Immunoassay market overflowing with change

Anne Ford

When is a negative actually a plus? When it's a negative predictive value, or NPV, that makes it possible for emergency medicine departments to exclude particular diagnoses. To that end, bioMérieux recently introduced the Vidas D-Dimer Exclusion assay–"the first and only FDA-cleared D-dimer assay for the exclusion of deep vein thrombosis and pulmonary embolism in outpatients presenting to the emergency department," says marketing manager Vince Tuminello. "The Vidas D-Dimer Exclusion offers a 99.9 percent NPV." For something negative, that sounds awfully positive.

The Vidas D-Dimer Exclusion is just one of myriad new assays for the immunoassay analyzers profiled in this month's instrumentation survey. With at least 30 assays recently or soon to be launched—to say nothing of multiple new analyzers and a number of software upgrades—laboratories are presented with an abundance of riches.

Take The Binding Site. "We've greatly expanded our menu offering on the DSX [analyzer] over the past year," marketing manager Gary Tremain says. "We've added an automated anti-CCP and a C1q binding circulating immune complex assay, expanded our celiac disease panel with tTG IgG, and launched a whole new line of infectious disease markers," such as those for mumps, Lyme disease, *H. pylori*, and syphilis. The Binding Site's customers can also look forward to the impending release of updated software for the DSX analyzer. The software, Tremain says, "incorporates many customer-requested features," such as an improved continuous sample load feature, a new deep-well incubation feature, and greater ease of use.

Beckman Coulter's list of forthcoming assays is similarly long. "We're going to launch anywhere from seven to 10 new assays by the end of the year, including intact PTH," says Jim Rigo, global marketing manager for immunodiagnostics. "That includes new tests for anemia, skeletal, cardiac, and more." The new anemia assays will include an assay for EPO and soluble transferrin receptor. Earlier this year, Beckman Coulter introduced a fast hTSH, an intrinsic factor, and an enhanced free T_3 test, along with an enhanced test for folate and RBC folate. The company will also launch its new chemistry-immunoassay system, the UniCel DxC 600i, later this year.

Tosoh has the second-generation AIA-360 under development with the primary change resulting in expanded test menu capabilities. Hepatitis B markers are in the final stages of optimization in the ST format and will be released as soon as they clear the regulatory process. As with all Tosoh analytes, these assays will be available on Tosoh AIA platforms.

Nichols Institute Diagnostics recently added aldosterone, H-hCG, IGF-I and IGFBP-3 with age- and gender-specific reference ranges, and Tg with recovery to the menu of its Nichols Advantage Specialty System immunoassay analyzer.

And this summer, DiaSorin is planning to introduce three assays on its Liaison chemiluminescent system: EBV IgM, VCA IgG, and EBNA IgG. "These assays will complement our existing menu of 25-OH vitamin D and intact PTH," says product manager Mari Kelly. "The DiaSorin EBV assays will be the first automated EBV chemiluminescence assays on the U.S. market. The time to first result is only 35 minutes."

Rounding out the bunch are Hycor, which plans to continue to expand the product menu of its Hy•Tec 288 instrument to include infectious disease assays, and Randox, which, says U.S. business manager Stuart Menary, has "a wide range of assays currently in development, including expansion of routine parameters as well as more esoteric parameters like a maternal screening array, cerebrovascular array, and further applications for screening, diagnosis, and monitoring of various tumors."

In addition to the scores of new assays, vendors are flaunting new instruments, such as Olympus America's AU3000i automated immunoassay system. "We will begin placing the AU3000i at customer sites in Europe later this year, and we anticipate release in the States in early 2006," says Bruce Gernaey, director of marketing. "In the first year of launch, we'll have a 20-test menu including thyroid, fertility, cardiac, and tumor markers. In 2007 we plan to add additional tumor markers, anemia, and infectious disease assays." The new instrument will be available as a standalone analyzer or as part of a workcell with Olympus AU chemistry systems.

Visitors to the annual meeting of the American Association for Clinical Chemistry should keep an eye out for two new instruments from Abbott—the Architect i1000SR immunoassay analyzer and the Architect c16000 chemistry system. "These instruments will utilize common reagents, common software, common sample management, and common detection technology of our current Architect systems," U.S. product manager Chris Dillman reports. Also scheduled for availability this summer is Bayer's Advia Centaur CP immunoassay system, which John Leach, global senior marketing manager in immunology marketing for Bayer Health Care Diagnostics Division, calls "a compact benchtop system designed to maximize productivity." The Advia Centaur CP uses the same reagents, sample tips, and cuvettes as the full-size Advia Centaur, and offers a throughput of 180 tests per hour along with a menu of disease state assay groups. It's "the ideal solution for the specialty testing center or laboratory with a high stat workload," Leach says.

Instruments already introduced include Randox's Evidence analyzer, based on biochip array technology, which, says Menary, "promotes a more holistic approach to disease diagnosis." He adds, "Simultaneous detection of multiple analytes on a biochip offers much higher test throughput than conventional systems. Complete automation of the tests offers full sample, reagent, and inventory tracking as well as the flexibility to request only those analytes ordered by the physician." Randox also recently launched the Evidence Investigator, a semiautomated biochip array benchtop analyzer Menary calls "suited to lower-throughput clinical laboratories and research applications due to the rapidly expanding test portfolio."

Diagnostic Products Corp.'s recently introduced Immulite 2500 SMS offers an optional robotic sample management system. DPC plans to launch an immunoassay workcell before AACC. Senior marketing manager Mark Smith says, "The open design of the sample management system enables the unit to become a single sample-entry point for two Immulite 2000/2500 systems, creating the immunoassay workcell. In the workcell configuration, even though the systems are linked, they are functionally independent: If one system is unavailable, testing can continue on the other." Smith also touts his company's new RealTime Solutions, a support service that includes online reports such as Levey-Jennings reports, peer group reports, adjustment reports, and target range reports, viewable from any computer with Internet access.

Then, too, customers can begin looking for improvements to the software of instruments that were launched as early as last year. In mid-2004, Pharmacia Diagnostics introduced its ImmunoCAP 250 system, a mid-sized continuous random access allergy diagnostics instrument. The system's software, which could already link to the ImmunoCAP 1000, can now connect to ImmunoCAP 100E instruments as well, "eliminating the need to learn more than one software program," says senior product manager Lorraine Damico. "The new command-central software can link up to 15 ImmunoCAP instruments with a lab's information system. Other features include setting inventory reorder points, printing of reorder lists, and viewing lot numbers and expiration dates of onboard and externally stored reagents, plus optional remote service capability."

All that not enough for you? Awareness Technology has a chemiluminescent microwell reader in research and development; this year's AACC attendees will be able to see a prototype. "Within nine to 12 months, we also hope to have an eight-channel microplate reader released to market," says sales manager Chris Schneider. Trinity Biotech marketing manager Marlene Jinks says studies now show that the company's Nexgen Four instrument, which has dual independent robotic pipetting arms, "saves up to 45 minutes over traditional one-arm sequential microplate processing instruments for full-load runs." And Diamedix's Parsec System, introduced at the 2004 AACC meeting, is on schedule for delivery in the second quarter of this year. The system, says marketing manager Linda Schwartz, is designed with modularity and flexibility: "Modularity provides the ability to simultaneously run different technologies such as EIA, chemiluminescence, IFA, and histopathology," while "flexibility . . . offers the ability to build the Parsec system to [the customer's] specific needs."

CAP TODAY's survey of immunoassay analyzers includes products from the manufacturers named above and from Bio-Rad, Dade Behring, Grifols USA, Ortho-Clinical Diagnostics, and Roche Diagnostics. Vendors supplied the information listed in the tables. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities. □

Anne Ford is a writer in Chicago.

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 1 of 22	**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	**Abbott Diagnostics** **Chris Dillman** christopher.dillman@abbott.com **100 Abbott Park Rd., Dept. 0ZZ2, AP6C-5** **Abbott Park, IL 60064-3500** **847-938-4467** www.abbott.com
See accompanying article on page 18		
Name of instrument/First year sold/Where designed	**AxSym Plus/1993 worldwide, 1994 U.S./U.S.**	**Architect i2000SR; i2000; i4000/—/U.S.**
Country where manufactured/Where reagents manufactured	**U.S./U.S.**	**U.S./U.S.**
No. of units in clinical use in U.S./Outside U.S.	**2,800/16,000**	**88/2,500**
Operational type/Model type/Sample handling system	**cont. random access/stat, batch floor-standing/segment**	**batch, random access, cont. random access/floor-standing/track & LAS**
Dimensions in inches (H x W x D)/Instrument footprint in square feet	**60.5 x 63 x 33.5 in/14.6 sq ft**	**i200SR, 48 x 61 x 49/20.3 sq ft; i2000, 48 x 68 x 44 in/22.7 sq ft per module**
Tests available on instrument in U.S.	**hTSH II, TT3, TT4, FT3, FT4, T-uptake, total βhCG, FSH, LH, estrad., prolac., testosterone, CK-MB, homocysteine, myogl., trop. I, PSA, 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**	**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**
Tests cleared but not clinically released	**—**	**AFP, B12, folate, ferritin, testosterone**
Tests not available in U.S. but submitted for clearance	**B12**	**—**
Tests not available in U.S. but available in other countries	**B12, folate, ferritin, CA 19-9, AUSAB, CORE, CORE-M, HAVAB 2.0 quant, HBsAg, HBsAg confirm, HIV combo, HIV 1/2, progesterone, CMV IgM, β-2-microglobulin, insulin, 3rd gen TSH, digitoxin, HBe, anti-HBe**	**testosterone, B12, folate, RBC folate, ferritin, AFP, CA 19-9, pepsinogen I & II, SCC, anti-HCV, HBsAg, HBsAg confirm, HAVAB-IgM, HAVAB-IgG, anti-HBs anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, HIV Ag/Ab combo, anti-Tg & TPO**
Research-use-only assays	**n/a**	**n/a**
Tests in development	**B12, folate, ferritin, CA 19-9, AUSAB, CORE, CORE-M, HAVAB 2.0 quant, HBsAg, HBsAg confirm, HIV combo, HIV 1/2, progesterone, CMV IgM, β-2-microglobulin, insulin, 3rd gen TSH, digitoxin, HBe, anti-HBe**	**BNP, β-2-microglobulin, cyclosporine, sirolimus, tacrolimus, anti-CCP, C-peptide, cortisol, homocysteine, vitamin D, CMV IgG, CMV IgM, rubella IgG & IgM, TOXO IgG & IgM, estriol, PTH, RBC folate, CA 19-9, pepsinogen I & II, SCC, anti-HCV, HBsAg, HBsAG confirm, HAVAB-IgM, HAVAB-IgG, anti-HBs, anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, HIV Ag/Ab combo**
User-defined methods implemented for what analytes	**n/a**	**none**
Tests not available on other manufacturers' analyzers	**n/a**	**none**
Fully automated microplate system	**no**	**no**
No. of each analyte performed in separate disposable unit	**n/a**	**n/a**
No. of wells in microplate	**n/a**	**n/a**
Methods supported/Separation methods	**FPIA, MEIA, ion capture, REA/heterogeneous, bead (microparticle), fiber matrix filter**	**Chemiflex (enhanced chemiluminescence) w/5 flexible protocols/magnetic microparticle**
No. of different measured assays onboard simultaneously	**20**	**25**
No. of different assays programmed, calibrated at once	**20**	**25**
No. of user-definable (open) channels	**0**	**n/a**
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	**20/100**	**25/100-test & 500-test per kit**
Shortest/Median onboard reagent stability/Refrigerated onboard	**onboard reagent stability: 112, 224, 336/no**	**30 days/30 days/yes (2–12ºC)**
Multiple reagent configurations supported	**no**	**yes**
Reagent container placed directly on system for use	**yes**	**yes**
Reagents bar coded/Information in bar code	**yes/assay name, reag. lot No., expir. date, pack No. ID**	**yes/assay No., reagent serial No., lot No., tests per kit, exp. date, onboard stability time, master calibration curve**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**no/< 0.1 ppm**	**n/a/no**
Walkaway capacity in minutes/Specimens/Tests-assays	**60/90/90**	**300/135/12,500**
System is open (home-brew methods can be used)/Liquid or dry system	**no/liquid**	**no/liquid**
Uses disposable cuvettes/Max. No. stored	**yes/90 reaction vessels**	**yes/1,200**
Uses washable cuvettes/Replacement frequency	**no**	**no/n/a**
Minimum specimen vol. required	**83 uL/150 uL**	**50 uL**
Minimum sample vol. aspirated precisely at once/Min. dead vol.	**10 uL/73 uL for sample cup, 450 uL for aliquot, 4.5 mL for primary**	**150 uL/50 uL for all tube types**
Supplied with UPS (backup power)/Requires floor drain	**yes (soft close of files only)/optional**	**yes/no**
Requires dedicated water system/Water consumption	**no/—**	**no/n/a**
Noise generated	**52–68 decibels**	**48–70 decibels**
Has dedicated pediatric sample cup/Dead vol.	**no**	**no**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/100 & 75 mm/no**	**yes/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	**yes/no**	**no/no**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/yes**
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	**no/no**	**no/no**
Time between initial result & reaspiration of sample for rerun	**seconds**	**<20 seconds**
Autocalibration or autocalibration alert	**no**	**no**
No. of calibrators required for each analyte	**6 pt. or 2 pt. w/ master calib., index calib.**	**2–6 pt. curve**
Calibrants can be stored onboard/Avg. calibration frequency	**no/4 weeks**	**no/minimum 30 days or once per lot**
Multipoint calib. supported/Multiple calibs. stored for same assay	**yes/yes (up to 4 curves/analyte)**	**yes/yes**
How often QC required	**shortest interval: 8 hr, longest: 24 hr**	**3 levels every 24 h for quantitative, 2 levels for qualitative**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
Automatic shutdown/Startup is programmable/Startup time	**no/no/1 min**	**n/a/no/10 min**
Stat time to completion of ß-hCG test	**10 min**	**15.6 min**
Time delay from ordering stat test to aspir. of sample	**30 sec from standby**	**<20 sec**
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)**	**67/200 tests per hour**
Can auto transfer QC results to LIS/Onboard capability to review QC	**yes/yes**	**yes/yes**
Data management capability/Instrument vendor supplies LIS interface	**onboard/no**	**onboard/no**
Interfaces up and running in active user sites with	**all major LIS vendors**	**all major LIS vendors**
LIS interface operates simultaneously w/ running assays	**yes**	**yes**
Uses LOINC to transmit orders and results	**no**	**no**
How labs get LOINC codes for reagent kits	**n/a**	**n/a**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes (broadcast download & host query)**
Results transmitted to LIS as soon as test time complete	**yes**	**yes**
Interface available (or will be) to auto specimen handling system	**yes**	**yes**
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	**no/yes/yes**	**yes/yes/yes**
Can order (via modem) malfunctioning part(s) w/o operator	**yes, Abbott Link**	**yes, Abbott Link**
On-site response time of service engineer	**12 hr**	**8 business hr**
Mean time between failures/To repair failures	**5 months/within 12 hr per customer request**	**11 weeks/—**
Onboard error codes to facilitate troubleshooting	**yes**	**yes**
Avg. time to complete maintenance by lab personnel	**daily: 14 min; weekly: 65 min; monthly: 11 min**	**daily: <10 min; weekly: <10 min; monthly: none**
Onboard maintenance records/Maintenance training demo module	**no/no**	**yes/yes**
List price/Targeted bed size or daily volume	**$124,000/200 IA tests per day**	**$169,500/500 immunoassays per day**
Annual service contract cost (24 hours/7 days)	**$16,800 extended hours coverage**	**n/a**
Training provided w/ purchase/Advanced operator training	**yes/yes**	**yes/yes**
Distinguishing features (supplied by vendor)	**menu, reliability, online exception help, pressure monitoring, clot detection, ratio calculation, stat TAT**	**Chemiflex technology delivers excellent sensitivities and extended linearities while the RSH allows for priority and routine samples to be processed simultaneously without compromising stats**

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Survey editor: Raymond Aller, MD

Automated immunoassay analyzers

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	Abbott Park, IL 60064-3500	Palm City, FL 34990
	847-938-4467 www.abbott.com	772-283-6540 www.awaretech.com
Name of instrument/First year sold/Where designed	Architect ci8200/2003/U.S.	ChemWell/1998/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S.	U.S./open system
No. of units in clinical use in U.S./Outside U.S.	55/321	8/700+
Operational type/Model type/Sample handling system	batch, random access, cont. random access/floor-standing/features a patented Retest Sample Handler that uses multi-dimensional sample handling	batch, random access/benchtop/rack
Dimensions in inches (H x W x D)/Instrument footprint in square feet	48 x 127 x 49 in/43.2 sq ft	16 x 34 x 20 in/4 sq ft
Tests available on instrument in U.S.	trop. I, CK-MB, myoglobin, TSH, free T3 & T4, Total T3 & T4, T-uptake, β-HCG, estradiol, FSH, LH, progesterone, prolactin, CA 125 & 15-3, CEA, free & total PSA, acid phosphatase, albumin BCG & BCP, alkaline phosphatase, ALT, ALT – Act, amylase, AST, AST – Act, bilirubin (direct, total & neonatal), calcium, cholesterol, CK, CO2, creatinine, DLDL, GGT, glucose, iron, lactic acid, LDH, lipase, magnesium, phosphorus, TIBC, total protein, triglyceride, urea nitrogen, uric acid, chloride, potassium, sodium, amphet/meth, others (contact company for full test menu)	unlimited—open system
Tests cleared but not clinically released	AFP, B12, folate, ferritin, testosterone	—
Tests not available in U.S. but submitted for clearance	ferritin, ASO, hsCRP	—
Tests not available in U.S. but available in other countries	testosterone, B-12, folate, RBC folate, ferritin, AFP, CA 19-9, pepsinogen I & II, SCC, anti-HCV, HBsAg, HBsAg confirm, HAVAB-IgM, HAVAB-IgG, anti-HBs, anti-HBc, anti-HBc IgM, anti-HBe, HBe Ag, HIV Ag/Ab combo, anti-Tg & TPO (contact company for full test menu)	unlimited—open system
Research-use-only assays	n/a	unlimited—open system
Tests in development	BNP, β-2-micro., cyclosporine, sirolimus, tacrolimus, anti-CCP, C-peptide, cortisol, homocyst., vit. D, CMV IgG/IgM, rubella IgG/IgM, toxo IgG/IgM, estriol, PTH, B-12, folate, ferritin, AFP, lithium, ammonia, D-dimer, others	—
User-defined methods implemented for what analytes	—	general biochemistries
Tests not available on other manufacturers' analyzers	n/a	n/a
Fully automated microplate system	n/a	yes
No. of each analyte performed in separate disposable unit	n/a	up to 12
No. of wells in microplate	n/a	min. strip, 8; max. full plate, 96
Methods supported/Separation methods	photometric, potentiometric, & Chemiflex (enhanced chemiluninescence)	EIA/coated microwell
No. of different measured assays onboard simultaneously	93	up to 12
No. of different assays programmed, calibrated at once	93	unlimited
No. of user-definable (open) channels	220	unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	93/50–1,700	27/assay dependent
Shortest/Median onboard reagent stability/Refrigerated onboard	8 hr/28 days/yes	assay dependent/assay dependent/yes (10°C below ambient)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/assay name, reagent No., lot No., tests per kit, expiration date, others	no
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	open system/SmartWash technology	no/none
Walkaway capacity in minutes/Specimens/Tests-assays	300/367/>75,000	assay dependent/96/12
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	both disposable and semi-permanent glass/1,200 or 165	yes/96
Uses washable cuvettes/Replacement frequency	yes/as needed, 1-yr minimum	yes/assay dependent
Minimum specimen vol. required	2 uL	2 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	50 uL	2µL/—
Supplied with UPS (backup power)/Requires floor drain	yes/yes	no/no
Requires dedicated water system/Water consumption	yes/30 L per hr	no
Noise generated	48-70 decibels	—
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10–16 mm diameter, up to 75–100 mm height/no	yes/12 x 75 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	no/—
Bar-code placement per NCCLS standard Auto2A	yes	—
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	no/no
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/yes	no/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	yes/yes
Time between initial result & reaspiration of sample for rerun	<20 sec	assay dependent
Autocalibration or autocalibration alert	no (to be available in next SW revision)	no
No. of calibrators required for each analyte	2 or 6 pt.	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	yes/assay dependent
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	from 2 levels after calibration, to 3 to 24 hr	shortest interval: each run; longest: daily
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	n/a/no/10 min	yes/yes/2 min
Stat time to completion of ß-hCG test	<15.6 min	assay dependent
Time delay from ordering stat test to aspir. of sample	<20 sec	30 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	400/1,200	assay dependent
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data management capability/Instrument vendor supplies LIS interface	onboard/no	onboard/yes (included)
Interfaces up and running in active user sites with	all major LIS vendors	—
LIS interface operates simultaneously w/ running assays	yes	no
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	n/a	n/a
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	yes, Abbott Link	no
On-site response time of service engineer	8 business hr	within 48 hr
Mean time between failures/To repair failures	7.3 weeks/—	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: <10 min; weekly: <10 min	daily: <10 min; weekly: <10 min; monthly: <10 min
Onboard maintenance records/Maintenance training demo module	yes/yes	no/no
List price/Targeted bed size or daily volume	$375,000/200–500 immunoassay tests per day	$25,000/up to 500 tests per day
Annual service contract cost (24 hours/7 days)	n/a	$4,000
Training provided w/ purchase/Advanced operator training	yes/yes	3 days on site/no
Distinguishing features (supplied by vendor)	integration of CC and IA without compromising stat TAT, results, or throughput, because of patented SmartWash technology, which minimizes carryover to <0.1 ppm; large reagent capacity of 93 assays, with sample load up to 367; efficiency provided via multiple patented technologies	ability to perform general biochemistries

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Automated immunoassay analyzers

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Name of instrument/First year sold/Where designed	ADVIA Centaur/1998/U.S.	ADVIA Centaur CP Immunoassay System/available September 2005/U.S.
Country where manufactured/Where reagents manufactured	Ireland/U.S.	Germany/U.S.
No. of units in clinical use in U.S./Outside U.S.	>1,300/>3,100	—/—
Operational type/Model type/Sample handling system	cont. random access/floor standing/rack or direct track sampling	batch, random access, continuous random access/benchtop/7 x 12 position racks
Dimensions in inches (H x W x D)/Instrument footprint in square feet	51.5 x 72.5 x 41.5 in/21 sq ft	43 x 29 in/8.7 sq ft
Tests available on instrument in U.S.	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*	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 ** subject to permarket approval in U.S.*
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	HBsAg, HBsAg conf., HIV1/0/2	—
Tests not available in U.S. but available in other countries	specific allergens, mixes, allergy screen, HBsAg conf., HBsAg, HIVI/0/2	—
Research-use-only assays	—	—
Tests in development	HBeAg, anti-HBe, cyclosporine, high-sensitivity troponin I, ANA, CMV IgG, CMV IgM	—
User-defined methods implemented for what analytes	none	—
Tests not available on other manufacturers' analyzers	cPSA, HER-2/*neu*	cPSA, HER-2/*neu*
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	n/a	—
No. of wells in microplate	n/a	—
Methods supported/Separation methods	chemiluminescence/magnetic particle	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	30	15
No. of different assays programmed, calibrated at once	30	100
No. of user-definable (open) channels	0	—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	30/50–100	15/50–100
Shortest/Median onboard reagent stability/Refrigerated onboard	96 hr/28 days/yes (4°C)	96 hr/28 days/yes (2–8°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/assay name, lot No., expir., pack ID	yes/reagent ID, lot No., expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	n/a/zero carryover	no/zero carryover
Walkaway capacity in minutes/Specimens/Tests-assays	230/180/840	210/400/400
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/1,000	yes/400
Uses washable cuvettes/Replacement frequency	no	no
Minimum specimen vol. required	10 µL, assay dependent	100 uL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL/50 µL	10 uL/50 uL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no
Requires dedicated water system/Water consumption	no/~2.5 L per hr	no
Noise generated	<64 decibels w/in 1 meter	up to 65 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/multiple/no	yes/multiple/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codaboar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	yes/yes
Time between initial result & reaspiration of sample for rerun	15 sec minimum	20 sec
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte	2	2
Calibrants can be stored onboard/Avg. calibration frequency	no/varies, avg. 21 days	no
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	24 hr	user defined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/none	yes/yes/<5 min
Stat time to completion of ß-hCG test	18 min	15.6 min
Time delay from ordering stat test to aspir. of sample	15 sec	<1 min
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	80/240 (15 sec)	60/180 (20 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/—	onboard/no
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLFC, DI, Triple G, and most other major vendors	ADVIA Centaur CP is compatible with ADVIA Centralink Networking Solution
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	—	no
How labs get LOINC codes for reagent kits	custom definable via LIS	—
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	yes (IDS, Lab InterLink, Labotix, CLIDS, PSS, Hitachi CLAS, A&T)	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/—
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	4 hr, 24 hr max.	4 hr, 24 hr max.
Mean time between failures/To repair failures	n/a/n/a	not available/not available
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 3 min; weekly: 20 min; monthly: 30 min	daily: 3 min; weekly: 20 min; monthly; 30 min
Onboard maintenance records/Maintenance training demo module	yes/yes	yes/yes
List price/Targeted bed size or daily volume	$225,000/300+ beds or 400 tests per day	$150,000/community hospitals, satellite labs
Annual service contract cost (24 hours/7 days)	$21,500	to be determined
Training provided w/ purchase/Advanced operator training	varies on site, 4 days at vendor offices/yes	4 days at vendor offices/yes
Distinguishing features (supplied by vendor)	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	add reagents, consumables, samples without interuption; uses same reagents/consumables as ADVIA Centaur; throughput 180 tests/hour

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Automated immunoassay analyzers

Part 4 of 22

See accompanying article on page 18

	Beckman Coulter Inc. **Joel Greiner** jcgreiner@beckman.com **200 S. Kraemer Blvd.** **Brea, CA 92822** **714-993-8329** www.beckmancoulter.com	**Beckman Coulter Inc.** **Joel Greiner** jcgreiner@beckman.com **200 S. Kraemer Blvd.** **Brea, CA 92822** **714-993-8329** www.beckmancoulter.com
Name of instrument/First year sold/Where designed	**Access Immunoassay System/1993/U.S., France**	**Access 2 Immunoassay System/2001/U.S.**
Country where manufactured/Where reagents manufactured	**U.S./U.S., France**	**U.S./U.S. & France**
No. of units in clinical use in U.S./Outside U.S.	**1,500/2,500**	**1,000/800**
Operational type/Model type/Sample handling system	**Cont. random access/benchtop/rack**	**cont. random access/benchtop/rack**
Dimensions in inches (H x W x D)/Instrument footprint in square feet	**18.5 x 39 x 24 in/6.5 sq ft**	**18.5 x 39 x 24 in/6.5 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**	**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**
Tests cleared but not clinically released	**—**	**—**
Tests not available in U.S. but submitted for clearance	**—**	**—**
Tests not available in U.S. but available in other countries	**HIV 1/2, HBsAg, HBsAg confirm., HBsAB, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM**	**HIV 1/2, HBsAg, HBsAg confirm., HBsAB, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM**
Research-use-only assays	**none**	**none**
Tests in development	**CMV IgG & IgM, rubella IgM, PTH, anti-TPO, EPO, soluble transferrin receptor, IL-6, B2-glycoprotein 1 Ab, ANA, anti-dsDNA**	**CMV IgG & IgM, rubella IgM, PTH, anti-TPO, EPO, soluble transferrin receptor, IL-6, B2-glycoprotein 1 Ab, ANA, anti-dsDNA**
User-defined methods implemented for what analytes	**none**	**none**
Tests not available on other manufacturers' analyzers	**chlam. Ag & confirm., AFP-ONTD, hybritech PSA & fPSA, intrinsic factor Ab**	**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**	**n/a**
No. of wells in microplate	**n/a**	**n/a**
Methods supported/Separation methods	**chemiluminescence/magnetic particle**	**chemiluminescence/magnetic particle**
No. of different measured assays onboard simultaneously	**24**	**24**
No. of different assays programmed, calibrated at once	**24**	**24**
No. of user-definable (open) channels	**0**	**0**
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	**24/50 tests per cartridge, 100 tests per kit**	**24/100 tests per kit, 50 tests per cartridge**
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 reag. pack ID No.**	**yes/assay No., lot No., expir., unique reagent pack ID No.**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**no/ 10 ppm**	**no/ 10 ppm**
Walkaway capacity in minutes/Specimens/Tests-assays	**180/60/300-31**	**180/60/300**
System is open (home-brew methods can be used)/Liquid or dry system	**no/liquid**	**no/liquid**
Uses disposable cuvettes/Max. No. stored	**yes/294**	**yes/294**
Uses washable cuvettes/Replacement frequency	**no**	**no**
Minimum specimen vol. required	**specimen container dependent**	**specimen container dependent**
Minimum sample vol. aspirated precisely at once/Min. dead vol.	**5 µL/100 µL**	**5 µL/100 µL**
Supplied with UPS (backup power)/Requires floor drain	**no/no**	**yes (when networked)/no**
Requires dedicated water system/Water consumption	**no/n/a**	**no**
Noise generated	**<70 decibels**	**<70 decibels**
Has dedicated pediatric sample cup/Dead vol.	**no**	**yes/100 µL**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/13 x 75 & 100, 16 x 75 & 100, 2 mL & 3 mL sample cups/no**	**yes/13x75 & 100, 16x75 & 100, 2 µL & 3 µL cups; 13x75, 13x100 aliquot tubes/no**
Sample bar-code reading capability/Autodiscrimination	**yes/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/no**	**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**	**no/no**
Time between initial result & reaspiration of sample for rerun	**n/a**	**36 sec**
Autocalibration or autocalibration alert	**no**	**no**
No. of calibrators required for each analyte	**6**	**6**
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**	**15 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 (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 addt'l cost—negotiable)**	**onboard/yes (included or additional cost—negotiable)**
Interfaces up and running in active user sites with	**all major LIS vendors**	**all major LIS vendors**
LIS interface operates simultaneously w/ running assays	**yes**	**yes**
Uses LOINC to transmit orders and results	**no**	**no**
How labs get LOINC codes for reagent kits	**—**	**—**
Bidirectional interface capability	**yes (host query)**	**yes (broadcast download & host query)**
Results transmitted to LIS as soon as test time complete	**yes**	**yes**
Interface available (or will be) to auto specimen handling system	**no**	**no**
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	**no/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 w/in 6 hr**	**24 hr max., usually within 6 hr**
Mean time between failures/To repair failures	**not available/not available**	**TBD/TBD**
Onboard error codes to facilitate troubleshooting	**yes**	**yes**
Avg. time to complete maintenance by lab personnel	**daily: 15 min; weekly: 30 min; monthly: none**	**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	**$129,800/all vols. & hospital sizes**	**$149,800/all volumes & hospital sizes**
Annual service contract cost (24 hours/7 days)	**$14, 800**	**$15,800**
Training provided w/ purchase/Advanced operator training	**4 days at vendor offices/yes**	**4 days at vendor offices/yes**
Distinguishing features (supplied by vendor)	**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**	**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**

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Automated immunoassay analyzers

Part 5 of 22

See accompanying article on page 18

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Name of instrument/First year sold/Where designed	Synchron LXi 725/2002/U.S.	UniCel DxI 800/2003/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S.	U.S./U.S., France
No. of units in clinical use in U.S./Outside U.S.	—/—	300/300
Operational type/Model type/Sample handling system	cont. random access/floor standing/rack-closed tube	cont. random access/floor standing/rack, direct track sampling
Dimensions in inches (H x W x D)/Instrument footprint in square feet	60 x 134.5 x 48 in/44.8 sq ft	66.7 x 67.5 x 37.7 in/17.7 sq ft
Tests available on instrument in U.S.	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	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
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for clearance	—	—
Tests not available in U.S. but available in other countries	—	HIV 1/2, HBsAg, HBsAg confirm., HBsAB, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM
Research-use-only assays	—	—
Tests in development	CMV IgG & IgM, rubella IgM, PTH, anti-TPO, EPO, soluble transferrin receptor, IL-6, B2-glycoprotein 1 Ab, ANA, anti-dsDNA	CMV IgG & IgM, rubella IgM, PTH, anti-TPO, EPO, soluble transferrin receptor, IL-6, B2-glycoprotein 1 Ab, ANA, anti-dsDNA
User-defined methods implemented for what analytes	—	none
Tests not available on other manufacturers' analyzers	only system to perform heterogeneous immunoassays & general chemistry on a single platform using closed tube sampling	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	—	—
No. of wells in microplate	—	—
Methods supported/Separation methods	chemiluminescence/magnetic particle	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	65	50
No. of different assays programmed, calibrated at once	65	50
No. of user-definable (open) channels	100	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	65/50 tests per cartridge, 100 tests per kit (immuno), 300 tests per container set (general)	50/50 tests per cartridge, 100 or 1,000 tests per kit
Shortest/Median onboard reagent stability/Refrigerated onboard	336 hr/28 days/yes (4°C)	336 hr/28 days/yes (3–10°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/assay No., lot No., expir., unique reagent pack ID	yes/assay No., lot No., expir., unique reagent pack ID No.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/ 10 ppm	n/a/< 10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	180/132/5,280	288 (avg.—assay mix dependent)/120/1,200 (avg.)
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/294	yes/>1,000
Uses washable cuvettes/Replacement frequency	yes, 2 yr warranty (general chem.)	no
Minimum specimen vol. required	—	specimen container dependent
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/100 µL	5 µL/160 µL
Supplied with UPS (backup power)/Requires floor drain	—/yes	yes (PC only)/optional
Requires dedicated water system/Water consumption	yes/—	no/—
Noise generated	—	<60 decibels
Has dedicated pediatric sample cup/Dead vol.	no/—	yes/100 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13x75 & 100, 16x75 & 100 mm/yes	yes/12x75 to 16x100 mm/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes for general chemistry/yes for general chemistry	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	36 sec	<9 sec (min.)
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte	6	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	24 hr	24 h
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/remains in ready mode	no/no/remains in ready mode
Stat time to completion of ß-hCG test	17 min	15 min
Time delay from ordering stat test to aspir. of sample	36 sec	18 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	33/100 (36 sec)	min. 67, max. 133/min. 200, max. 400 (9 or 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 (included or additional cost is negotiable)	onboard/yes (included or additional cost is negotiable)
Interfaces up and running in active user sites with	n/a	all major LIS vendors
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	yes	no
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no	yes (Beckman Coulter automation systems)
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	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	—/—	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	—	daily: <10 min; weekly: TBD; monthly: none
Onboard maintenance records/Maintenance training demo module	yes/no	yes/yes
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
Training provided w/ purchase/Advanced operator training	yes/yes	5 days at vendor office for 2 employees/yes
Distinguishing features (supplied by vendor)	workstation consolidation without compromise through the use of innovative automation; single point-of-sample entry using closed tube sampling, dual scheduling, and parallel processing with full menu equivalence to the Synchron and Access product lines	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 console; stores sample aliquot onboard

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Automated immunoassay analyzers

Part 6 of 22

See accompanying article on page 18

	The Binding Site Inc.	bioMérieux Inc.
	Gary Tremain gary.tremain@thebindingsite.com	Vincent Tumminello vincent.tumminello@na.biomerieux.com
	5889 Oberlin Dr., #101	100 Rodolphe St.
	San Diego, CA 92121	Durham, NC 27712
	800-633-4484 www.bindingsite.co.uk	919-620-2000 www.biomerieux-usa.com
Name of instrument/First year sold/Where designed	DSX Automated System/2000/Guernsey, U.K.	Vidas & MiniVidas/1989/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.K.	Italy/France
No. of units in clinical use in U.S./Outside U.S.	>150/>500	2,200/>20,000
Operational type/Model type/Sample handling system	batch/benchtop/rack	batch, random access/benchtop/n/a
Dimensions in inches (H x W x D)/Instrument footprint in square feet	32 x 42 x 36 in/7 sq ft	Vidas: 16 x 32 x 21 in; MiniVidas: 21 x 21 x 17 in/Vidas 4.5, MiniVidas 4 sq ft
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	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., cortisol (serum & urine), total IgE, digoxin, *H. pylori* IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM., quant. D-dimer, tPSA, toxo competition, testosterone
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for clearance	t. tox, ASCA IgG/IgA	myoglobin, trop. I
Tests not available in U.S. but available in other countries	open system—any ELISA	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
Research-use-only assays	open system	none
Tests in development	phosphatidylinositol IgG/IgM/IgA, phosphatidylethanolamine IgG/IgM/IgA, phosphatidylglycerol IgG/IgM/IgA, phosphatidylcholine IgG/IgM/IgA, phosphatidic acid IgG/IgM/IgA, prothrombin, C3d CIC, SMA, LKM	EBV, HbA1c
User-defined methods implemented for what analytes	open system	none
Tests not available on other manufacturers' analyzers	open system	all assays for use on Vidas instruments only
Fully automated microplate system	yes	no
No. of each analyte performed in separate disposable unit	n/a	1 test per strip
No. of wells in microplate	min. strip 1 x 8; max. full plate 96 x 4 plates	n/a
Methods supported/Separation methods	EIA/coated microwell	fluorescence, EIA/coated solid phase receptacle (SPR)/pipetting device
No. of different measured assays onboard simultaneously	12 assays per plate	Vidas: 30, MiniVidas: 12
No. of different assays programmed, calibrated at once	unlimited	total menu
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	25/96 per 4 plates	unit dose format/30 or 60
Shortest/Median onboard reagent stability/Refrigerated onboard	24 hr/n/a/no	n/a/n/a/no
Multiple reagent configurations supported	yes	no
Reagent container placed directly on system for use	requires operator prehandling/preparation	yes
Reagents bar coded/Information in bar code	no	yes/assay name, lot No., sequence No., expir.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/0	no/zero carryover
Walkaway capacity in minutes/Specimens/Tests-assays	assay dependent/92/assay dependent	assay dependent/12–30/12–30
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	no/dry
Uses disposable cuvettes/Max. No. stored	no	no
Uses washable cuvettes/Replacement frequency	no	no
Minimum specimen vol. required	200 µL	100 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/200 µL (50 µL with microtubes)	100 µL/n/a
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no	no/no
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	yes/50 µL	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/various/no	no/n/a/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	n/a
Onboard test auto inventory (determines vol. in container)	no	n/a
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	yes/no	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	no/no
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	n/a	n/a
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte	assay specific	1
Calibrants can be stored onboard/Avg. calibration frequency	yes/once per analyte per plate	no/14 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	no (mftr.-determined calib. curves)/yes
How often QC required	per plate	shortest interval: 8 hr, longest: 24 hr
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/no	yes/yes
Automatic shutdown/Startup is programmable/Startup time	yes/—/1–2 min	no/no/remains ready
Stat time to completion of ß-hCG test	n/a	30 min
Time delay from ordering stat test to aspir. of sample	n/a	no delay
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	assay dependent	Vidas: 20, MiniVidas: 8/Vidas: 60, MiniVidas: 24 (—)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data management capability/Instrument vendor supplies LIS interface	onboard/yes (additional)	onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Misys	Misys, Meditech, McKesson, Advanced Lab Systems (Path Lab), Cerner, Citation, SCC, Siemens, SAIC/CHCS, CompuLab, Antrim, Dawning, Genesys (Dynamedix), others
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	n/a	n/a
Bidirectional interface capability	yes (host query)	yes (broadcast download)
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/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	within 24 hr	w/in 24 hr
Mean time between failures/To repair failures	n/a/<24 hr	Vidas: 350 days, MiniVidas: 1,000 days/<2 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: 10–15 min;, weekly: 10–15 min; monthly: 30 min
Onboard maintenance records/Maintenance training demo module	no/no	yes/yes
List price/Targeted bed size or daily volume	$49,000 (dependent on modules)/200+ beds	Vidas: $51,800, MiniVidas: $28,100/400 beds
Annual service contract cost (24 hours/7 days)	$7,950	$2,340–$4,680 (MiniVidas 30)
Training provided w/ purchase/Advanced operator training	3 days on site, 2 days at vendor offices/yes	as needed on site, 3 days at vendor offices/yes
Distinguishing features (supplied by vendor)	fully open, true four-plate system, modular design of reader, washer, incubators, bar-code reader and ambient drawer enables easy upgrades and express shipping of replacement modules reducing downtime; software can be trained for learned error recovery	unique dual-function combination solid phase & pipetting device (SPR); assay menu mix (antigen detection, serology, fertility, thyroid, endocrine, coagulation) makes Vidas the ideal instrument for routine batch testing as well as emergency stat testing

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Automated immunoassay analyzers

Part 7 of 22 *See accompanying article on page 18*	Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Dr. 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	Coda/outside U.S. 1996; in U.S. 1997/Japan	PhD System/2000/Belgium
Country where manufactured/Where reagents manufactured	Japan/U.S., U.K., France, Korea, Australia	Belgium/U.S.
No. of units in clinical use in U.S./Outside U.S.	6/550	150/250
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	21.6 x 39.5 x 26 in/7.13 sq ft	35 x 66 x 35 in/16 sq ft
Tests available on instrument in U.S.	contact Bio-Rad representative	ANA (EIA), anti-Centvomere (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
Tests cleared but not clinically released	contact Bio-Rad representative	—
Tests not available in U.S. but submitted for clearance	—	—
Tests not available in U.S. but available in other countries	biotinidase, leucine, IRT, TSH, PICU, TGAL, GALT, 17OHP	—
Research-use-only assays	n/a	—
Tests in development	—	—
User-defined methods implemented for what analytes	STC drugs of abuse, Ostex Ntx, DSL assays—contact companies represented	—
Tests not available on other manufacturers' analyzers	—	—
Fully automated microplate system	yes	no
No. of each analyte performed in separate disposable unit	—	1
No. of wells in microplate	min. strip: 1 sample; max. full plate, 96	min. strip: 1; max. full plate: 96
Methods supported/Separation methods	EIA/coated microwell & noncoated microwell	EIA/coated microwell
No. of different measured assays onboard simultaneously	9	8
No. of different assays programmed, calibrated at once	9	8
No. of user-definable (open) channels	unlimited	no limit
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	9 assays, 24 containers/288 tests	8/192
Shortest/Median onboard reagent stability/Refrigerated onboard	n/a/n/a/no	4 hr/—/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	requires operator prehandling/preparation	requires operator prehandling/preparation
Reagents bar coded/Information in bar code	no	no/n/a
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/reduced w/software version 4.0 & updated firmware, depends on amount of washing	yes/—
Walkaway capacity in minutes/Specimens/Tests-assays	varies by assay/90-270/up to 9	195/184/1
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid, reconst. onboard	yes/liquid
Uses disposable cuvettes/Max. No. stored	no (yes for dils.)	no/n/a
Uses washable cuvettes/Replacement frequency	no	no/n/a
Minimum specimen vol. required	10 µL specimen out of 110 µL	1 µL specimen
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL/200 µL, 130 µL in microtubes	1 µL/200 µL
Supplied with UPS (backup power)/Requires floor drain	optional/no	yes/no
Requires dedicated water system/Water consumption	no/—	no
Noise generated	n/a	—
Has dedicated pediatric sample cup/Dead vol.	yes/130 µL	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	not claimed, but some users have validated for their own use/—	no/—/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)/no
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	no	yes
Clot detection/Reflex testing capability	no/no	no/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	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	1–6	1–5
Calibrants can be stored onboard/Avg. calibration frequency	no/most assays require calib. w/ each run, some as long as 2 weeks w/ 1 & 2 pt. updates	no/each run
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/no
How often QC required	shortest interval: user determined, longest: w/in run recommended	each run
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes (late 2000 through Unity QC program)	no/no
Automatic shutdown/Startup is programmable/Startup time	for hardware/6 min	no/no/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)	~90 tests per hr w/ all results in approx. 3 hr (assay dependent)/(protocol specific)	n/a/n/a
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes (not yet tested)	no/yes
Data management capability/Instrument vendor supplies LIS interface	onboard/customer acquires through LIS company, can be added to contract	onboard/yes (included)
Interfaces up and running in active user sites with	homegrown systems, Cerner, Dawning, & Sunquest in development	—
LIS interface operates simultaneously w/ running assays	not possible on batch analyzer	yes
Uses LOINC to transmit orders and results	can be customized	can be customized
How labs get LOINC codes for reagent kits	www.bio-rad.com	—
Bidirectional interface capability	yes (broadcast download)	no
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	no/no/no	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	24 hr	<24 hr
Mean time between failures/To repair failures	—/4 hr	6 months/4 hr
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5 min; weekly: 20 min; monthly: 20 min	daily: 15 min; weekly: 15 min; monthly: 30 min
Onboard maintenance records/Maintenance training demo module	no/no	no/no
List price/Targeted bed size or daily volume	$48,000/50–350 beds, 4–6 plates per days	$38,000/>50 tests per day
Annual service contract cost (24 hours/7 days)	$4,800	$6,000
Training provided w/ purchase/Advanced operator training	as needed on site, 3 days at vendor offices/—	2 days on site/no
Distinguishing features (supplied by vendor)	Coda 4.0 adds powerful, new fluidic controls, dilution capabilities, audible alarms, and new wash parameters; able to perform pretreatment of sample (pipette, incubate, transfer to coated well); five methods for creating sample dilutions; easy-to-operate programming	accurate pipetting at 1 µL; connection of 1–10 pipetting stations together through an ethernet hub, graphical user interface; added module for IFA slide processing

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SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 8 of 22 *See accompanying article on page 18*	Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Dr. Hercules, CA 94547 510-724-7000 www.bio-rad.com	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 800-242-3233 www.dadebehring.com
Name of instrument/First year sold/Where designed	Evolis/2001/Germany	Stratus CS Stat Fluorometric Analyzer/1998/U.S.
Country where manufactured/Where reagents manufactured	Germany/U.S.	U.S./U.S.
No. of units in clinical use in U.S./Outside U.S.	100/250	700/700
Operational type/Model type/Sample handling system	batch/benchtop/rack	random access/benchtop/whole blood collection tube
Dimensions in inches (H x W x D)/Instrument footprint in square feet	37 x 44 x 30 in/10 sq ft	18 x 27 x 22 in./4.1 sq. ft.
Tests available on instrument in U.S.	contact Bio-Rad representative	mass CK-MB, trop. I, myoglobin, β-hCG, D-dimer, NT-pro BNP
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	yes	no
No. of each analyte performed in separate disposable unit	—	—
No. of wells in microplate	min. strip, 1; max. full plate, 96	—
Methods supported/Separation methods	EIA/coated microwell	fluorescence, EIA, dendrimer technology/fiber matrix filter
No. of different measured assays onboard simultaneously	4	up to 4
No. of different assays programmed, calibrated at once	4	1
No. of user-definable (open) channels	closed in U.S. market	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	4/96	n/a/unit dose test packs
Shortest/Median onboard reagent stability/Refrigerated onboard	30 min/assay dependent/n/a	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	no	yes/assay ID, lot No., expir., calib. param.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/no (disposable tips)	no/zero carryover
Walkaway capacity in minutes/Specimens/Tests-assays	varies by assay/180/4	14 min to 1st result, subsequent results in 4 min intervals/1/up to 4
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	microplates	no
Uses washable cuvettes/Replacement frequency	microplates	no
Minimum specimen vol. required	0.2 µL	2.5 mL whole blood
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL/100 µL	n/a
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no
Requires dedicated water system/Water consumption	no	no/n/a
Noise generated	60 decibels	<65 decibels
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5, 7, 10 mL/no	yes/4 or 5 mL/yes
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/no	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	no	yes
Onboard test auto inventory (determines vol. in container)	yes	n/a
Measures No. of tests remaining/Short sample detection	no/no	n/a/yes
Auto detection of adequate reagent or specimen	no	yes
Clot detection/Reflex testing capability	yes/no	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	not affected
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	yes
No. of calibrators required for each analyte	assay dependent	1 cal pack
Calibrants can be stored onboard/Avg. calibration frequency	no/with each run	no/30–90 days same lot, new lot
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/yes
How often QC required	user determined	shortest interval: daily electronic QC, longest: every 30 days for liquid controls
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes (through Unity QC program)	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no	no/no/30 min. to warm up
Stat time to completion of ß-hCG test	n/a	14 min
Time delay from ordering stat test to aspir. of sample	n/a	immediately
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	assay dependent	3/9
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	yes/yes (additional)
Interfaces up and running in active user sites with	in development	all major LIS vendors
LIS interface operates simultaneously w/ running assays	no	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	n/a	—
Bidirectional interface capability	yes (broadcast download)	no
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/no/no	no/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	24 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: 5 min; weekly: 10 min; monthly: 30 min	daily: none; weekly: none; monthly: 10 min
Onboard maintenance records/Maintenance training demo module	yes/no	no/yes
List price/Targeted bed size or daily volume	$65,000/50–400 tests per day	—/any size emergency department
Annual service contract cost (24 hours/7 days)	inquire	multiple types
Training provided w/ purchase/Advanced operator training	3 days in Redmond, Wash./no	3 days on site/no
Distinguishing features (supplied by vendor)	fully automated microplate system that meets the highest level of safety (positive identification of samples, reagents, microplates, clot detection, no contamination), flexibility (continuous loading of samples, reagents, and microplates), and productivity (four plates, 180 samples, four different assays can be processed simultaneously)	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

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Automated immunoassay analyzers

Part 9 of 22

See accompanying article on page 18

	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 800-242-3233 www.dadebehring.com	Dade Behring Inc. P.O. Box 6101, Newark, DE 19714-6101 800-242-3233 www.dadebehring.com
Name of instrument/First year sold/Where designed	Dimension Xpand Plus Integrated Chemistry System/2001/U.S.	Dimension RxL Max/Max Suite Integrated Chemistry System/2003/U.S.; Dimension RxL Integrated Chemistry System/1997/U.S.
Country where manufactured/Where reagents manufactured	U.S./U.S.	U.S./U.S.
No. of units in clinical use in U.S./Outside U.S.	1,200/800	combined: 2,500/2,000
Operational type/Model type/Sample handling system	random access, cont. random access/floor-standing/racks	batch, random access, cont. random access/floor-standing/racks
Dimensions in inches (H x W x D)/Instrument footprint in square feet	45 x 51 x 31 in (without monitor)/10.6 sq ft	44 x 62.5 x 30.5 in./13.2 sq ft
Tests available on instrument in U.S.	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	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
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	system performs heterogeneous immunoassays and general assays on a 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	EIA, latex particle turbidimetric, direct turbidimetric/heterogeneous, magnetic particles	EIA, latex particle turbidimetric, direct turbidimetric/heterogeneous, magnetic particles
No. of different measured assays onboard simultaneously	47	47 (91 with optional reagent management system)
No. of different assays programmed, calibrated at once	190	190
No. of user-definable (open) channels	10	10
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	47/15–360	Max=47, Max Suite=91/15–360
Shortest/Median onboard reagent stability/Refrigerated onboard	72 hr/30 days/yes (2–8°C)	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/lot No., unique flex ID, stability, expiration date	yes/lot No., unique flex ID, stability, expiration date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/n/a due to probe washing	yes/n/a due to probe washing
Walkaway capacity in minutes/Specimens/Tests-assays	can be hours/60/>1,000	can be hours/60/>1,000
System is open (home-brew methods can be used)/Liquid or dry system	yes/reconstitutes onboard, no reagent prep required by operator for liquid	yes/no reagent prep required by operator for liquid
Uses disposable cuvettes/Max. No. stored	yes/12,000	yes/12,000
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum specimen vol. required	2 µL	2 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	2 µL/primary tube capable	2 µL/primary tube capable
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	yes/up to 2 L per hr	yes/3.2 L per hr
Noise generated	<70	<70
Has dedicated pediatric sample cup/Dead vol.	yes/10–20 µL	yes/10–20 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/5, 7, 10 mL/no	yes/5, 7, 10 mL/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes (HM)/yes	yes (HM)/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	yes/yes	yes/yes
Time between initial result & reaspiration of sample for rerun	<20 sec	<20 sec
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	varies—3 levels for most assays	varies—3 levels for most assays
Calibrants can be stored onboard/Avg. calibration frequency	yes (Na, K, Cl)/up to 90 days	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	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	not required	not required
Stat time to completion of ß-hCG test	16 min	16 min
Time delay from ordering stat test to aspir. of sample	24 sec	24 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	83/250 (14.4 sec)	55–166/167–500 (7.2 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	optional/yes (additional)	optional (DBNet–Dade Behring)/yes (addt'l cost)
Interfaces up and running in active user sites with	all major LIS vendors	all major LIS vendors
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	yes	yes
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	2–8 hr	2–8 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: <5 min; weekly: 10 min; monthly: 15 min	daily: 5 min, weekly: 10 min, monthly: 15 min
Onboard maintenance records/Maintenance training demo module	yes/yes	yes/yes
List price/Targeted bed size or daily volume	—/—	—/—
Annual service contract cost (24 hours/7 days)	multiple types	multiple types
Training provided w/ purchase/Advanced operator training	5 days on site; 4 days at vendor offices/no	5 days on site, 4 days at vendor offices/yes
Distinguishing features (supplied by vendor)	consolidated low-volume workstation that integrates immunoassays onboard with other chemistries; allows single platform to meet over 95 percent of testing needs; eliminates sample splitting, aliquotting	analyzer integrates heterogeneous immunoassays onboard with other chemistries; allows single platform for over 95 percent of most requested tests; eliminates sample splitting between general tests and immunoassays

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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 10 of 22	**Diagnostic Products Corp.**	**Diagnostic Products Corp.**
	Joe Kelly info@dpconline.com	**Joe Kelly** info@dpconline.com
	5210 Pacific Concourse Dr., Los Angeles, CA 90045-6900	**5210 Pacific Concourse Dr., Los Angeles, CA 90045-6900**
See accompanying article on page 18	**310-645-8200** www.dpcweb.com	**310-645-8200** www.dpcweb.com
Name of instrument/First year sold/Where designed	**IMMULITE/1993; IMMULITE Turbo/1999; IMMULITE 1000/2002/U.S.**	**IMMULITE 2000/1998/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.	**>6,300 worldwide**	**>3,600 worldwide**
Operational type/Model type/Sample handling system	**cont. random access/benchtop/loading platform**	**Cont. random access/floor-standing/rack**
Dimensions in inches (H x W x D)/Instrument footprint in square feet	**19 x 46 x 26 in/7.98 sq ft**	**47 x 60 x 30 in/12.5 sq ft**
Tests available on instrument in U.S.	**AlaTOP allergy scr., total IgE, EPO, ferr., fol. acid, B12, intact PTH, Pyrilinks-D, carbamazep., phenytoin, valp. acid, phenobarb., CMV IgG, herpes I & II IgG, rubella IgG quant., toxo IgG quant., DHEA-SO4, estrad., unconj. estriol, FSH, hCG, LH, progest., prolac., testost., digitox., digox., theoph., anti-TG Ab, anti-TPO Ab, FT3, FT4, rapid TSH, TBG, 3rd-gen. TSH, T-uptake, TT3, TT4, thyrogl., AFP, CEA, OM-MA, PAP, PSA, 3rd-gen. PSA, canine TT4 & TSH, C-pep., insul., CK-MB, myogl., trop. I, ACTH, β-2-microgl., cortisol, HsCRP, hGH, rubella IgM, toxo IgM, SHBG, homocysteine, *H. pylori* IgG, Turbo menu: CK-MB, myoglob., intact PTH, trop. I, hCG, HBsAg, HBsAg confirm, BR-MA (CA 15-3) (contact company for full menu)**	**AlaTOP allergy scr., 3gAllergy (>360 specific allergens & allergy panels; includes test for animals, drugs, dust, foods, grasses, insects, mites, molds, occupational, parasites, trees, weeds), total IgE, EPO, AFP, CEA, OM-MA (CA 125), PSA, 3rd-gen. PSA, FT3, TT3, FT4, TT4 TBG, thyrogl., anti-TG Ab, anti-TPO Ab, T-uptake, rapid TSH, 3rd-gen. TSH, DHEA-SO4, estrad., FSH, hCG, LH, progest., prolac., total testost., β-2-microgl., cortisol, ferr., intact PTH, C-pep., folic acid, B12, insulin, unconj. estriol, carbamazep., phenytoin, valp. acid, HsCRP, hGH, ACTH, PAP, pheno, homocysteine, CMV IgG (qualit)., *H. pylori* IgG, rubella IgG, toxo IgG, troponin I, CK-MB, herpes I & II IgG, ALA top allergy screen, Pyrilinks-D, myoglobin, toxo IgM, canine TSH, rubella IgM, digoxin, GENT (contact company for full menu)**
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	**GI-MA (CA 19-9), free PSA, TPS, nicotine metabolite, cytokines, free βHCG, IL-6, IL-8, IL-10, LBP, PAPP-A**	**GI-MA (CA 19-9), fβHCG, IL-6, nicotine metabolite, PAPP-A, fPSA**
Research-use-only assays	**—**	**ECP**
Tests in development	**ANA scr., celiac markers, CMV IgM, D-dimer (Turbo), dsDNA Ab, EBV-EA IgG, EBV-EBNA IgG, EBV-VCA IgG, EBV-VCA IgM, gastrin, anti-HAV total & IgM, HBeAg, anti-HBe, HSV I/II IgG, Lyme screen, NT-proBNP, syphilis, canine & feline TL1, vit. D**	**ANA scr., celiac markers, CMV IgM, D-dimer, dsDNA Ab, EBV-EA IgG, EBV-EBNA IgG, EBV-VCA IgG/IgM, gentamicin, anti-HAV total & IgM, HBeAg, anti-HBs, HSV I/II IgG, allergen-specific IgG & IgG4, IL2R, LBP, Lyme screen, NT-proBNP, osteocalcin, syphilis, canine & feline TL1, vancomycin, vit. D**
User-defined methods implemented for what analytes	**none**	**none**
Tests not available on other manufacturers' analyzers	**3rd-gen. PSA, AlaTOP allergy screen, allergy food panel FP5E, SHBG, TBG, EPO, canine TSH, thyroglob., intact PTH, ACTH. Turbo: intact PTH**	**TBG, thyrogl., SHBG, intact PTH, C-peptide, 3rd-gen. PSA**
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	**12; Turbo: 5**	**24**
No. of different assays programmed, calibrated at once	**unlimited; Turbo: 5**	**unlimited**
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	**12/100; Turbo: 50 for intact PTH only**	**24/200**
Shortest/Median onboard reagent stability/Refrigerated onboard	**n/a/30 days/yes (15°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., expir.**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**no/<10 ppm**	**no/<3 ppm**
Walkaway capacity in minutes/Specimens/Tests-assays	**100/—/70**	**300/90/1,300**
System is open (home-brew methods can be used)/Liquid or dry system	**no/liquid**	**no/liquid**
Uses disposable cuvettes/Max. No. stored	**yes/n/a**	**yes/1,300**
Uses washable cuvettes/Replacement frequency	**no**	**no**
Minimum specimen vol. required	**5 µL**	**5 µL to 100 µL sample**
Minimum sample vol. aspirated precisely at once/Min. dead vol.	**5 µL/100 µL**	**5 µL/50 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes/no**	**yes/no**
Requires dedicated water system/Water consumption	**no/0.5 L per h**	**no/—**
Noise generated	**55 min., max. 68**	**52 decibels**
Has dedicated pediatric sample cup/Dead vol.	**no**	**yes/50 µL**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**no/n/a/—**	**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)/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	**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	**n/a**	**n/a**
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**	**no/no**
Time between initial result & reaspiration of sample for rerun	**n/a**	**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); Turbo: 2 weeks**	**no/1–4 weeks (assay dependent)**
Multipoint calib. supported/Multiple calibs. stored for same assay	**no/yes**	**yes/yes**
How often QC required	**customer determined**	**cutomer determined**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**no/yes**	**yes/yes**
Automatic shutdown/Startup is programmable/Startup time	**no/no/5 min**	**yes/no/4 min**
Stat time to completion of ß-hCG test	**42 min; Turbo: 15 min**	**35 min**
Time delay from ordering stat test to aspir. of sample	**2.5 min**	**18 sec**
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	**120/120 (—)**	**200/200 (18 sec)**
Can auto transfer QC results to LIS/Onboard capability to review QC	**no/yes**	**yes/yes**
Data management capability/Instrument vendor supplies LIS interface	**onboard/yes (addt'l cost)**	**onboard/yes (additional cost)**
Interfaces up and running in active user sites with	**CIS, CPSI, CCA, Mysis, McKesson, Cerner, Antek, CSS, 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	**no**	**yes (universal interface)**
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	**4 hr**	**4 hr**
Mean time between failures/To repair failures	**11 mos/4 hr**	**3 mos/5 hr**
Onboard error codes to facilitate troubleshooting	**yes**	**yes**
Avg. time to complete maintenance by lab personnel	**daily: 5 min; weekly: 10 min; monthly: 20 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	**$75,000; Turbo: $77,500/>1,000 tests per month**	**$124,500/>4,000 tests per month**
Annual service contract cost (24 hours/7 days)	**$8,000**	**$14,500**
Training provided w/ purchase/Advanced operator training	**3.5 days at vendor offices/yes**	**varies on site, 5 days at vendor offices/yes**
Distinguishing features (supplied by vendor)	**system performance reliability; worldwide user satisfaction; breadth of immunoassay menu**	**high throughput system with Windows-based, fully multitasking software; integrated training via tutorial and interactive training CD series; clot detection; sample/reagent level detection; auto dilutions and auto reflex testing; remote diagnostics**

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Automated immunoassay analyzers

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See accompanying article on page 18

	Diagnostic Products Corp. Joe Kelly info@dpconline.com 5210 Pacific Concourse Dr., Los Angeles, CA 90045-6900 310-645-8200 www.dpcweb.com	Diamedix Corp. Pat Ahmad pat_ahmad@ivaxdiagnostics.com 2140 North Miami Ave., Miami, FL 33127 305-324-2300 or 800-327-4565
Name of instrument/First year sold/Where designed	Immulite 2500 SMS/2004/U.S.	Mago Plus Automated EIA Analyzer/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.	see IMMULITE 2000	—/—
Operational type/Model type/Sample handling system	continuous random access/floor standing/rack	Batch, random access/benchtop/2 racks, 120 samples total
Dimensions in inches (H x W x D)/Instrument footprint in square feet	79 x 112 x 40 in/30.69 sq ft	28 x 48 x 26 in/8.7 sq ft, incl. onboard computer, reagents, spectrophotometer
Tests available on instrument in U.S.	cortisol, AlaTOP, 3rd gen allergen-specific IgE, 3gAllergy (>360 specific allergens & allergy panels; includes tests for animals, drugs, dust, foods, grasses, insects, mites, occupational, parasites, trees, weeds) total IgE, ferritin, EPO, calcitonin, pyril. D, homocy., hsCRP, insulin, C peptide, urin. albumin, IGF 1, hCG, CMV IgG, rubella IgG/IgM, toxoplasma IgG/IgM, *H. pylori* IgG, AFP, androstenedione, DHEA SO4, estrad., unconj. estriol, FSH, LH, prolactin, progesterone, testosterone, SHBG, CK-MB, HCG, stat troponin I, myoglobin, carbamazepine, digoxin, phenytoin, pheonobarbital, theophylline, valp. acid, ACTH, β-2-micro., calcitonin, TB, anti-TG Ab (contact company for full menu)	Autoimmune: anti-SSA/Ro, anti-SSB/La, anti-Sm, anti-Sm/RNP, anti-Scl-70, anti-Jo-1, anti-dsDNA, RF, ENA-6 scr., ANA ELISA scr., anti-MPO, anti-PR-3, anti-TPO, anti-TG, anti-cardio. scr., anti-cardio. IgG, IgM, IgA, anti-β-2-glycopr. IgG, IgM, anti-gliadin IgG & IgA; Infectious: toxo IgG, toxo IgM capture, rubella IgG, rubella IgM capture, CMV IgG, CMV IgM capture, HSV I & II IgG & IgM, measles IgG, VZV IgG, EBV-VCA IgG & IgM, EBNA-1 IgG & IgM, EBV-EA-D IgG & IgM, anti-*B. burgdorferi* IgG/IgM, mumps IgG, *H. pylori* IgG, syphilis Trep-Chek, mycoplasma IgG & IgM, HSV 1 IgG, HSV 2 IgG
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	GI-MA (CA 19-9), fβHCG, IL-6, gastrin, PAPP-A, fPSA, anti-HBc, anti-HBc IgM, HBsAg & confirm, anti-HBs	all products available in the U.S. plus allergy tests (total and specific IgE) and a variety of additional kits for infectious and autoimmune diseases; please contact company for a complete international listing
Research-use-only assays	none	none
Tests in development	ANA scr., CMV IgM, D-dimer, digitoxin, dsDNA Ab, EBV-EA IgG, EBV-EBNA IgG, EBV-VCA IgG, EBV-VCA IgM, fol. acid, gentamicin, anti-HAVIgM, anti-HAV total, HBeAg, anti-HBe, HSV I/II IgG, IGFBP-3, LBP, Lyme screen, NT-proBNP, osteocalcin, stat PTH, Pyrilinks-D, syphilis scr., tobramycin, vancomycin, B12, vit. D	tTG IgA, CCP, *C. diff.* A&B, measles IgM, mumps IgM
User-defined methods implemented for what analytes	none	varied programs by customer at customer location
Tests not available on other manufacturers' analyzers	—	assays designed/FDA cleared for this analyzer; tests can be validated on other anals.
Fully automated microplate system	no	yes
No. of each analyte performed in separate disposable unit	—	usually 1 analyte per well; multiple analytes per well in screen tests
No. of wells in microplate	—	min. strip: 8 or less (breakapart wells), max. full plate: 96, up to 4 plates simul.
Methods supported/Separation methods	chemiluminescence/bead, centrifugation	EIA/microtiter
No. of different measured assays onboard simultaneously	24	9
No. of different assays programmed, calibrated at once	unlimited	~50 tests preprogrammed, ready for use
No. of user-definable (open) channels	n/a	20
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	24/200	9/96
Shortest/Median onboard reagent stability/Refrigerated onboard	n/a/90 days/yes (4°C)	>16 h/6 days/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	available/kit lot No., expir. date
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/3 ppm	yes/not susceptible to carryover, has continuous internal cleaning
Walkaway capacity in minutes/Specimens/Tests-assays	300/90/1,300	varies from 150 min–240 min/9 tests & 384 results per run
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	yes/1,300	yes/120
Uses washable cuvettes/Replacement frequency	no	no/n/a
Minimum specimen vol. required	5 µL to 100 µL sample	50 µL in pediatric tube
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/50 µL	4 µL/100 µL
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	insignificant
Has dedicated pediatric sample cup/Dead vol.	yes/50 µL	possible–can use 1.5 mL vial/100 µL
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/75–100 mm height; 12–16 mm width/no	yes/up to 16 x 100/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	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	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	varies: 2 (single point curve tests), 6 (6 pt. curve tests), 3 (3 pt. curve tests)
Calibrants can be stored onboard/Avg. calibration frequency	no/1–4 weeks (assay dependent)	yes/every run
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/no
How often QC required	customer determined	each 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	yes/yes/<5 min
Stat time to completion of ß-hCG test	15 min	n/a
Time delay from ordering stat test to aspir. of sample	18 sec	<15 min set-up time
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	200/200 (18 sec)	120/360 (~4 h)
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
Interfaces up and running in active user sites with	Antek, Cerner, CIS, CPSI, CCS, CCA, LabSoft, Meditech, McKesson, Mysis, SCC, others	Cerner, Misys, Sunquest, others (LIS at hospital site, addt'l cost)
LIS interface operates simultaneously w/ running assays	yes	no
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 (universal interface)	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	4 hr	w/in 24 hr
Mean time between failures/To repair failures	2 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: 3 min; weekly: 5 min; monthly: none
Onboard maintenance records/Maintenance training demo module	no/yes	no/no (tracking of usage time for PM service)
List price/Targeted bed size or daily volume	$200,000 includes SMS & RTS/200+ beds	$62,000/all bed sizes, all test volumes
Annual service contract cost (24 hours/7 days)	$19,500	service during business hours included in reagent rental
Training provided w/ purchase/Advanced operator training	varies on site, 5 days at vendor offices/yes	1–2 days at vendor's facility or on site/as needed
Distinguishing features (supplied by vendor)	large 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; auto reflex, auto dilute; remote diagnostics; RealTime Solutions (RTS) Internet-based service and support system	only system (reagents & instrument) FDA cleared; moderate complexity rating; automation-ready reagents and containers; user-friendly SW for rapid training; built-in safeguards to prevent aborted runs

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Automated immunoassay analyzers

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	Linda Schwartz linda_schwartz@ivaxdiagnostics.com	**Dawn Franzmeier** dawn.franzmeier@diasorin.com
	2140 N. Miami Ave.	**1951 Northwestern Ave., Stillwater, MN 55082**
	Miami, FL 33127	**800-328-1482/651-439-9710** www.diasorin.com
	305-324-2300 www.diamedix.com	
Name of instrument/First year sold/Where designed	**Parsec System/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.	**—/—**	**>125/>600**
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: anti-SSA/Ro, anti-SSB/La, anti-Sm, anti-Sm/RNP, anti-Scl-70, anti-Jo-1, anti-dsDNA, RF, ENA-6 scr., ANA ELISA scr., anti-MPO, anti-PR-3, anti-TPO, anti-TG, anti-cardio. scr, anti-cardio. IgG, IgM, IgA, anti-β-2-glycopr. IgG, IgM, anti-gliadin IgG & IgA; infectious: toxo IgG, toxo IgM capture, rubella IgG, rubella IgM capture, CMV IgG, CMV IgM capture, HSV I & II IgG & IgM, measles IgG, VZV IgG, EBV-VCA IgG & IgM, EBNA-1 IgG & IgM, EBV-EA-D IgG & IgM, anti-B. *burgdorferi* IgG/IgM, mumps IgG, H. pylori IgG, syphilis Trep-Chek, mycoplasma IgG & IgM, HSV 1 IgG, HSV 2 IgG, anti-HAV**	**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	**allergy tests (total and specific IgE), anti-RA/CCP, anti-ASCA IgG/IgA, anti-annexin V, anti-prothrombin-IgA, anti-AMA-M2, anti-histone, HBsAg, HBs confirm., anti-HBs, anti-HBc (total), anti-HBc IgM, HBeAg, anti-HBe, anti-HAV IgM, HCV, AB AU STD SET plus, HIV tests, anti-coxiella IgG, anti-chlamydia IgG/M, anti-tetanus IgG, anti-adenovirus, anti-B. pertussis IgG/M/A, anti-Brucella IgG/M, anti-influenza A & B (IgG/M), others (contact company for full menu)**	**none**
Research-use-only assays	**none in U.S.**	**none**
Tests in development	**tTG IgA, CCP, C. difficile A & B, measles IgM, mumps IgM**	**none**
User-defined methods implemented for what analytes	**varies, can be programmed by user**	**n/a**
Tests not available on other manufacturers' analyzers	**—**	**n/a**
Fully automated microplate system	**yes**	**yes**
No. of each analyte performed in separate disposable unit	**—**	**—**
No. of wells in microplate	**<8 wells (breakapart)/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, continuous loading/unloading**	**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	**16/90**	**volume dependent**
Shortest/Median onboard reagent stability/Refrigerated onboard	**>16 hr/6 days/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, test**	**yes/—**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**no/none, when using disposable tips**	**yes/no**
Walkaway capacity in minutes/Specimens/Tests-assays	**210/90/1**	**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/—**	**no**
Uses washable cuvettes/Replacement frequency	**no**	**no**
Minimum specimen vol. required	**—**	**10 µL**
Minimum sample vol. aspirated precisely at once/Min. dead vol.	**2 ul/—**	**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	**insignificant**	**—**
Has dedicated pediatric sample cup/Dead vol.	**yes/—**	**no**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/up to 16 x 95/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**	**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/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	**yes**	**no**
No. of calibrators required for each analyte	**2 (single point); up to 6 (for 6-point); 3 (cut/off)**	**varies per kit**
Calibrants can be stored onboard/Avg. calibration frequency	**yes/once per run**	**no/each run**
Multipoint calib. supported/Multiple calibs. stored for same assay	**yes/yes**	**yes/no**
How often QC required	**each 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/no/20 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 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**	**yes/yes**
Interfaces up and running in active user sites with	**Sunquest, Misys, Cerner, others (addt'l cost)**	**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**
Mean time between failures/To repair failures	**n/a**	**n/a/n/a**
Onboard error codes to facilitate troubleshooting	**yes**	**yes**
Avg. time to complete maintenance by lab personnel	**daily: none; weekly: 20 min; monthly: none**	**daily: 5 min; weekly: 30 min**
Onboard maintenance records/Maintenance training demo module	**no/no**	**yes/no**
List price/Targeted bed size or daily volume	**$110,000 basic (3 modules)/all bed sizes/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**	**—**
Training provided w/ purchase/Advanced operator training	**2 days on site; 2 days at vendor offices/yes**	**3 days/yes**
Distinguishing features (supplied by vendor)	**scalability—modules can be added to increase capacity; flexibility—can perform multiple technologies simultaneously; continuous loading and results reporting; Internet data enabled; remotely monitors session run status; remote service diagnostics capable**	**selectively open system; multiple assays on a plate; Windows 2000 software; continuous loading of samples, reagents, and microplates; primary tube sampling; bidirectional interface**

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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 13 of 22

See accompanying article on page 18

	DiaSorin Inc. Brian Lauber brian.lauber@diasorin.com 1951 Northwestern Ave. Stillwater, MN 55082 800-328-1482/651-439-9710 www.diasorin.com	Grifols USA Inc. John Medders john.medders@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.	25/1,250	100/1,000
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	system is completely open, any 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	toxo IgG, toxo IgM, rubella IgG, dsDNA, CMV IgG & IgM	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, CMV IgG, CMV IgG avidity, toxo IgG avidity, HSV 2 IgG, HSV I/II IgM, HSV I/II IgG, HCG, β-2-microglobulin, HAV, HAV IgM, 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, cortisol, C-peptide, Brahms procalcitonin, borrelia IgG & IgM, total treponema, tTG IgA, testosterone, NSE, progesterone	n/a
Research-use-only assays	—	n/a
Tests in development	ANA screen, cyclosporine, everolimus, HSV-I 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	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	requires operator prehandling/preparation
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/<5 ppm
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		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	24–48 hr
Mean time between failures/To repair failures	—/—	—/24–48 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	$12,000
Training provided w/ purchase/Advanced operator training	3 days on site/yes	4 days on site/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

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Automated immunoassay analyzers

Part 14 of 22	**Hycor Biomedical Inc.** cs@hycorbiomedical.com **7272 Chapman Ave.** **Garden Grove, CA 92841** **714-933-3000** www.hycorbiomedical.com	**Hycor Biomedical Inc.** cs@hycorbiomedical.com **7272 Chapman Ave.** **Garden Grove, CA 92841** **714-933-3000** www.hycorbiomedical.com
See accompanying article on page 18		
Name of instrument/First year sold/Where designed	**Hy•Tec 288/outside U.S. 1998, U.S. 1999/Netherlands**	**Hy•Tec 480/1994/Switzerland**
Country where manufactured/Where reagents manufactured	**Netherlands/U.S., Scotland**	**Switzerland/U.S., Scotland**
No. of units in clinical use in U.S./Outside U.S.	**50/102**	**8/57**
Operational type/Model type/Sample handling system	**random batches/benchtop/rack-robotics**	**random batches/benchtop/rack-robotics**
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**	**19.7 x 55 x 28 in/10.6 sq ft**
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**	**specific IgE, total IgE, >1,000 allergens; ANA scr., TG, TPO, dsDNA, RF IgG & IgM, PR-3 c-ANCA, ENA-6 scr., SS-A, SS-B, gliadin IgG & IgA, Sm, Sm/RNP, Scl-70, Jo-1, GPC, GBM, MPO p-ANCA, mitochondrial, cardiolipin IgG & IgM, cardiolipin scr.; anti-β-2 GPI, user-definable software**
Tests cleared but not clinically released	**anti-tissue transglutaminase IgA and IgG**	**anti-tissue transglutaminase IgA and IgG**
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**	**IgG, cardiolipin IgA, ssDNA, total rheumatoid factor, anti-phosphatidyl serine scr., anti-phosphatidyl serine IgG & IgM, anti-tissue transglutaminase IgA and IgG**
Research-use-only assays	**none**	**none**
Tests in development	**ANCA profile, centromere**	**ANCA profile, centromere**
User-defined methods implemented for what analytes	**—**	**—**
Tests not available on other manufacturers' analyzers	**allergy & autoimmune testing on fully automated system**	**allergy & autoimmune testing on fully automated system**
Fully automated microplate system	**yes**	**yes**
No. of each analyte performed in separate disposable unit	**8 (1 analyte per well; multiple analytes per well/screens; up to 8 analytes per run)**	**8 (1 analyte per well; multiple analytes per well/screens)**
No. of wells in microplate	**96–min. strip: 1 strip/8 wells; max. full plate: 12 strips/96 wells**	**96-min. strip: 8 wells/1 strip; max. full plate: 12 strips/96 wells**
Methods supported/Separation methods	**EIA, tube-based & microplate-based assays/activated cellulose & coated well**	**EIA, tube-based & microplate-based assays/activated cellulose & coated well**
No. of different measured assays onboard simultaneously	**varies by assay, up to 288 allergens or 8 autoimmune**	**varies by assay, up to 480**
No. of different assays programmed, calibrated at once	**multiple**	**multiple**
No. of user-definable (open) channels	**unlimited**	**multiple**
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**	**1/200-allergy, 96-autoimmune**
Shortest/Median onboard reagent stability/Refrigerated onboard	**8 hr/12 hr/no**	**8 hr/12 hr/no**
Multiple reagent configurations supported	**yes**	**yes**
Reagent container placed directly on system for use	**yes**	**yes**
Reagents bar coded/Information in bar code	**no**	**no**
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	**yes/<1 part in 10,000**	**yes/<1 part in 10,000**
Walkaway capacity in minutes/Specimens/Tests-assays	**assay dependent/100/288**	**assay dependent/100/480**
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	**10 µL, 110 µL w/ dead vol.**	**10 µL, 310 µL w/ dead vol.**
Minimum sample vol. aspirated precisely at once/Min. dead vol.	**10 µL–50 µL, assay dependent//100 µL**	**10 µL–50 µL, assay dependent//300 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes/no**	**yes/no**
Requires dedicated water system/Water consumption	**no/—**	**no/—**
Noise generated	**—**	**—**
Has dedicated pediatric sample cup/Dead vol.	**no**	**no**
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	**yes/—/no**	**yes/—/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)/n/a**
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	**no/no**	**no/no**
Hemolysis detection-quantitation/Turbidity detection-quantitation	**no/no**	**no/no**
Dilution of patient samples onboard/Automatic rerun capability	**yes/no**	**yes/no**
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	**no/no**	**no/no**
Time between initial result & reaspiration of sample for rerun	**n/a**	**n/a**
Autocalibration or autocalibration alert	**yes**	**yes**
No. of calibrators required for each analyte	**1–5**	**1–5**
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	**every assay**	**every assay**
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/no/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)	**n/a**	**n/a**
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/no**
Interfaces up and running in active user sites with	**25**	**30**
LIS interface operates simultaneously w/ running assays	**no**	**no**
Uses LOINC to transmit orders and results	**no**	**no**
How labs get LOINC codes for reagent kits	**n/a**	**n/a**
Bidirectional interface capability	**yes**	**yes**
Results transmitted to LIS as soon as test time complete	**optional**	**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**	**no/yes/no**
Can order (via modem) malfunctioning part(s) w/o operator	**no**	**no**
On-site response time of service engineer	**48 hr**	**48 hr**
Mean time between failures/To repair failures	**7 months/4 hr**	**10 months/4 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: 10–15 min; weekly: 20–25 min; monthly: 20–25 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	**$55,000/all sites, variable test vols.**	**$75,000/all sites, variable test vols.**
Annual service contract cost (24 hours/7 days)	**$5,500**	**$7,500**
Training provided w/ purchase/Advanced operator training	**3 days on site/yes**	**3 days on site/yes**
Distinguishing features (supplied by vendor)	**fully automated allergy and autoimmune testing; >1,000 allergens; user-definable software**	**fully automated allergy and autoimmune testing; >1,000 allergens; user-definable software**

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

Automated immunoassay analyzers

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See accompanying article on page 18

	Nichols Institute Diagnostics Bill Wilson wilsonb@nicholsdiag.com 1311 Calle Batido, San Clemente, CA 92673 800-286-4NID (4643) nicholsdiag.com	Olympus America Inc. Susan Watanabe susan.watanabe@olympus.com Two Corporate Center Dr., Melville, NY 11747 800-223-0125 www.olympus.com
Name of instrument/First year sold/Where designed	Nichols Advantage Specialty System/1997/Germany	AU400e/2002; AU400/1999/Japan
Country where manufactured/Where reagents manufactured	U.S./U.S.	Japan/U.S., Ireland
No. of units in clinical use in U.S./Outside U.S.	>250/>350	>500/>1,500
Operational type/Model type/Sample handling system	batch, cont. random access/benchtop/rack	cont. random access/floor-standing/rack & turntable
Dimensions in inches (H x W x D)/Instrument footprint in square feet	44 x 45 x 26 in/8 sq ft	47.6 x 57.1 x 29.9 in/70 x 129 in
Tests available on instrument in U.S.	ACTH, cortisol, urinary cortisol, EPO, ferritin, sTfR, CT, intact PTH, hGH, IGF-1, FT3, FT4, 3rd-gen. TSH, TG, anti-TG, anti-TPO, DHEAS, Bio-Intact PTH (I-84), 25 hydroxyvit D, direct renin, IGF BP-3, aldosterone, *H. pylori* IgG, Quick-IntraOperative Bio-Intact PTH (1–84), H-hCG	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, trans-ferrin, acetamin., amikacin, caffeine, carbamaz., digoxin, disopyramide, ethosux., gentamicin, lidocaine, methotrexate, N-acetylprocain., phenobarb., phenytoin, primi-done, 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	none	ceruloplasmin, HbA1c, lithium, cholinesterase, urinary protein
Tests not available in U.S. but submitted for clearance	—	none
Tests not available in U.S. but available in other countries	ITA, TG with recovery	cotinine
Research-use-only assays	osteocalcin	none
Tests in development	1,25 dihydroxyvit D, *H. pylori* IgA, total hCG, AFP, UE3, C-peptide, insulin	none
User-defined methods implemented for what analytes	none	fructosamine
Tests not available on other manufacturers' analyzers	IGF-I, calcitonin, Bio-Intact PTH (I-84), 25 hydroxyvit D, direct renin, aldosterone sTfR, Quick-IntraOperative Bio-Intact PTH (1–84), H-hCG	none
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	n/a	n/a
No. of wells in microplate	n/a	n/a
Methods supported/Separation methods	chemiluminescence/magnetic particle	EIA, photometric, potentiometric, calc. results/none (all homogeneous)
No. of different measured assays onboard simultaneously	15	>40
No. of different assays programmed, calibrated at once	15	99
No. of user-definable (open) channels	0	95
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	15/varies, typically 100	76/100–6,160
Shortest/Median onboard reagent stability/Refrigerated onboard	8 h/—/yes (17°C)	168 h/60 days/yes (4–12°C)
Multiple reagent configurations supported	no	yes
Reagent container placed directly on system for use	no, requires operator prehandling, preparation	yes
Reagents bar coded/Information in bar code	yes/assay ID, lot No., serial No., expir.	yes/reag. ID, lot No., bottle No., expir.
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/$5x10^{-5}$	yes/n/a
Walkaway capacity in minutes/Specimens/Tests-assays	up to 480/120/15 x 100=1,500	variable/up to 102/8,058
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	yes/liquid
Uses disposable cuvettes/Max. No. stored	yes/120	no
Uses washable cuvettes/Replacement frequency	no	yes/permanent
Minimum specimen vol. required	assay dependent	2 µL per test
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL/200 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	67 decibels	<65 decibels
Has dedicated pediatric sample cup/Dead vol.	yes/100 µL	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/10 x 75, 16 x 100 mm/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)/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)	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/yes
Time between initial result & reaspiration of sample for rerun	37 min	varies by run size
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte	2	1–6
Calibrants can be stored onboard/Avg. calibration frequency	no/7 days	yes/14 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/yes
How often QC required	shortest interval: 4 hr, longest: 8 hr	lab-defined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/no	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/10 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)	up to 55/up to 165 (—)	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/yes (included in price)	onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	all commercially available LISs	Cerner, Antrim, CCA, Chemware, Dawning, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Orchard, Citation
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	yes	no
How labs get LOINC codes for reagent kits	—	n/a
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	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	24 hr	<24 hr
Mean time between failures/To repair failures	90 days/24 hr	>30 weeks/<24 hr
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 10 min; weekly: 30–45 min; monthly: 5 min	daily: 3 min; weekly: 7 min; monthly: 45 min
Onboard maintenance records/Maintenance training demo module	no/no	yes (incl. audit trail of who replaced parts)/yes
List price/Targeted bed size or daily volume	$147,000/300+ beds	$130,000/200–2,000 tests per day (depending on menu)
Annual service contract cost (24 hours/7 days)	inquire	inquire
Training provided w/ purchase/Advanced operator training	4 days at vendor offices/yes	5 days on site, 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	the fully automated continuous random access chemiluminescence system can run specialty assays as if they are routine; bar coding of primary sample tubes, reagents, stored master curve and two-point calib.; assures ease of use and minimizes hands-on time; onboard refrigeration	open reagent system; 122-test menu includes general chemistry and homoge-neous 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 16 of 22

See accompanying article on page 18

	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 racks (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	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
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	CA 19-9, fß–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	NT-proBNP, rubella IgM, toxo. IgM, CMV IgG, CMV IgM	rubella IgM, toxo. IgM, CMV IgG, CMV IgM, NT-proBNP
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/60 µL	10 µL/60 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 day	once per day
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	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 with adjustable flat, low-glare touchscreen monitor and keyboard platform with a multi-purpose support arm

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Automated immunoassay analyzers

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	Pharmacia Diagnostics AB **Lorraine Damico** lorraine.damico@diagnostics.com **4169 Commercial Ave.** **Portage, MI 49002** **800-346-4364** www.us.diagnostics.com	**Pharmacia Diagnostics AB** **Lorraine Damico** lorraine.damico@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.	**24/280**	**27/~200**
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)	**$5,400 (business hours only)**	**$18,000**
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)	**allergy diagnostics is our core business; these are not "add-on" tests; this system and reagents are designed to provide the most accurate specific allergy diagnostic results and use well documented ImmunoCAP technology; supported by a dedicated sales force to drive business development programs that help labs increase the services they offer physicians and outreach revenue for lab**	**allergy diagnostics is our core business; these are not "add-on" tests; this system and reagents are designed to provide the most accurate specific allergy diagnostic results and use well documented ImmunoCAP technology; supported by a dedicated sales force to drive business development programs that help labs increase the services they offer physicians and outreach revenue for lab**

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Automated immunoassay analyzers

Part 18 of 22

See accompanying article on page 18

	Pharmacia Diagnostics AB Lorraine Damico lorraine.damico@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, County Antrim, BT29 4QY 44 (0) 28 9442 2413 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.	~300/4,000	—/—
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/—	66 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, amphetamines, methadone, PCP, opiates, cannabinoids, barbiturates, progesterone, prolactin, LH, FSH
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for clearance	—	benzodiazepines
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 I, testosterone
Research-use-only assays	*ImmunoCAP specific IgG tests, ECP, trytase are investigational use only (IUO)	EGF, IFNγ, IL-1α, IL-1β, IL-2, IL-4, IL-6, IL-8, IL-10, MCP-1, TNF-α, VEGF
Tests in development	—	allergen array, cell adhesion molecule array, anemia array, cerebral array, further cytokines and growth factors array, maternal screen array, platelet activation and vasoactive agents, additional tumor markers, breast cancer diagnosis and classification, bone markers, drugs of abuse array II
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-γ, FABP, GPBB, CAIII
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 technology
No. of different measured assays onboard simultaneously	4	35
No. of different assays programmed, calibrated at once	7	35
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	98/—
Shortest/Median onboard reagent stability/Refrigerated onboard	n/a	30 days/30 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/—
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/—	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 uL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	40 µL/40–200 µL (varies with tube type)	7 uL/50 uL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/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 others on request/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	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	135/405/45 min
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/yes (included)
Interfaces up and running in active user sites with	Misys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others	Torex LIMS/Clinisys LIMS
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	—/—	n/a/1 day
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, 400 tests per day
Annual service contract cost (24 hours/7 days)	$2,500 (swap contract only)	—
Training provided w/ purchase/Advanced operator training	3.5 days at vendor offices/yes	5 days on site/yes
Distinguishing features (supplied by vendor)	allergy diagnostics is our core business; these are not "add-on" tests; this system and reagents are designed to provide the most accurate specific allergy diagnostic results and use well documented ImmunoCAP technology; supported by a dedicated sales force to drive business development programs that help labs increase the services they offer physicians and outreach revenue for the lab	biochip enables simultaneous detection of multiple parameters in a single patient sample; arrays contain multiple test panels applicable to clinical research applications and specific disease groups; tests not reported may be retrieved and reported retrospectively; cost is based soley on number of tests reported; max throughput of 1,350 test results per hour; common reagents for all tests; new panels available for research markers, such as cytokines and growth factors, drugs of abuse

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Automated immunoassay analyzers

Part 19 of 22

See accompanying article on page 18

	Roche Diagnostics **Adam Sterle** adam.sterle@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us	Roche Diagnostics **Adam Sterle** adam.sterle@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us
Name of instrument/First year sold/Where designed	Elecsys 2010/1996/—	Elecsys 1010/1997/—
Country where manufactured/Where reagents manufactured	Japan/Germany	Switzerland/Germany
No. of units in clinical use in U.S./Outside U.S.	>600/>4,000	>200/>2,000
Operational type/Model type/Sample handling system	cont. random access/benchtop/rack or disk	random access/benchtop/sample disk
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	25.6 x 37 x 25.2 in/6.5 sq ft
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	TSH, T3, T4, T-uptake, FT3, FT4, FSH, LH, prolac., progest., estradiol, testost., CK-MB, TNT, myogl., digoxin, CEA, AFP, PSA (screen), CA 125, ferr., IgE, intact PTH, hCG, cortisol, insulin, fPSA, DHEAS, β-hCG, CA 15-3, anti-TPO, serum β crosslaps, pro BNP, cortisol urine, SHBG, 9-minute PTH, C-peptide
Tests cleared but not clinically released	TG	TG
Tests not available in U.S. but submitted for clearance	CA 19-9, anti-HBs, HBsAg, HBsAg confirm	CA 19-9
Tests not available in U.S. but available in other countries	osteocalcin, anti-HBc, cyfra 21-1, anti HBc IgM, anti-HBe, HBeAg, CA 72-4, NSE, anti-TG, PINP, anti-HCV, digitoxin	osteocalcin, cyfra 21-1, CA 72.4, NSE, anti-TG, PINP
Research-use-only assays	none	none
Tests in development	—	—
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	n/a
No. of wells in microplate	n/a	n/a
Methods supported/Separation methods	electrochemiluminescence/magnetic particle	electrochemiluminescence IA/ magnetic particle
No. of different measured assays onboard simultaneously	15	6
No. of different assays programmed, calibrated at once	60	—
No. of user-definable (open) channels	0	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	15/100–200	6/100–200
Shortest/Median onboard reagent stability/Refrigerated onboard	56 days/56 days/yes (20°C)	28 days/28 days/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/calib. curve, application params., lot No., expir., reag. name	yes/calib. curve, application params., lot No., expir., reag. name
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover (disposable sample tips)	no/<8 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	120/disk: 30, rack: 100/180	150/42 1° tube + 24 sample cups/128
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/128
Uses washable cuvettes/Replacement frequency	no	no
Minimum specimen vol. required	10 µL	10 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 µL/100 µL	10 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	—/no	no/no
Requires dedicated water system/Water consumption	no/—	no/—
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	no	yes/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13–16 mm diam./no	yes/13–16 mm diam./no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	—	—
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/no	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	—	—
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	2	2
Calibrants can be stored onboard/Avg. calibration frequency	no/monthly	no/7 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	no/no/4 min	no/no/5 min
Stat time to completion of ß-hCG test	9 min (hCG intact)	9 min (hCG intact)
Time delay from ordering stat test to aspir. of sample	42 sec	65 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	30/88 (42 sec)	20/55 (65 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)	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	no/yes/no	no/yes/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	<24 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: 1 min; biweekly: 5 min; monthly: 5 min
Onboard maintenance records/Maintenance training demo module	no/no (training CD-ROM)	no/—
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	included w/ reagent rental
Training provided w/ purchase/Advanced operator training	3 days at Indianapolis offices/yes	3 days at Indianapolis offices/yes
Distinguishing features (supplied by vendor)	connectable to Clinical Lab Automation System; liquid ready-to-use reagents; autocalib., autodil.; ECL technology for broad dynamic ranges, and fast turn-around time, stat interrupt; onboard reag. storage; minimal maintenance	liquid ready-to-use reagents; autocalib., autodil.; ECL detection system provides broad measuring range and short TAT; stat interrupt; onboard reagent storage; minimal maintenance; small footprint

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SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 20 of 22	Roche Diagnostics Lisa Davis lisa.davis@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074	TOSOH Bioscience Inc. Susan Kolarik susan.kolarik@tosohbioscience.com 347 Oyster Point Blvd., #201 South San Francisco, CA 94080 800-248-6764
See accompanying article on page 18	www.roche.com/labsystems/us	www.tosohbioscience.com
Name of instrument/First year sold/Where designed	Modular Analytics E170/2001/Japan	AIA-600 II/2000/Japan
Country where manufactured/Where reagents manufactured	Japan/Germany	Japan/Japan
No. of units in clinical use in U.S./Outside U.S.	>50/>300 (combination of E and EE systems) and >25 Integrated Modular Systems (U.S. only)	400/600
Operational type/Model type/Sample handling system	continuous random access/floor-standing/rack	cont. random access/benchtop/chain
Dimensions in inches (H x W x D)/Instrument footprint in square feet	96.25 (W) x 43.25 (D) in (Modular E configuration)/approx. 60 sq ft (one module system)	19.8 x 31.6 x 29.1 in/2.5 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, 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	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
Tests cleared but not clinically released	TG	—
Tests not available in U.S. but submitted for clearance	HBsAg, HBsAg (conf.), anti-HBs, CA 19-9	—
Tests not available in U.S. but available in other countries	osteocalcin, CA 72-4, cyfra 21-1, NSE, anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, anti-TG, digitoxin, PINP, anti-HCV, NSE	HBsAg, HBsAb, HBeAg, HbcAb, HbeAb, BNP
Research-use-only assays	none	—
Tests in development	—	RBC folate, PTH, HbA1c
User-defined methods implemented for what analytes	none	none
Tests not available on other manufacturers' analyzers	TNT	none
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	fluorescence, EIA/bead
No. of different measured assays onboard simultaneously	25 per E module, maximum of 60	26
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 moduule/100–200	n/a/unitized test cup
Shortest/Median onboard reagent stability/Refrigerated onboard	56 days/56 days/yes (20°C)	72 h/72 h/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/—/1,006	52/26/26
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/dry
Uses disposable cuvettes/Max. No. stored	yes/—	n/a/unitized test cup
Uses washable cuvettes/Replacement frequency	no	n/a
Minimum specimen vol. required	10 µL	500 µL tube, 100 µL cup
Minimum sample vol. aspirated precisely at once/Min. dead vol.	—/100 µL	10 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/no
Requires dedicated water system/Water consumption	yes/18 per module in full operation	no/n/a
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	yes/100 µL	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13 x 75 to 16 x 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 (2 of 5 interl., codabar, codes 39 & 128)/yes	yes/yes
Bar-code placement per NCCLS standard Auto2A	—	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/—	yes/no
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/yes
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/monthly	no/60–90 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	no/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	—	60 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	56/176 (21 sec)	20/60 (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 (addt'l cost)	optional add-on (all major LIS vendors—Schuyler House, Misys, LabForce, McKesson, Antrim, Data Innovations)/yes (addt'l cost)
Interfaces up and running in active user sites with	all major LISs	Schuyler House, Fletcher Flora
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	—	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	yes (Roche Modular Pre-Analytical Systems and task targeted automation)	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 hr	24 hr
Mean time between failures/To repair failures	—/—	98% uptime/—
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: 5 min; monthly: none
Onboard maintenance records/Maintenance training demo module	yes/yes	no/no
List price/Targeted bed size or daily volume	varies, based on contract	$70,000/500–2,500 tests per month
Annual service contract cost (24 hours/7 days)	incl. w/ reagent rental	$5,600
Training provided w/ purchase/Advanced operator training	5 days at vendor offices/yes	3 days at vendor offices/no
Distinguishing features (supplied by vendor)	expandable liquid ready-to-use reagents that are compatible with other Elecsys systems, compatible with Pre-Analytic Automation; ECL technology provides broad measuring range and market, best low-end sensitivity, troponin T, auto-rerun and dilute	unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use

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Automated immunoassay analyzers

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www.tosohbioscience.com

Name of instrument/First year sold/Where designed	**AIA-360/2004/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.	**275/100+**	**20/250+**
Operational type/Model type/Sample handling system	**continuous random access/benchtop/carousel**	**continuous random access/floor standing/rack, sort drawer, standard and LA**
Dimensions in inches (H x W x D)/Instrument footprint in square feet	**15.75 x 15.75 x 19.69 in/2.2 sq ft**	**65 x 50 x 37 in/6.3 sq ft**
Tests available on instrument in U.S.	**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**	**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	**BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg**	**BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg**
Research-use-only assays	**—**	**—**
Tests in development	**PTH, HbA1c, B12, folate, RBC folate**	**PTH, HbA1c, RBC folate**
User-defined methods implemented for what analytes	**—**	**—**
Tests not available on other manufacturers' analyzers	**—**	**—**
Fully automated microplate system	**n/a**	**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	**flourescence, EIA/bead**	**flourescence, EIA/bead**
No. of different measured assays onboard simultaneously	**25**	**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	**72hr/72hr/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	**58/25/25**	**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	**no**	**n/a/unitized test cup**
Uses washable cuvettes/Replacement frequency	**no**	**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.	**10–100 µL**	**10 µL/50 µL**
Supplied with UPS (backup power)/Requires floor drain	**no/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: 13 x 75 & 100; 16 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	**no/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**	**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/30–90 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	**yes/no/5 min**	**no/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)	**12/36 (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	**Antek. Schuyler House, more**	**yes/no**
Interfaces up and running in active user sites with	**n/a**	**yes**
LIS interface operates simultaneously w/ running assays	**—**	**yes**
Uses LOINC to transmit orders and results	**yes**	**yes**
How labs get LOINC codes for reagent kits	**package insert**	**package insert**
Bidirectional interface capability	**yes**	**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	**n/a**	**24 hr**
Mean time between failures/To repair failures	**>6 months**	**n/a**
Onboard error codes to facilitate troubleshooting	**yes**	**yes**
Avg. time to complete maintenance by lab personnel	**daily: 5 min**	**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	**$25,000/200–1,000 tests per month**	**TBD/65+ beds, 1,500–2,000 tests**
Annual service contract cost (24 hours/7 days)	**$2,000**	**TBD**
Training provided w/ purchase/Advanced operator training	**training DVD and DVD player; onsite install**	**4 days at vendor offices/no**
Distinguishing features (supplied by vendor)	**unitized test cups; primary tube sampling; no reagent preparation, room temp. stability for five days; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use; compact size; four tests per sample; random access**	**two models: standard and LA; unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use**

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Automated immunoassay analyzers

Part 22 of 22	Trinity Biotech Marlene Jinks marlene.jinks@trinityusa.com 1930 Innerbelt Business Center Dr. St. Louis, MO 63114 800-325-3424 www.trinitybiotech.com	Trinity Biotech Marlene Jinks marlene.jinks@trinityusa.com 1930 Innerbelt Business Center Dr. St. Louis, MO 63114 800-325-3424 www.trinitybiotech.com
See accompanying article on page 18		
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

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