

**Pharmacia Diagnostics is becoming Phadia*

Automated immunoassay analyzers

Part 20 of 23

See accompanying article on page 14

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Name of instrument/First year sold/Where designed	**Elecsys 2010/1996/—**	**Modular Analytics E170/2001/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**	**>50/>300 (combination of E and EE systems) and >25 Integrated Modular Systems (U.S. only)**
Operational type/Model type/Sample handling system	**cont. random access/benchtop/rack or disk**	**continuous random access/floor-standing/rack**
Dimensions in inches (H x W x D)/Instrument footprint in square feet	**22.1 x 47.2 x 28.7 in/9.4 sq ft**	**96.25 (W) x 43.25 (D) in (Modular E configuration)/approx. 60 sq ft (one module system)**
Tests available on instrument in U.S.	**TSH, FT4, T4, T3, FT3, T-uptake, LH, FSH, progest., estradiol, prolac., testost., CK-MB, TnT, myglobin, digoxin, PSA (screen), CEA, CA 125, AFP, ferr., B12, fol., RBC folate, IgE, intact PTH, hCG, cortisol, insulin, fPSA, DHEAS, β–hCG, CA 15-3, anti-TPO, serum β crosslaps, pro BNP, cortisol urine, anti-HBs, SHBG, C-peptide, CA 19-9, HBsAg, HBsAg confirm, osteocalcin**	**TnT, CK-MB, digoxin, myoglobin, T4, T-uptake, TSH 3rd gen, FT4, T3, FT3, ATPO, β–hCG, FSH, LH, progesterone, prolactin, estradiol, DHEA-S, testosterone, CEA, AFP, PSA (screen), fPSA, CA 125, CA 15-3, ferritin, B12, folate, RBC folate, intact PTH, β crosslaps, cortisol, insulin, IGE, pro BNP, cortisol urine, SHBG, C-peptide, CA 19-9, osteocalcin**
Tests cleared but not clinically released	**TG**	**TG**
Tests not available in U.S. but submitted for clearance	**—**	**HBsAg, HBsAg (conf.), anti-HBs**
Tests not available in U.S. but available in other countries	**anti-HBc, cyfra 21-1, anti HBc IgM, anti-HBe, HBeAg, CA 72-4, NSE, anti-TG, PINP, anti-HCV, digitoxin**	**CA 72-4, cyfra 21-1, NSE, anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, anti-TG, digitoxin, PINP, anti-HCV, NSE**
Research-use-only assays	**none**	**none**
Tests in development	**anti-TSH receptor, thyrogloblin, ACTH, anti-HAV, anti-HAVIgM, anti-HCV, HBe, Interleukin-6, rubella IgG, rubella IgM, toxo IgG, toxo IgM, CA72-4, CYFRA21-1, NSE, P1NP, vitamin D OH-25**	**anti-TSH receptor, thyrogloblin, interleukin-6, rubella IgG, rubella IgM, toxo IgG, toxo IgM, ACTH, homocysteine, anti-HAV, anti-HAV IgM, CA72-4, CYFRA21-1, NSE, P1NP, vitamin D OH-25**
User-defined methods implemented for what analytes	**none**	**none**
Tests not available on other manufacturers' analyzers	**TnT**	**TnT**
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, electrochemiluminescence**
No. of different measured assays onboard simultaneously	**15**	**25 per E module, maximum of 60**
No. of different assays programmed, calibrated at once	**60**	**25 per module**
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	**15/100–200**	**25 per moduule/100–200**
Shortest/Median onboard reagent stability/Refrigerated onboard	**56 days/56 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	**no/zero carryover (disposable sample tips)**	**n/a/zero, uses disposable sample tips**
Walkaway capacity in minutes/Specimens/Tests-assays	**120/disk: 30, rack: 100/180**	**360/—/1,006**
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/—**
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**	**—/100 µL**
Supplied with UPS (backup power)/Requires floor drain	**—/no**	**no/no**
Requires dedicated water system/Water consumption	**no/—**	**yes/18 per module in full operation**
Noise generated	**—**	**—**
Has dedicated pediatric sample cup/Dead vol.	**no**	**yes/100 µL**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/13–16 mm diam./no**	**yes/13 x 75 to 16 x 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	**—**	**—**
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/—**
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/no**	**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/monthly**
Multipoint calib. supported/Multiple calibs. stored for same assay	**yes/yes**	**yes/yes**
How often QC required	**once per 24 hr**	**24 hr**
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 min**	**yes/yes/11 min**
Stat time to completion of ß-hCG test	**9 min (hCG intact)**	**18 min**
Time delay from ordering stat test to aspir. of sample	**42 sec**	**—**
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	**30/88 (42 sec)**	**56/176 (21 sec)**
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 (addt'l cost)**
Interfaces up and running in active user sites with	**all major LISs**	**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 (Roche Modular Pre-Analytical Systems and task targeted automation)**
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	**no/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 hr**	**24 hr**
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 min; weekly: 5 min; biweekly: 25 min; monthly: none**	**daily: 5 min; weekly: 10 min; monthly: 15 min**
Onboard maintenance records/Maintenance training demo module	**no/no (training CD-ROM)**	**yes/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 w/ reagent rental**	**incl. w/ reagent rental**
Training provided w/ purchase/Advanced operator training	**3 days at Indianapolis offices/yes**	**5 days at vendor offices/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**	**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**

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 21 of 23	**Roche Diagnostics** **Gerard Byrne** gerard.byrne@roche.com **9115 Hague Rd.** **Indianapolis, IN 46250-0457** **800-428-5074** www.roche.com/labsystems/us	**TOSOH Bioscience Inc.** **Shanti Narayanan** shanti.narayanan@tosoh.com **6000 Shoreline Court, Ste. 101** **South San Francisco, CA 94080** **800-248-6764** www.tosoh.com
See accompanying article on page 14		
Name of instrument/First year sold/Where designed	**Cobas e 601 Analyzer/2006/—**	**AIA-360/2004/Japan**
Country where manufactured/Where reagents manufactured	**Japan/Germany**	**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 x W x D)/Instrument footprint in square feet	**46.1 x 71.8 x 40/19.73 sq ft**	**21 x 19 x 16/2.1 sq ft**
Tests available on instrument in U.S.	**TnT, CK-MB, digoxin, myoglobin, T4, T-uptake, TSH 3rd gen, FT4, T3, FT3, ATPO, β–hCG, FSH, LH, progesterone, prolactin, estradiol, DHEA-S, testosterone, CEA, AFP, CA 125, CA 15-3, ferritin, B12, folate, RBC folate, intact PTH, β crosslaps, cortisol, insulin, IgE, pro-BNP, cortisol urine, SHBG, C-peptide, osteocalcin, CA 19-9, tPSA (monitor only), PTH, TPO**	**10 min 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	**anti-TG**	**—**
Tests not available in U.S. but submitted for clearance	**HBsAg, HBsAg (conf.), anti-HBs, ACTH**	**—**
Tests not available in U.S. but available in other countries	**CA 72-4, cyfra 21-1, NSE, anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, digitoxin, anti-HCV, PINP**	**BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg**
Research-use-only assays	**none**	**—**
Tests in development	**anti-HAV, anti-HAV IgM, vitamin D OH-25, IL-6, rubella IgG, rubella IgM, toxo IgG, toxo IgM**	**PTH, HbA1c, RBC folate**
User-defined methods implemented for what analytes	**none**	**—**
Tests not available on other manufacturers' analyzers	**TnT**	**—**
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	**electrochemiluminescence/magnetic particle**	**flourescence, EIA/bead**
No. of different measured assays onboard simultaneously	**25 per module**	**25**
No. of different assays programmed, calibrated at once	**25 per module**	**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	**25 per module/100-200**	**n/a/unitized test cup**
Shortest/Median onboard reagent stability/Refrigerated onboard	**56 days/56 days/yes (20° C)**	**72hr/72hr/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/calib. curve, application params., lot No., expir., reag. name**	**yes/lot No., test code**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**n/a/zero, uses disposable sample tips**	**no/zero carryover**
Walkaway capacity in minutes/Specimens/Tests-assays	**360/300/1,000**	**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/1,000**	**no**
Uses washable cuvettes/Replacement frequency	**no/—**	**no**
Minimum specimen vol. required	**10 µL**	**500 µL tube, 100 µL cup**
Minimum sample vol. aspirated precisely at once/Min. dead vol.	**10 µL/100 µL**	**10–100 µL**
Supplied with UPS (backup power)/Requires floor drain	**—/—**	**no/no**
Requires dedicated water system/Water consumption	**yes/20 L per hr**	**no/n/a**
Noise generated	**<65 decibels**	**—**
Has dedicated pediatric sample cup/Dead vol.	**yes/100µL**	**no**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/13 x 75 to 16 x 100/no**	**yes/primary draw tubes: 13 x 75 & 100; 16 x 75 & 100/no**
Sample bar-code reading capability/Autodiscrimination	**yes (2 of 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	**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	**yes/yes**	**no/no**
Time between initial result & reaspiration of sample for rerun	**—**	**n/a**
Autocalibration or autocalibration alert	**yes**	**no**
No. of calibrators required for each analyte	**2**	**2 or 6-analyte dependent**
Calibrants can be stored onboard/Avg. calibration frequency	**no/every 28 days**	**no/30–90 days**
Multipoint calib. supported/Multiple calibs. stored for same assay	**yes/yes**	**yes/yes**
How often QC required	**24 hr**	**24 hr**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**no/no**
Automatic shutdown/Startup is programmable/Startup time	**yes/yes/11 min**	**yes/no/5 min**
Stat time to completion of ß-hCG test	**18 min**	**~18 min**
Time delay from ordering stat test to aspir. of sample	**42 sec**	**60 sec**
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	**56/176 (21 sec)**	**12/36 (1 min)**
Can auto transfer QC results to LIS/Onboard capability to review QC	**yes/yes**	**yes/no**
Data management capability/Instrument vendor supplies LIS interface	**onboard/yes (additional cost)**	**Antek. Schuyler House, more**
Interfaces up and running in active user sites with	**all major laboratory information systems**	**n/a**
LIS interface operates simultaneously w/ running assays	**yes**	**—**
Uses LOINC to transmit orders and results	**yes**	**yes**
How labs get LOINC codes for reagent kits	**Web site**	**package insert**
Bidirectional interface capability	**yes (broadcast download & host query)**	**no**
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-Analytics)**	**no**
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	**yes/yes/no**	**no/no/no**
Can order (via modem) malfunctioning part(s) w/o operator	**no**	**no**
On-site response time of service engineer	**24 hrs**	**n/a**
Mean time between failures/To repair failures	**—/—**	**>6 months/24 hr**
Onboard error codes to facilitate troubleshooting	**yes**	**yes**
Avg. time to complete maintenance by lab personnel	**daily: 5 min.; weekly: 10 min; monthly: 15 min**	**daily: 5 min**
Onboard maintenance records/Maintenance training demo module	**yes (includes audit trail of who replaced parts)/yes**	**no/no**
List price/Targeted bed size or daily volume	**varies, based on contract/—**	**$25,000/200–1,000 tests per month**
Annual service contract cost (24 hours/7 days)	**—**	**$2,050-$3,500**
Training provided w/ purchase/Advanced operator training	**5 days at vendor offices/yes**	**training DVD; on-site install**
Distinguishing features (supplied by vendor)	**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**	**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**

Automated immunoassay analyzers

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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 x W x D)/Instrument footprint in square feet	19.8 x 31.6 x 29.1 in/2.5 sq ft	65 x 50 x 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	—	—
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 h/72 h/n/a	72hr/72hr/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 minutes/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 x 75 & 100, 13 x 75 & 100/no	yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100; 13 x 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 hr	24 hr
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 min	yes/no/5–8 min
Stat time to completion of ß-hCG test	~18 min	~18 min
Time delay from ordering stat test to aspir. of sample	60 sec	40 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	20/60 (1 min)	60/180 (20 sec)
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 hr	24 hr
Mean time between failures/To repair failures	98% uptime/—	5 months/24 hr
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 min; weekly: 5 min; monthly: none	daily: 5–8 min; weekly: 5 min; 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

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

Automated immunoassay analyzers

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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 x W x D)/Instrument footprint in square feet	**24 x 26 x 25.6 in/4.6 sq ft**	**28 x 53.2 x 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 x 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 minutes/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 x 100–11 x 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 min**	**no/no/10 min**
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 hr 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 hr**	**by contract**
Mean time between failures/To repair failures	**—/<24 hr**	**—/—**
Onboard error codes to facilitate troubleshooting	**yes**	**yes**
Avg. time to complete maintenance by lab personnel	**daily: 6–10 min; weekly: 10 min; monthly: 15 min**	**daily: 5 min; weekly: 5–10 min; monthly: 10–15 min**
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 aspir. 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**