Automated immunoassay analyzers

The nuts and bolts of selecting instruments

Anne Ford

CAP TODAY's annual lineup of immunoassay analyzers begins here—40 systems from 19 companies. These analyzers can solve virtually any service challenge. But which one is right for your laboratory, and when should you make the move?

Choosing a new capital item for the laboratory can be intimidating, but Stan Schofield, MHA, MT(ASCP), knows how to make the process manageable. It begins, he says, by asking three basic questions about every potential purchase: "One, will it improve service? Two, will it improve quality? And three, will it decrease costs?"

In a CAP audioconference Jan. 14, Schofield, president of NorDx, a laboratory network for the Maine Health System, Scarborough, Me., laid out the guidelines laboratories should follow when selecting new instruments. If a lab's current equipment is more than five years old, or if its maintenance costs are steadily increasing, it's time to consider new equipment, he says. In the process, several working assumptions must be taken into account, such as flexibility, testing capability, and maintenance.

"Is the instrument flexible enough to be used in multiple settings?" he asks. "Can it handle multiple aliquots, reduce workstations, improve data flow? It should have superior testing capabilities over existing instrumentation." Schofield recommends that laboratories aim for a 50 percent cost reduction in overall instrumentation maintenance. "The purchase of any instrument in maintenance cost," he adds, "should not exceed the cost of the instrument based on the reagent level or cost-per-reportable basis."

Gathering critical information—such as total department expenses, direct and indirect costs for each analyte, and personnel resources—is a must. "Do not consider the FTE savings unless the positions are eliminated or transferred to other responsibilities," Schofield says. "Partial FTE savings are almost impossible to capture. We call those 'sneak-a-bodies' around here. People say, 'I'm going to save half of an FTE, or a quarter of an FTE.' We've gotten out of that mode because it just never happens." Laboratories should also decide on a savings target; Schofield considers a 10 to 15 percent operating cost reduction realistic.

To collect, summarize, and evaluate instrument information, says Schofield, construct a side-by-side comparison for each instrument under consideration. "The best sources of information are the vendors, your colleagues, and your own employees. Peer reviews and colleague networking are absolutely critical. I also like going to national meetings and looking at equipment."

Finally, the initial selection phase of the instrument "should involve all levels of the laboratory," Schofield says. "Without staff participation and buy-in, the implementation and execution of new technologies often is fraught with additional problems that you could have avoided." □

Anne Ford is CAP TODAY *senior editor.*

Part 1 of 21	Abbott Diagnostics Troy Henry troy.henry@abbott.com 100 Abbott Park Rd., Dept. ZZ2, AP6C-5 Abbott Park, IL 60064-3500 847-937-9785 www.abbott.com
Name of instrument/first year sold/where designed	AxSym/1993 worldwide, 1994 U.S./U.S.
Country where manufactured/where reagents manufactured	U.S./U.S.
No. of units in clinical use in U.S./outside U.S.	4,000+/15,000+
Operational type/model type/sample handling system	cont. random access/floor-standing/segment
Dimensions (H x W x D)/instrument footprint	59 x 63 x 33.5 in/22 sq ft
Tests available on instrument in U.S.	hTSH II, TT_3, TT_4, FT_3, FT_4, T-uptake, βhCG, FSH, LH, estrad., prolac., progest., CK-MB, homocysteine, myogl., trop. I, PSA, CEA, CA 125, CA-19-9, CA 15-3, AFP, CMV IgG, rubella IgG & IgM, toxo IgG & IgM, carbamazep., digitox., digox., gentamicin, NAPA, phenytoin, phenobarb., procain., quinidine, theoph., tobramycin, valp. acid, vanc., amph/meth, barbit., benzodiazep., cannab., cocaine, methadone, opiates, PCP, acetamin., ethanol, salicylates, tricyc., 3rd-gen. TSH
Tests cleared but not clinically released	n/a
Tests not available in U.S. but submitted for clearance	n/a
Tests not available in U.S. but available in other countries	B_{12}, ferr., fol.
Research-use-only assays	none
Tests in development	hepatitis, retrovirus, metabolic, fertility
User-defined methods implemented for what analytes	none
Tests not available on other manufacturers' analyzers	drugs of abuse and congenitals
Fully automated microplate system	no
No. of each analyte performed in separate disposable unit	n/a
No. of wells in microplate	n/a
Methods supported/separation methods	FPIA, MEIA, ion capture, REA/heterogeneous, bead (microparticle), fiber matrix filter
No. of different measured assays onboard simultaneously	20
No. of different assays programmed, calibrated at once	20
No. of user-definable (open) channels	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	20/100
Shortest/median onboard reagent stability/refrigerated onboard	onboard reagent stability: 48, 112, 224, 336/no
Multiple reagent configurations supported	no
Reagent container placed directly on system for use	yes
Reagents bar coded/information in bar code	yes/assay name, reag. lot No., expir., pack No. ID
Same capabilities when 3rd-party reagents used/susceptibility to carryover	no/<1 ppm
Walkaway capacity in minutes/specimens/tests-assays	60/90/90
System is open (home-brew methods can be used)/liquid or dry system	no/liquid
Uses disposable cuvettes/max. No. stored	yes/90 reaction vessels
Uses washable cuvettes/replacement frequency	no
Minimum specimen vol. required	—
Minimum sample vol. aspirated precisely at once/min. dead vol.	10 µL/73 µL for sample cup, 450 µL for aliquot, 4.5 mL for primary
Supplied with UPS (backup power)/requires floor drain	yes (soft close of files only)/optional
Requires dedicated water system/water consumption	no/—
Noise generated	52–68 decibels
Has dedicated pediatric sample cup/dead vol.	no
Primary tube sampling/tube sizes/pierces caps on primary tubes	yes/100 & 75 mm/no
Sample bar-code reading capability/autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	yes
Onboard test auto inventory (determines vol. in container)	yes
Measures No. of tests remaining/short sample detection	yes/yes
Auto detection of adequate reagent or specimen	yes
Clot detection/reflex testing capability	yes w/ AxSym Plus
Hemolysis/turbidity detection-quantitation	yes/no
Dilution of patient samples onboard/automatic rerun capability	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/increased to rerun out-of-linear range low results	no/no
Time between initial result & reaspiration of sample for rerun	seconds
Autocalibration or autocalibration alert	no
No. of calibrators required for each analyte	6 pt. or 2 pt. w/ master calib., index calib.
Calibrants can be stored onboard/avg. calibration frequency	no/4 weeks
Multipoint calib. supported/multiple calibs. stored for same assay	yes/yes (up to 4 curves/analyte)
How often QC required	shortest interval: 8 h, longest: 24 h
Onboard real-time QC/support multiple QC lot Nos. per analyte	yes/yes
Automatic shutdown/startup is programmable/startup time	no/no/1 min
Stat time to completion of ß-hCG test	13 min.
Time delay from ordering stat test to aspir. of sample	30 sec from standby
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	68–120 tests/flexible platform—load list dependent (assay dependent)
Can auto transfer QC results to LIS/onboard capability to review QC	yes/yes
Data management capability/instrument vendor supplies LIS interface	onboard/no
Interfaces up and running in active user sites with	all major LIS vendors
LIS interface operates simultaneously w/ running assays	yes
Uses LOINC to transmit orders and results	yes
How labs get LOINC codes for reagent kits	—
Bidirectional interface capability	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes
Interface available (or will be) to auto specimen handling system	yes
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	no/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no
On-site response time of service engineer	12 h
Mean time between failures/to repair failures	5 mos/within 12 h per customer request
Onboard error codes to facilitate troubleshooting	yes
Avg. time to complete maintenance by lab personnel	daily: 5 min; weekly: 30 min; monthly: 30 min
Onboard maintenance records/maintenance training demo module	no/no
List price/targeted bed size or daily volume	$124,000/>100 patients tests per day
Annual service contract cost (24 hours/7 days)	$16,800 extended hours coverage
Training provided w/ purchase/advanced operator training	5 days on site, 5 days at vendor offices/yes
Distinguishing features	menu, reliability, online exception help, pressure monitoring

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

Survey editor: Raymond Aller, MD

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 2 of 21 *See accompanying article on page 72*	**Abbott Diagnostics** **Michael Welch** michael.welch@abbott.com **100 Abbott Park Rd., Dept. 094K, AP6C-4** **Abbott Park, IL 60064-3500** **847-936-3385** www.abbott.com	**Abbott Diagnostics** **Michael Welch** michael.welch@abbott.com **100 Abbott Park Rd., Dept. 094K, AP6C-4** **Abbott Park, IL 60064-3500** **847-936-3385** www.abbott.com
Name of instrument/first year sold/where designed	**Architect iSystem/1999/U.S.**	**Architect i2000 SR/2003/worldwide**
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.	**100+/1,200**	**100+/1,200**
Operational type/model type/sample handling system	**batch, random access, cont. random access/floor-standing/rack**	**batch, random access, cont. random access/floor-standing/rack**
Dimensions (H x W x D)/instrument footprint	**48 x 44 x 68 in/23 sq ft per module**	**48 x 61 x 49 in/23 sq ft per module**
Tests available on instrument in U.S.	**stat βhCG, FSH, LH, prolac., progest., CEA, TSH, Total T_4, FT_4, FT_3, TT_3, estradiol**	**stat βhCG, FSH, LH, prolac., progest., CEA, TSH, total T_4, FT_4, FT_3, TT_3, estradiol**
Tests cleared but not clinically released	**none**	**none**
Tests not available in U.S. but submitted for clearance	**n/a**	**n/a**
Tests not available in U.S. but available in other countries	**testost., B_{12}, ferr., fol.**	**testost., B_{12}, ferr., fol., AFP, CA 19-9, fPSA, tPSA, anti-HBc, anti-HBs, HBsAg, anti-HBc IgM, HBsAg confirm, HCV**
Research-use-only assays	**none**	**none**
Tests in development	**hepatitis, retrovirus, thyroid, metabolic, cancer, TDM, cardiac**	**hepatitis, retrovirus, thyroid, metabolic, cancer, TDM, cardiac**
User-defined methods implemented for what analytes	**none**	**none**
Tests not available on other manufacturers' analyzers	**none**	**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 w/ flexible protocols/magnetic microparticle**	**chemiluminescence w/ flexible protocols/magnetic microparticle**
No. of different measured assays onboard simultaneously	**25 per module*, max. 4 modules=100 assays max.**	**25 per module*, max. 4 modules=100 assays max.**
No. of different assays programmed, calibrated at once	**100+**	**100+**
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	**25 per module*/100-test & 500-test kits**	**25 per module*/100-test & 500-test kits**
Shortest/median onboard reagent stability/refrigerated onboard	**30 days/30 days/yes (2–12°C)**	**30 days/30 days/yes (2–12°C)**
Multiple reagent configurations supported	**yes**	**yes**
Reagent container placed directly on system for use	**yes**	**yes**
Reagents bar coded/information in bar code	**yes/2D bar code, lot. No., No. tests, calib. data**	**yes/2D bar code, lot. No., No. tests, calib. data**
Same capabilities when 3rd-party reagents used/susceptibility to carryover	**no/0.3 ppm**	**no/0.3 ppm**
Walkaway capacity in minutes/specimens/tests-assays	**300/250/1,000**	**300/250/1,000**
System is open (home-brew methods can be used)/liquid or dry system	**no/liquid**	**no/liquid**
Uses disposable cuvettes/max. No. stored	**yes/1,200**	**yes/1,200**
Uses washable cuvettes/replacement frequency	**no**	**no**
Minimum specimen vol. required	**—**	**—**
Minimum sample vol. aspirated precisely at once/min. dead vol.	**150 µL/50 µL**	**150 µL/50 µL**
Supplied with UPS (backup power)/requires floor drain	**yes/no**	**yes/no**
Requires dedicated water system/water consumption	**no/—**	**no/—**
Noise generated	**60–65 decibels**	**60–65 decibels**
Has dedicated pediatric sample cup/dead vol.	**no**	**no**
Primary tube sampling/tube sizes/pierces caps on primary tubes	**yes/10–16 mm, up to 75–100 mm/no**	**yes/10–16 mm, up to 75–100 mm/no**
Sample bar-code reading capability/autodiscrimination	**yes (2 of 5 interl., codabar, codes 39 & 128)/yes**	**yes (2 of 5 interl., codabar, codes 39 & 128)/yes**
Bar-code placement per NCCLS standard Auto2A	**yes**	**yes**
Onboard test auto inventory (determines vol. in container)	**yes**	**yes**
Measures No. of tests remaining/short sample detection	**yes/yes**	**yes/yes**
Auto detection of adequate reagent or specimen	**yes**	**yes**
Clot detection/reflex testing capability	**yes/no**	**yes/no**
Hemolysis/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**	**yes/yes**
Time between initial result & reaspiration of sample for rerun	**seconds**	**seconds**
Autocalibration or autocalibration alert	**yes**	**yes**
No. of calibrators required for each analyte	**2–6 pt. curve**	**2–6 pt. curve**
Calibrants can be stored onboard/avg. calibration frequency	**no/30 days**	**no/30 days**
Multipoint calib. supported/multiple calibs. stored for same assay	**yes/yes**	**yes/yes**
How often QC required	**3 levels every 24 h**	**3 levels every 24 h**
Onboard real-time QC/support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
Automatic shutdown/startup is programmable/startup time	**n/a/no/10 min**	**n/a/no/10 min**
Stat time to completion of ß-hCG test	**n/a**	**18 min**
Time delay from ordering stat test to aspir. of sample	**every 18 sec from positive sample ID**	**every 18 sec from positive sample ID**
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	**67/200 per module (aspir. to result: 29 min)**	**67/200 per module (aspir. to result: 29 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/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	**—**	**—**
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	**12 h**	**12 h**
Mean time between failures/to repair failures	**not available/not available**	**not available/not available**
Onboard error codes to facilitate troubleshooting	**yes**	**yes**
Avg. time to complete maintenance by lab personnel	**daily: <15 min; weekly: <10 min; monthly: none**	**daily: <15 min; weekly: <10 min; monthly: none**
Onboard maintenance records/maintenance training demo module	**yes (includes audit trail of who replaced parts)/yes**	**yes (includes audit trail of who replaced parts)/yes**
List price/targeted bed size or daily volume	**$169,500/500 immunoassays per day**	**$150,000/up to 300 immunoassays per day**
Annual service contract cost (24 hours/7 days)	**$27,450 (list price)**	**$27,450 (list price)**
Training provided w/ purchase/advanced operator training	**5 days at vendor offices/yes (5 days on-site integration)**	**5 days at vendor offices/yes (5 days on-site integration)**
Distinguishing features	**Chemiflex: advanced, patented chemiluminescence detection technology with flexible protocols delivers superior assay performance; modularity: seamlessly integrates multiple instruments to single workstation, throughput from 200–800 tests/hour; flexibility: integrate to TLA, as workcell or standalone unit; five-hour walk-away**	**Chemiflex: advanced, patented chemiluminescence detection technology with flexible protocols delivers superior assay performance; modularity: seamlessly integrates multiple instruments to single workstation, throughput from 200–800 tests per hour; flexibility: five-hour walk-away; unique multi-dimensional sample handling with immediate start and repeat testing**
	**** for kits with ≤3 reagent bottles***	**** for kits with ≤3 reagent bottles***

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

Automated immunoassay analyzers

Part 3 of 21

See accompanying article on page 72

	Adaltis U.S. Inc. **Elaine Soltes** generalinfo.usa@adaltis.com **754 Roble Rd., Ste. 70** **Allentown, PA 18109** **610-264-0885** www.adaltis.com	**Adaltis U.S. Inc.** **Elaine Soltes** generalinfo.usa@adaltis.com **754 Roble Rd., Ste. 70** **Allentown, PA 18109** **610-264-0885** www.adaltis.com
Name of instrument/first year sold/where designed	**Labotech/1996/Italy**	**PersonalLab/1998/Italy**
Country where manufactured/where reagents manufactured	**Italy/n/a (open system)**	**Italy/n/a (open system)**
No. of units in clinical use in U.S./outside U.S.	**300/3,000**	**200/>400 worldwide**
Operational type/model type/sample handling system	**batch/benchtop/carousel**	**batch/benchtop/rack**
Dimensions (H x W x D)/instrument footprint	**20 x 34.5 x 20 in/4.8 sq ft**	**24 x 26 x 25.6 in/4.6 sq ft**
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**
Tests not available in U.S. but submitted for clearance	**open system**	**open system**
Tests not available in U.S. but available in other countries	**open system**	**open system**
Research-use-only assays	**open system**	**open system**
Tests in development	**open system**	**open system**
User-defined methods implemented for what analytes	**open platform**	**open platform**
Tests not available on other manufacturers' analyzers	**n/a (open platform)**	**n/a (open platform)**
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: 8; max. full plate: 96**
Methods supported/separation methods	**EIA/coated microplate, varies acc. to kit mftr.**	**EIA/coated microplate, varies acc. to kit mftr.**
No. of different measured assays onboard simultaneously	**8 (3 plates)**	**6 (2 plates)**
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	**8/96 (3 plates)**	**6/96 (2 plates)**
Shortest/median onboard reagent stability/refrigerated onboard	**mftr. dependent/no**	**mftr. dependent/no**
Multiple reagent configurations supported	**yes**	**yes**
Reagent container placed directly on system for use	**no, requires operator prehandling/preparation**	**no, requires operator prehandling/preparation**
Reagents bar coded/information in bar code	**no**	**no**
Same capabilities when 3rd-party reagents used/susceptibility to carryover	**yes/zero carryover option**	**yes/zero carryover option**
Walkaway capacity in minutes/specimens/tests-assays	**—/96-8/8**	**—/96-6/6**
System is open (home-brew methods can be used)/liquid or dry system	**yes/—**	**yes/—**
Uses disposable cuvettes/max. No. stored	**yes/288-3 plates**	**yes/192-2 plates**
Uses washable cuvettes/replacement frequency	**no**	**no**
Minimum specimen vol. required	**200 µL plus amount required by mftr.**	**200 µL plus amount required by mftr.**
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/n/a**
Noise generated	**—**	**—**
Has dedicated pediatric sample cup/dead vol.	**no**	**no**
Primary tube sampling/tube sizes/pierces caps on primary tubes	**yes/11 x 55–16 x 100 mm/no**	**yes/16 x 100–11 x 55 mm/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)/—**
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	**no/yes**	**no/yes**
Hemolysis/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)**	**yes/yes (mftr. & assay dependent)**
Time between initial result & reaspiration of sample for rerun	**n/a**	**n/a**
Autocalibration or autocalibration alert	**n/a**	**n/a**
No. of calibrators required for each analyte	**mftr. & assay dependent**	**mftr. & assay dependent**
Calibrants can be stored onboard/avg. calibration frequency	**—/mftr. & assay dependent**	**—/mftr. & assay dependent**
Multipoint calib. supported/multiple calibs. stored for same assay	**yes/—**	**yes/—**
How often QC required	**mftr. & assay dependent**	**mftr. & assay dependent**
Onboard real-time QC/support multiple QC lot Nos. per analyte	**yes/yes**	**no/n/a**
Automatic shutdown/startup is programmable/startup time	**no/no/5 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)	**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/yes (included in price)**	**onboard/yes (included in price)**
Interfaces up and running in active user sites with	**—**	**—**
LIS interface operates simultaneously w/ running assays	**yes**	**yes**
Uses LOINC to transmit orders and results	**—**	**—**
How labs get LOINC codes for reagent kits	**—**	**—**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes (broadcast download & host query)**
Results transmitted to LIS as soon as test time complete	**yes**	**yes**
Interface available (or will be) to auto specimen handling system	**no**	**no**
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	**yes/yes/yes**	**yes/yes/yes**
Can order (via modem) malfunctioning part(s) w/o operator	**no**	**no**
On-site response time of service engineer	**within 24 h**	**within 24 h**
Mean time between failures/to repair failures	**—/<24 h**	**—/<24 h**
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: 6–10 min; weekly: 10 min; monthly: 15 min**
Onboard maintenance records/maintenance training demo module	**yes/no**	**yes/no**
List price/targeted bed size or daily volume	**$64,500/>100 beds**	**$38,000/>100 beds**
Annual service contract cost (24 hours/7 days)	**depends on acquisition option**	**depends on acquisition option**
Training provided w/ purchase/advanced operator training	**3–5 days on site/yes**	**3–5 days on site/yes**
Distinguishing features	**open platform; largest installed base of automated microplate analyzer in its class; proven performance and reliability; accommodates various sample tube sizes including primary tubes within same run**	**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**

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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 4 of 21	**Adaltis U.S. Inc.**	**Adaltis U.S. Inc.**
	Elaine Soltes generalinfo.usa@adaltis.com	**Elaine Soltes** generalinfo.usa@adaltis.com
	754 Roble Rd., Ste. 70	**754 Roble Rd., Ste. 70**
	Allentown, PA 18109	**Allentown, PA 18109**
See accompanying article on page 72	**610-264-0885**	**610-264-0885**
	www.adaltis.com	www.adaltis.com
Name of instrument/first year sold/where designed	**PersonalLab Junior/2002/Italy**	**Nexgen Four/2003/Italy**
Country where manufactured/where reagents manufactured	**Italy/U.S., Italy, Ireland, Germany**	**Italy/U.S., Italy, Ireland, Germany**
No. of units in clinical use in U.S./outside U.S.	**<10/—**	**<10/<10**
Operational type/model type/sample handling system	**—/benchtop/rack**	**batch, random access, continuous random access/benchtop/ring (carousel)**
Dimensions (H x W x D)/instrument footprint	**25 x 26 x 25.6 in/—**	**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 system**	**open system—any microplate assay**
Tests not available on other manufacturers' analyzers	**open system**	**open system—any microplate assay**
Fully automated microplate system	**yes**	**yes**
No. of each analyte performed in separate disposable unit	**—**	**n/a**
No. of wells in microplate	**min. strip: 1; max. full plate: 12**	**min. strip: 1; max. full plate: 96 x 4 plates**
Methods supported/separation methods	**EIA/—**	**EIA/coated microwell**
No. of different measured assays onboard simultaneously	**500**	**500+**
No. of different assays programmed, calibrated at once	**500**	**500+**
No. of user-definable (open) channels	**—**	**500+**
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	**6/manufacturer defined**	**16/manufacturer defined**
Shortest/median onboard reagent stability/refrigerated onboard	**—/—/no**	**—/—/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	**yes/—**	**yes/—**
Same capabilities when 3rd-party reagents used/susceptibility to carryover	**yes/zero carryover—disposable tips**	**yes/zero carryover with plastic tips**
Walkaway capacity in minutes/specimens/tests-assays	**complete**	**varies/varies/varies**
System is open (home-brew methods can be used)/liquid or dry system	**yes/liquid**	**yes/liquid**
Uses disposable cuvettes/max. No. stored	**yes/—**	**yes/—**
Uses washable cuvettes/replacement frequency	**yes (reagents)/—**	**yes/—**
Minimum specimen vol. required	**200 µL plus amount req**	**200 µL deal 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 (optional)/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/11–12.5 mm/no**	**yes/—/no**
Sample bar-code reading capability/autodiscrimination	**yes (2 of 5 interl., codabar, codes 39 & 128)/yes**	**yes (2 or 5 interl., codabar, codes 39 & 128)/—**
Bar-code placement per NCCLS standard Auto2A	**yes**	**yes**
Onboard test auto inventory (determines vol. in container)	**no**	**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	**yes/yes (not automatic)**	**yes/yes**
Hemolysis/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	**manufacturer dependent/manufacturer dependent**	**no/no**
Time between initial result & reaspiration of sample for rerun	**—**	**—**
Autocalibration or autocalibration alert	**—**	**n/a**
No. of calibrators required for each analyte	**manufacturer dependent**	**manufacturer dependent**
Calibrants can be stored onboard/avg. calibration frequency	**yes/manufacturer dependent**	**manufacturer dependent/manufacturer dependent**
Multipoint calib. supported/multiple calibs. stored for same assay	**yes/yes**	**yes/manufacturer dependent**
How often QC required	**manufacturer dependent**	**manufacturer dependent**
Onboard real-time QC/support multiple QC lot Nos. per analyte	**no/yes**	**—/—**
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)	**manufacturer dependent**	**—/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	**no/yes (optional)**	**onboard/yes**
Interfaces up and running in active user sites with	**—**	**—**
LIS interface operates simultaneously w/ running assays	**no**	**—**
Uses LOINC to transmit orders and results	**—**	**—**
How labs get LOINC codes for reagent kits	**—**	**—**
Bidirectional interface capability	**yes (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/no/yes**	**yes/yes/yes**
Can order (via modem) malfunctioning part(s) w/o operator	**no**	**no**
On-site response time of service engineer	**12–24 h**	**by 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: 5 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	**—/—**	**$86,950/>100**
Annual service contract cost (24 hours/7 days)	**—**	**varies**
Training provided w/ purchase/advanced operator training	**3 days on site/yes (with additional fee)**	**3–4 days on site/no**
Distinguishing features	**—**	**dual arm pipetting with independent wash capabilities; specimen delivery with metal needle or plastic tip within same run; continuous loading; remote desktop operation via Internet/modem; touchscreen**

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

Automated immunoassay analyzers

Part 5 of 21

See accompanying article on page 72

	Awareness Technology Inc. **Mary Freeman** info@awaretech.com 1935 SW Martin Hwy. Palm City, FL 34990 772-283-6540 www.awaretech.com	Bayer Health Care Diagnostics Division **Jay Snyder** jay.snyder.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6134 www.bayerdiag.com
Name of instrument/first year sold/where designed	ChemWell/1998/U.S.	ACS: 180 SE/1997/U.S.
Country where manufactured/where reagents manufactured	U.S./open system	U.S./U.S.
No. of units in clinical use in U.S./outside U.S.	4/250	>800/>2,000
Operational type/model type/sample handling system	batch, random access/benchtop/rack	cont. random access/benchtop/ring
Dimensions (H x W x D)/instrument footprint	16 x 34 x 20 in/4 sq ft	24 x 59 x 23 in/9.5 sq ft
Tests available on instrument in U.S.	unlimited—open system	T_3, T_4, FT_4, FT_3, T-uptake, TSH, 3rd-gen. TSH, B_{12}, fol., RBC fol., ferr., IgE, urine & serum cortisol, deoxypyrid., hCG, FSH, LH, prolac., progest., estradiol, testost., equimolar PSA, cPSA, anti-TPO, anti-TG, CEA, AFP, BR 27.29, CK-MB, trop. I, myogl., digitoxin, digoxin, theoph., phenobarb., phenytoin, vancomycin, gentamicin, carbamazep., tobramycin, valporic acid, C-peptide, insulin, homocyst., iPTH
Tests cleared but not clinically released	—	none
Tests not available in U.S. but submitted for clearance	—	none
Tests not available in U.S. but available in other countries	unlimited—open system	none
Research-use-only assays	unlimited—open system	CA 19-9 (RUO), OV (RUO)
Tests in development	—	BNP
User-defined methods implemented for what analytes	general biochemistries	none
Tests not available on other manufacturers' analyzers	n/a	none
Fully automated microplate system	yes	no
No. of each analyte performed in separate disposable unit	up to 12	n/a
No. of wells in microplate	min. strip, 8; max. full plate, 96	n/a
Methods supported/separation methods	EIA/coated microwell	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	up to 12	13
No. of different assays programmed, calibrated at once	unlimited	13
No. of user-definable (open) channels	unlimited	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	27/assay dependent	13/50
Shortest/median onboard reagent stability/refrigerated onboard	assay dependent/assay dependent/yes (10°C below ambient)	40 h/1.7 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	no	yes/assay name, lot No., expir., pack ID
Same capabilities when 3rd-party reagents used/susceptibility to carryover	no/none	n/a/—
Walkaway capacity in minutes/specimens/tests-assays	assay dependent/96/12	150/60/450
System is open (home-brew methods can be used)/liquid or dry system	yes/liquid	no/liquid
Uses disposable cuvettes/max. No. stored	yes/96	yes/450
Uses washable cuvettes/replacement frequency	yes/assay dependent	no
Minimum specimen vol. required	2 µL	60 µL, assay dependent
Minimum sample vol. aspirated precisely at once/min. dead vol.	2µL/—	10 µL/50 µL
Supplied with UPS (backup power)/requires floor drain	no/no	no/no
Requires dedicated water system/water consumption	no	no/~1.8 L per h
Noise generated	—	—
Has dedicated pediatric sample cup/dead vol.	no	no
Primary tube sampling/tube sizes/pierces caps on primary tubes	yes/12 x 75 mm/no	yes/multiple/no
Sample bar-code reading capability/autodiscrimination	no/—	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	—	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/short sample detection	no/no	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/reflex testing capability	no/yes	yes/no
Hemolysis/turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/automatic rerun capability	yes/no	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/increased to rerun out-of-linear range low results	yes/yes	no/no
Time between initial result & reaspiration of sample for rerun	assay dependent	20 sec
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	assay dependent	2
Calibrants can be stored onboard/avg. calibration frequency	yes/assay dependent	no/varies by assay, generally 28 days
Multipoint calib. supported/multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	shortest interval: each run; longest: daily	24 h
Onboard real-time QC/support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/startup is programmable/startup time	yes/yes/2 min	no/no/<5 min, generally remains on
Stat time to completion of ß-hCG test	assay dependent	15 min
Time delay from ordering stat test to aspir. of sample	30 sec	<60 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	assay dependent	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/yes (included)	onboard/no
Interfaces up and running in active user sites with	—	Cerner, Soft, Meditech, Antrim, Misys, McKesson, Citation, Triple G, Dynamic Healthcare (all major vendors)
LIS interface operates simultaneously w/ running assays	no	yes
Uses LOINC to transmit orders and results	yes	yes
How labs get LOINC codes for reagent kits	n/a	customer definable via LIS
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no	yes
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	within 48 h	4 h
Mean time between failures/to repair failures	—/—	4 mos/3 h
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: <10 min; weekly: <10 min; monthly: <10 min	daily: 15 min; weekly: 15 min; monthly: 15 min
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	$25,000/up to 500 tests per day	$130,000/≥50 immunoassays per day
Annual service contract cost (24 hours/7 days)	$4,000	$13,000
Training provided w/ purchase/advanced operator training	3 days on site/no	varies on site, 4 days at vendor offices/yes
Distinguishing features	ability to perform general biochemistries	automatic dilutions, repeats performed onboard; clot detection and management; CD-ROM offers online operators manual and help

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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 6 of 21 *See accompanying article on page 72*	Bayer Health Care Diagnostics Division **Jay Snyder** jay.snyder.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6134 www.bayerdiag.com	Bayer Health Care Diagnostics Division **Nancy McLean** nancy.mclean.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6037 www.bayerdiag.com
Name of instrument/first year sold/where designed	Bayer Immuno I Immunoassay System/1993/U.S.	Advia Centaur/1998/U.S.
Country where manufactured/where reagents manufactured	Ireland/U.S., U.K.	Ireland/U.S.
No. of units in clinical use in U.S./outside U.S.	400/~400	>700/>2,000
Operational type/model type/sample handling system	cont. random access/floor-standing/rack	cont. random access/floor-standing/rack or direct track sampling
Dimensions (H x W x D)/instrument footprint	54 x 65 x 29 in/13.1 sq ft	51.5 x 72.5 x 41.5 in/21 sq ft
Tests available on instrument in U.S.	T_3, T_4, T-uptake, FT_4, FT_3, TSH, 3rd-gen. TSH, digoxin, theoph., gentamicin, tobramycin, phenytoin, phenobarb., valp. acid, vancomycin, carbamazep., quinidine, NAPA, procain., ferr., B_{12}, fol., RBC fol., CK-MB, myogl., trop. I, rubella IgG, toxo IgG & IgM, cortisol, β2-microgl., deoxypyrid., AFP, CA 15-3, CA 125 II, CEA, complexed PSA, PSA, hCG, hCG/extended range-100,000 mIU/mL, LH, FSH, prolac., progest., estradiol, testost., unconj. estriol, HER-2/*neu*	TSH, 3rd-gen. TSH, T_4, FT_4, T-uptake, T_3, FT_3, B_{12}, 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
Tests cleared but not clinically released	none	HER2/*neu*
Tests not available in U.S. but submitted for clearance	none	anti-HBC total, anti-HBs, HBsAg, HBsAg conf., anti-HBC IgM, BNP
Tests not available in U.S. but available in other countries	CA 19-9, CA 72-4, rubella IgM	specific allergens, anti-HBs, HBsAg, HBsAg conf., anti-HBC IgM, anti-HBc total, BNP
Research-use-only assays	CA 19-9 (RUO)	CA 19-9
Tests in development	—	HBsAg, HBsAb, HBcAb IgM, HBcAb, HBeAb, HBeAg, HAV, HAV-IgM, CMV IgG, CMV IgM, HIV 1/2 & "O," HCV
User-defined methods implemented for what analytes	none	none
Tests not available on other manufacturers' analyzers	cPSA, HER-2/*neu*	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	EIA, rate turbidimetry (homogeneous latex agglut.)/magnetic particle	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	22	30
No. of different assays programmed, calibrated at once	22	30
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	22/50–200, assay dependent	30/50–100
Shortest/median onboard reagent stability/refrigerated onboard	21 h/30 days/yes (4°–11°C)	96 h/28 days/yes (4°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes (T_3 & cortisol require oper. prehandling, preparation)	yes
Reagents bar coded/information in bar code	yes/test name, expir., No. of tests, lot No., pack ID	yes/assay name, lot No., expir., pack ID
Same capabilities when 3rd-party reagents used/susceptibility to carryover	n/a/≤5 ppm	n/a/zero carryover
Walkaway capacity in minutes/specimens/tests-assays	437/78/875	230/180/840
System is open (home-brew methods can be used)/liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/max. No. stored	no	yes/1,000
Uses washable cuvettes/replacement frequency	yes/24 h	no
Minimum specimen vol. required	75 µL, assay dependent	60 µL, assay dependent
Minimum sample vol. aspirated precisely at once/min. dead vol.	2 µL/75 µL w/ 1 mL sample cup	10 µL/50 µL
Supplied with UPS (backup power)/requires floor drain	yes/no	yes/no
Requires dedicated water system/water consumption	no/n/a	no/~2.5 L per h
Noise generated	—	<64 decibels w/in 1 meter
Has dedicated pediatric sample cup/dead vol.	yes/30 µL	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., 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 (auto countdown)/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/reflex testing capability	yes/no	yes/yes
Hemolysis/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	30 sec	15 sec minimum
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	6	2
Calibrants can be stored onboard/avg. calibration frequency	no/varies by assay, generally 60 days	no/varies, avg. 21 days
Multipoint calib. supported/multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	shortest interval: each shift, longest: 24 h	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/3 min, generally remains on	no/no/none
Stat time to completion of ß-hCG test	38 min	18 min
Time delay from ordering stat test to aspir. of sample	30 sec	15 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	40/120 (30 sec)	80/240 (15 sec)
Can auto transfer QC results to LIS/onboard capability to review QC	yes/yes	yes/yes
Data management capability/instrument vendor supplies LIS interface	onboard/no	onboard/—
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, McKesson, Citation, Soft, Dawning, Antrim, Dynamic Healthcare, Data Innovations (all major vendors)	Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLFC, DI, Triple G, and most other major vendors
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	yes	—
How labs get LOINC codes for reagent kits	customer definable via LIS	custom definable via LIS
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	yes (Advia LabCell, Lab Interlink)	yes (IDS, Lab InterLink, Labotix, CLIDS, PSS, Hitachi CLAS, A&T)
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	no/—/—	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	—	no
On-site response time of service engineer	4 h	4 h, 24 h max.
Mean time between failures/to repair failures	4 mos/2 h	n/a/n/a
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	no daily maintenance	daily: 3 min; weekly: 20 min; monthly: 30 min
Onboard maintenance records/maintenance training demo module	no/no	yes/yes
List price/targeted bed size or daily volume	$139,000/≥50 tests per day	$225,000/300+ beds or ≥400 tests per day
Annual service contract cost (24 hours/7 days)	—	$21,500
Training provided w/ purchase/advanced operator training	varies on site, 5 days at vendor offices/yes	varies on site, 4 days at vendor offices/yes
Distinguishing features	broad menu includes unique oncology testing; unparalleled accuracy, precision; universal solid phase for all assays; clot detection and management; true onboard reagent refrigeration extends calibration and reagent stability	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

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

Automated immunoassay analyzers

Part 7 of 21

See accompanying article on page 72

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	250/125
Operational type/model type/sample handling system	Cont. random access/benchtop/rack	cont. random access/benchtop/rack
Dimensions (H x W x D)/instrument footprint	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, T_3, T_4, T-uptake, 3rd-gen. TSH, FT_4, FT_3, βhCG, prolac, FSH, LH, progest., estrad., unconj. estriol, B_{12}, fol., RBC fol., ferr., CK-MB, myogl., cortisol, urine cortisol, insulin, AFP-open neural tube defect, total IgE, digox., theoph., chlam. Ag, urine chlam. Ag, chlam. Ag confirm., toxo IgG, rubella IgG, hybritech PSA & fPSA, testosterone, ostase, toxo IgM, antithyroglob., hypersensitive human growth hormone, thyroglobulin, AccuTnI	same as Access
Tests cleared but not clinically released	OV monitor (CA 125 antigen)	same as Access
Tests not available in U.S. but submitted for clearance	—	same as Access
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	same as Access
Research-use-only assays	none	none
Tests in development	CMV IgG & IgM, rubella IgM, PTH, DHEAS, BNP, GI monitor (CA 19.9 antigen), BR monitor (CA 15.3 antigen), free T_3, anti-TPO, anti-intrinsic factor, D-dimer	same as Access
User-defined methods implemented for what analytes	none	none
Tests not available on other manufacturers' analyzers	chlam. Ag & confirm., AFP-ONTD, hybritech PSA & fPSA	same as Access
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 h/28 days/yes (4°C)	336 h/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 within 1 meter	<70 decibels within 1 meter
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/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 h	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	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 h max., usually w/in 6 h	24 h max., usually within 6 h
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	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

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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 8 of 21

See accompanying article on page 72

	Beckman Coulter Inc. **Kathleen O'Kane** kaokane@beckman.com **200 S. Kraemer Blvd.** **Brea, CA 92822** **714-993-8329** www.beckmancoulter.com	**Beckman Coulter Inc.** **Bernhard Spiess** bspiess@beckman.com **1000 Lake Hazeltine Dr.** **Chaska, MN 55318** **952-368-1259** www.beckmancoulter.com
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.	**—/—**	**commercially available 2003**
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 (H x W x D)/instrument footprint	**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, T_3, T_4, TU, 3rd gen TSH, FT_4, FT_3, βhCG, prolac, FSH, LH, progest, estrad., unconj. estriol, B_{12}, fol., ferr., 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, plus >100 Synchron chem tests, including critical care, general, esoteric, urine & CSF chemistries, all current Synchron DATs, TDMs, proteins, serologies**	**same as Access/Access 2 (excluding chlamydia Ag)**
Tests cleared but not clinically released	**OV monitor**	**—**
Tests not available in U.S. but submitted for clearance	**—**	**—**
Tests not available in U.S. but available in other countries	**—**	**same as Access/Access 2**
Research-use-only assays	**—**	**—**
Tests in development	**same as Access/same as Synchron**	**same as Access/Access 2**
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**	**none**
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 h/28 days/yes (4°C)**	**336 h/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 dba**
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/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 h**	**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 h max., usually within 6 h**	**per negotiated contract**
Mean time between failures/to repair failures	**—/—**	**—/TBD**
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	**TBD/—**	**TBD/300+ beds or >400 tests per day**
Annual service contract cost (24 hours/7 days)	**—**	**TBD**
Training provided w/ purchase/advanced operator training	**yes/—**	**TBD/yes**
Distinguishing features	**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**

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

Automated immunoassay analyzers

Part 9 of 21

See accompanying article on page 72

The Binding Site Inc.
Anne Grainger
5889 Oberlin Dr., #101
San Diego, CA 92121
800-633-4484
www.bindingsite.co.uk

bioMérieux Inc.
Vincent Tumminello vincent.tumminello@na.biomerieux.com
100 Rodolphe St.
Durham, NC 27712
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.	U.S., Italy/U.S., France
No. of units in clinical use in U.S./outside U.S.	>40/>100 (total)	1,500/>15,000
Operational type/model type/sample handling system	batch/benchtop/rack	batch, random access/benchtop/n/a
Dimensions (H x W x D)/instrument footprint	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 screen, SS-A, SS-B, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, GBM, M2, MPO, PR3, Tg, TPO, cardiolipin IgG, IgA, IgM and screen, B2GP1 IgG, IgA, IgM and screen, gliadin IgG, IgA and screen, tissue transglutaminase IgA—all preprogrammed, plus system is totally open for any assay	same for both instruments: *C. diff.* toxin A, chlam. Ag, chlam. blocking, RSV, rotavirus, rubella IgG, toxo competition (IgG/IgM), measles IgG, mumps IgG, varicella IgG, Lyme (IgG/IgM), TSH, FT_4, T_4, T_3, hCG, estradiol, FSH, LH, prolac., progest., ferr., cortisol (serum & urine), total IgE, digoxin, theoph., *H. pylori* IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM., quant. D-dimer, tPSA
Tests cleared but not clinically released	none	testosterone
Tests not available in U.S. but submitted for clearance	t. tox, phosphatidyl serine, IgG, IgA, IgM, C1q CIC, ANCA screen	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, FT_3, fPSA, CEA, AFP, CA 15.3, CA 19.9, CA 125, vWT, prot. C, B_2, microglobulin, stallergy
Research-use-only assays	open system	none
Tests in development	SMA, LKM	amplified *C. trach.*, amplified *N. gonorr.*, amplified *M. tuberc.*, quant. HIV-1 RNA, TPHA, EBV, HbA1c
User-defined methods implemented for what analytes	open system	none
Tests not available on other manufacturers' analyzers	open system	quant. D-dimer, *C. difficile* toxin A, Lyme IgG/IgM, VZG, mumps IgG, measles IgG, RSV
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 h/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/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 h, longest: 24 h
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	in development	Misys, Meditech, McKesson, Advanced Lab Systems (Path Lab), Cerner, Citation, SCC, Siemens, SAIC/CHCS, CompuLab, Antrim, Dawning, Genesys (Dynamedix), Data-Innovations, call technical support for 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 24–72 h, dependent on service contract	w/in 24 h
Mean time between failures/to repair failures	n/a/<24 h	Vidas: 350 d, MiniVidas: 1,000 days/<2 h
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)	varies	$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	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); ability to perform immunoassay & amplified probe assay (in development) on same platform; 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

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

Automated immunoassay analyzers

Part 10 of 21

See accompanying article on page 72

Bio-Rad Laboratories Clinical Diagnostics Group
David Hagebush david_hagebush@bio-rad.com
4000 Alfred Nobel Dr.
Hercules, CA 94547
510-724-7000
www.bio-rad.com

Bio-Rad Laboratories Clinical Diagnostics Group
Tom Williamson tom_williamson@bio-rad.com
4000 Alfred Nobel Dr.
Hercules, CA 94547
510-741-4611
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.	—/—	80/10
Operational type/model type/sample handling system	batch/benchtop/rack	batch/benchtop/rack
Dimensions (H x W x D)/instrument footprint	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.	newborn screening—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)
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	contact Bio-Rad representative	—
Research-use-only assays	n/a	—
Tests in development	—	anti-thyroglobulin, anti-TPO, anti-MPO, anti-PR3, anti-GBM, anti-Gliadin IgG, anti-gliadin IgA, ASCA IgG, ASCA IgA, aCL IgG/IgM, aCL IgA, aPS IgG/IgM, anti-β2GPI IgG, anti-β2GPI IgM, anti-β2GPI IgA, aPT IgG, aPT IgM
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 h/—/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/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 h w/ all results in approx. 3 h (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 under 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; david_hadgebush@bio-rad.com	www.bio-rad.com; tom_williamson@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 h	<24 h
Mean time between failures/to repair failures	—/4 h	6 mo/4 h
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	$35,000/>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	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

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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 11 of 21 *See accompanying article on page 72*	Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Dr. Hercules, CA 94547 800-224-6723 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.	5/175	600/600
Operational type/model type/sample handling system	batch/benchtop/rack	random access/benchtop/whole blood collection tube
Dimensions (H x W x D)/instrument footprint	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
Tests cleared but not clinically released	HIV Ab, HIV Ab/Ag, HIV Ag, HBsAg, HBc Ab, HCV Ab, HTLV-1, anti-HBs, toxo IgG, toxo IgM	none
Tests not available in U.S. but submitted for clearance	—	none
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	none
Research-use-only assays	—	none
Tests in development	infectious disease & autoimmune panels	none
User-defined methods implemented for what analytes	none	none
Tests not available on other manufacturers' analyzers	none	none
Fully automated microplate system	yes	no
No. of each analyte performed in separate disposable unit	—	n/a
No. of wells in microplate	min. strip, 1; max. full plate, 96	n/a
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/n/a/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	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	no	no
Uses washable cuvettes/replacement frequency	no	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	no/no	no/no
Requires dedicated water system/water consumption	no	no/n/a
Noise generated	60 dBA	<65
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)	no	n/a
Measures No. of tests remaining/short sample detection	no/no	no/yes
Auto detection of adequate reagent or specimen	no	yes
Clot detection/reflex testing capability	yes/no	yes/yes
Hemolysis/turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	n/a	n/a
Autocalibration or autocalibration alert	no	yes
No. of calibrators required for each analyte	assay dependent	1 cal pack in triplicate
Calibrants can be stored onboard/avg. calibration frequency	no/with each run	60–90 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 system check, longest: every 60 d for liquid controls
Onboard real-time QC/support multiple QC lot Nos. per analyte	yes/yes (through Unity QC program)	yes/no
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	instantly
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	no/yes (incl. in price)
Interfaces up and running in active user sites with	in development	Cerner, Sunquest
LIS interface operates simultaneously w/ running assays	no	yes
Uses LOINC to transmit orders and results	no	no
How labs get LOINC codes for reagent kits	n/a	n/a
Bidirectional interface capability	yes (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	—	—
Mean time between failures/to repair failures	—/—	6 mos or 180 d/2.99 h; 12 mos or 163 d/2.94 h
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: 5 min; weekly: none; monthly: 10 min
Onboard maintenance records/maintenance training demo module	no/no	no/—
List price/targeted bed size or daily volume	$65,000/50–400 tests per day	$35,000/stat locations
Annual service contract cost (24 hours/7 days)	inquire	$5,900
Training provided w/ purchase/advanced operator training	3 days in Redmond, Wash./no	3 days on site/no
Distinguishing features	Evolis is a 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 testpaks; color-coded calibrators packaged on Calpaks; diluent paks for dilutions; self-contained system (no waste lines, etc.); closed container sampling; electronic QC

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

CMYK Page 83

Automated immunoassay analyzers

Part 12 of 21

See accompanying article on page 72

	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 Integrated Chemistry System/2001/U.S.	Dimension RxL Max 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.	431/—	RxL Max: 150/—; RxL: 1,955/—
Operational type/model type/sample handling system	random access, cont. random access/floor-standing/segmented sample wheel	batch, random access, cont. random access/floor-standing/segmented sample wheel
Dimensions (H x W x D)/instrument footprint	45 x 51 x 31 in (without monitor)/—	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, 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. (see Dimension RxL Max at right for full general chemistry menu)	See Dimension Xpand test menu at left for endocrinology, enzymes, heterogeneous immunoassays, specialty, immunology, TDM & toxicology. General chemistry test menu: album., calcium, cholest., creatinine, dir. & total bili., enzymatic CO_2, 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	fPSA	fPSA
Research-use-only assays	—	—
Tests in development	procainamide, quinidine, lidocaine, triiodothyronine, n-acetylprocainamide, tacrolimus, microalbumin	see Dimension Xpand system
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/magnetic particle	EIA, latex particle turbidimetric, direct turbidimetric/heterogeneous, magnetic particles
No. of different measured assays onboard simultaneously	47	48 (92 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/avg. 80–120	44–88/max. 240
Shortest/median onboard reagent stability/refrigerated onboard	72 h/30 days/yes (2–8°C)	72 h/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	yes/lot No., unique flex ID, stability
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
System is open (home-brew methods can be used)/liquid or dry system	yes/reconstitutes onboard	yes/reconstitutes onboard
Uses disposable cuvettes/max. No. stored	yes/12,000	yes/12,000
Uses washable cuvettes/replacement frequency	no/—	no/—
Minimum specimen vol. required	32 µL	52 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 h	yes/3.2 L per h
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/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	yes/yes	yes/yes
Time between initial result & reaspiration of sample for rerun	<20 sec	<20 sec
Autocalibration or autocalibration alert	no	no
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	no/30–90 days	yes/30–90 days
Multipoint calib. supported/multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	24 h	24 h
Onboard real-time QC/support multiple QC lot Nos. per analyte	no/yes	no/yes
Automatic shutdown/startup is programmable/startup time	no/no/5 min	no/no/2 min tech time, 5 min instrument time
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 add-on/no (additional)	optional add-on (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 h	2–8 h
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: 10 min; monthly: 20–30 min	daily: 5 min, weekly: 10 min, monthly: 15 min
Onboard maintenance records/maintenance training demo module	yes/no	yes/no
List price/targeted bed size or daily volume	$173,500/50,000–200,000 tests per year	$300,000/—
Annual service contract cost (24 hours/7 days)	$21,000	$23,000
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	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 13 of 21

See accompanying article on page 72

	Diagnostic Products Corp. **Joe Kelly** jkelly@dpconline.com **5700 W. 96th St., Los Angeles, CA 90045-5597** **310-642-5180** www.dpcweb.com	**Diagnostic Products Corp.** **Joe Kelly** jkelly@dpconline.com **5700 W. 96th St., Los Angeles, CA 90045-5597** **310-642-5180** www.dpcweb.com
Name of instrument/first year sold/where designed	**Immulite/1993; Immulite Turbo/1999/U.S.**	**Immulite 2000/1998/U.S.**
Country where manufactured/where reagents manufactured	**U.S./U.S., U.K.**	**U.S./U.S.**
No. of units in clinical use in U.S./outside U.S.	**5,000 worldwide**	**2,000 worldwide**
Operational type/model type/sample handling system	**cont. random access/benchtop/loading platform**	**Cont. random access/floor-standing/rack**
Dimensions (H x W x D)/instrument footprint	**16 x 42 x 24.75 in (w/o computer)/7.2 sq ft**	**79 x 60 x 30/12.5 sq ft**
Tests available on instrument in U.S.	**AlaTOP allergy scr., allergy food panel FP5E, total IgE, EPO, ferr., fol. acid, B_{12}, intact PTH, Pyrilinks-D, carbamazep., phenytoin, valp. acid, phenobarb., CMV IgG, herpes I & II IgG, rubella IgG quant., toxo IgG quant., DHEA-SO_4, estrad., unconj. estriol, FSH, hCG, LH, progest., prolac., testost., digitox., digox., theoph., anti-TG Ab, anti-TPO Ab, FT_3, FT_4, rapid TSH, TBG, 3rd-gen. TSH, T-uptake, TT_3, TT_4, thyrogl., AFP, CEA, OM-MA, PAP, PSA, 3rd-gen. PSA, canine TT_4 & TSH, C-pep., insul., CK-MB, myogl., trop. I, ACTH, ß2-microgl., cortisol, HsCRP, hGH, rubella IgM, toxo IgM, SHBG, urinary albumin, homocysteine, *H. pylori* IgG, AFP-NTD, THCA. Turbo menu: CK-MB, myoglob., intact PTH, trop. I, hCG, HBsAg, a-HBs, aHBc, HBcIgM, HBsAg confirm, BR-MA (CA 15-3)**	**AFP, CEA, OM-MA, PSA, 3rd-gen. PSA, FT_3, TT_3, FT_4, TT_4 TBG, thyrogl., anti-TG Ab, anti-TPO Ab, T-uptake, rapid TSH, 3rd-gen. TSH, DHEA-SO_4, estrad., FSH, hCG, LH, progest., prolac., total testost., β-2-microgl., cortisol, ferr., total IgE, intact PTH, C-pep., folic acid, B_{12}, 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, allergy, tobramycin, theophylline, SHBG, AFT-NTD, HBsAg +confirm, aHBs, aHBc, HBc IgM, BR-MA (CA 19-9)**
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	**—**	**—**
Research-use-only assays	**GI-MA (CA 19-9), free PSA, TPS, Lyme screen, ECP osteocalcin, nicotine metabolite, cytokines, free βHCG**	**fPSA, Lyme screen, nicotine metabolite, CA 19-9 (GIMA)**
Tests in development	**ANA scr., *C. diff.*, calcitonin, chagas, CMV IgM, dsDNA Ab, hep. A, IGF BP3, IGF-1, Lyme IgG & IgG/IgM, Hbe, Hbe IgM, androstenedione, cryptosporidium Ag, D-dimer, EBV, gastrin giardia Ag, *H. pylori* A, HSV IgM, ILIO, NMP 22, NSE, PAPP-A**	**anti-HBe, HBeAg, ANA screen, Chagas, CMV IgG avidity, dsDNA, EBV, HAV total, HAV IgM, *H. pylori* IgA, rubella IgG avidity, toxo IgG avidity, vancomycin, urinary albumin, androstendione, calcitonin, D-dimer, ECP, free βHCG, gastrin, HSV IgM, IGF1, IGF BP3, NMP22, NSE, PAPP-A, CMV IgM**
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 or 500; Turbo: 50 for intact PTH only**	**24/200 or 600**
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/<10 ppm**
Walkaway capacity in minutes/specimens/tests-assays	**100/—/70**	**cycle dependent/90/1,000**
System is open (home-brew methods can be used)/liquid or dry system	**no/liquid**	**no/liquid**
Uses disposable cuvettes/max. No. stored	**yes/n/a**	**yes/1,000**
Uses washable cuvettes/replacement frequency	**no**	**no**
Minimum specimen vol. required	**5 µL**	**5 µL**
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/1.5 L per h**
Noise generated	**55 min., max. 68**	**52**
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/12 x 75 & 100; 13 x 75 & 100; 16 x 75 & 100 mm/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)	**no**	**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/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**	**min. 18 sec**
Autocalibration or autocalibration alert	**no**	**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**	**n/a/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**	**no/no/5 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)	**40/120 (—)**	**67/200 (—)**
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 (addt'l cost)**
Interfaces up and running in active user sites with	**Sunquest, Cerner, Citation, ALG, CHC, DynaMedix, Antrim, Antek, CSS**	**Sunquest, Cerner, HBOC, CCA, ALG**
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	**no/yes/no**	**yes/yes/no**
Can order (via modem) malfunctioning part(s) w/o operator	**no**	**no**
On-site response time of service engineer	**4 h**	**6 h**
Mean time between failures/to repair failures	**8 mos/4 h**	**2 mos/5 h**
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: none; 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 mo.**	**$124,500/>4,000 tests per month**
Annual service contract cost (24 hours/7 days)	**$7,500**	**$12,500**
Training provided w/ purchase/advanced operator training	**3.5 days at vendor offices/no, in development**	**3.5 days at vendor offices/no, in development**
Distinguishing features	**system performance reliability; worldwide user satisfaction; breadth of immunoassay menu**	**high throughput system with Windows-based, fully multitasking software, integrated training via tutorial & interactive training CD series, clot detection, sample/reagent level detection, auto dilutions and auto reflex testing, remote diagnostics, unrivaled service, support and menu**

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

Automated immunoassay analyzers

Part 14 of 21 *See accompanying article on page 72*	**Diagnostic Products Corp.** **Joe Kelly** jkelly@dpconline.com **5700 W. 96th St., Los Angeles, CA 90045-5597** **310-642-5180** 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 1000; Immulite 1000 Turbo/2002/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.	**100/200**	**—/—**
Operational type/model type/sample handling system	**random access, continuous random access/benchtop/loading platform**	**Batch, random access/benchtop/2 racks, 120 samples total**
Dimensions (H x W x D)/instrument footprint	**18.5 x 45 x 25 in/6.8 sq. ft.**	**28 x 48 x 26 in/8.7 sq ft, incl. onboard computer, reagents, spectrophotometer**
Tests available on instrument in U.S.	**AlaTOP allergy scr., allergy food panel FP5E, total IgE, EPO, ferr., fol. acid, B_{12}, intact PTH, Pyrilinks-D, carbamazep., phenytoin, valp. acid, phenobarb., CMV IgG, herpes I & II IgG, rubella IgG quant., toxo IgG quant., DHEA-SO_4, estrad., unconj. estriol, FSH, hCG, LH, progest., prolac., testost., digitox., digox., theoph., anti-TG Ab, anti-TPO Ab, FT_3, FT_4, rapid TSH, TBG, 3rd-gen. TSH, T-uptake, TT_3, TT_4, thyrogl., AFP, CEA, OM-MA, PAP, PSA, 3rd-gen. PSA, canine TT_4 & TSH, C-pep., insul., CK-MB, myogl., trop. I, ACTH, ß2-microgl., cortisol, HsCRP, hGH, rubella IgM, toxo IgM, SHBG, urinary albumin, homocysteine, *H. pylori* IgG, AFP-NTD, THCA. Turbo menu: CK-MB, myoglob., intact PTH, trop. I, hCG, HBsAg, a-HBs, aHBc, HBcIgM, HBsAg confirm, BR-MA (CA 15-3), calcitonin, IGF-BP3, IGF-1**	**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 & IgM, mumps IgG, *H. pylori* IgG, mycoplasma IgG, 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. scr., anti-β-2-glycopr. IgG, IgM, anti-gliadin IgG & IgA, legionella IgG/IgM/IgA, syphillis Trep-Chek, mycoplasma 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	**TPS, ECP, osteocalcin, GI-MA (CA 19-9), NMP22**	**none**
Tests not available in U.S. but available in other countries	**GI-MA (CA 19-9), fPSA, TPS, Lyme screen, ECP, osteocalcin, nicotine metabolite, cytokines, free βHCG, chagas, NMP22**	**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	**GI-MA (CA 19-9), fPSA, TPS, Lyme screen, ECP, osteocalcin, nicotine metabolite, cytokines, free βHCG, chagas, NMP22**	**none**
Tests in development	**ANA screen, C. difficile, crypotosporidium Ag, D-dimer, EBV, gastrin, giardia Ag, *H. pylori* A, HSV IgM, NSE, PAPP-A, CMV IgM, dsDNA AB, hepatitis A**	**anti-β2 glycoprotein IgA**
User-defined methods implemented for what analytes	**none**	**programmed by customer at customer location**
Tests not available on other manufacturers' analyzers	**3rd gen. PSA, 3rd gen. TSH, canine TSH, acatop allergy screen, SHBG, TBG EPO, intact PTH, ACTH, canine T_4**	**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	**n/a**	**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	**12; Turbo: 5**	**9**
No. of different assays programmed, calibrated at once	**unlimited, Turbo: 5**	**40 tests preprogrammed, ready for use**
No. of user-definable (open) channels	**0**	**20**
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	**12/100 or 500**	**9/96**
Shortest/median onboard reagent stability/refrigerated onboard	**n/a/30 days/yes (15°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/lot No., expir. date**	**available/kit lot No., expir. date**
Same capabilities when 3rd-party reagents used/susceptibility to carryover	**n/a/<10 ppm**	**yes/not susceptible to carryover, has continuous internal cleaning**
Walkaway capacity in minutes/specimens/tests-assays	**100/—/70**	**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/n/a**	**yes/120**
Uses washable cuvettes/replacement frequency	**no**	**no/n/a**
Minimum specimen vol. required	**5 µL**	**50 µL in pediatric tube**
Minimum sample vol. aspirated precisely at once/min. dead vol.	**5 µL/100 µL**	**4 µL/100 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/n/a**
Noise generated	**min. 55 decibels, max. 68**	**—**
Has dedicated pediatric sample cup/dead vol.	**no**	**possible–can use 1.5 mL vial/100 µL**
Primary tube sampling/tube sizes/pierces caps on primary tubes	**no/—/—**	**yes/up to 16 x 100/no**
Sample bar-code reading capability/autodiscrimination	**yes (2 or 5 interl., codabar, codes 39 & 128)/no**	**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	**no/no**	**no/no**
Hemolysis/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	**2 adjustors**	**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	**no/yes**	**yes/no**
How often QC required	**customer determined**	**each run**
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/yes/<5 min**
Stat time to completion of ß-hCG test	**42 min; Turbo: 15 min**	**n/a**
Time delay from ordering stat test to aspir. of sample	**2.5 min**	**<15 min set-up time**
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	**40/120**	**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 (addt'l cost)**	**onboard/yes (addt'l cost)**
Interfaces up and running in active user sites with	**Cerner, Citation, ACG, CHC, DynaMedix, Antrim, Antek, CSS, Misys**	**Cerner**
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	**no**	**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 h**	**w/in 24 h**
Mean time between failures/to repair failures	**10 mos/—**	**—/—**
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: 3 min; weekly: 5 min; monthly: none**
Onboard maintenance records/maintenance training demo module	**no/—**	**no/no**
List price/targeted bed size or daily volume	**$75,000/>1,000 tests per month**	**$59,000/all bed sizes, all test volumes**
Annual service contract cost (24 hours/7 days)	**$7,500**	**included in reagent rental**
Training provided w/ purchase/advanced operator training	**3.5 days at vendor offices/in development**	**1–2 days at vendor's facility or on site/as needed**
Distinguishing features	**system performance reliability; compact footprint; breadth of immunoassay menu**	**only system (reagents & instrument) FDA cleared; moderate complexity rating; automation-ready reagents; user friendly SW for rapid training**

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

Automated immunoassay analyzers

Part 15 of 21

See accompanying article on page 72

	DiaSorin Inc. **Mike Brown** mike.brown@diasorin.com 1951 Northwestern Ave. Stillwater, MN 55082 800-328-1482 www.diasorin.com	Grifols-Quest Inc. **John Medders** john.medders@grifols.com 8880 NW 18th Terr. Miami, FL 33172 800-379-0957 www.grifols-quest.com
Name of instrument/first year sold/where designed	ETI-Max/2002/Germany	Triturus/1999/Spain
Country where manufactured/where reagents manufactured	Germany/U.S., Italy	Spain/n/a
No. of units in clinical use in U.S./outside U.S.	50/200	35/280
Operational type/model type/sample handling system	batch, random access/benchtop/rack	batch, random access & cont. random access/benchtop/carousel
Dimensions (H x W x D)/instrument footprint	40 x 45 x 30 in/10 sq ft	28.3 x 41.3 x 34.3 in/10 sq ft
Tests available on instrument in U.S.	HBsAg, anti-HBs, HCV, anti-HBc, IgM anti-HBc, HBeAg, anti-HBe, anti-HAV, IgM anti-HAV, EA-IgG, EBNA-IgG, VCA-IgG, EBV-M, toxo-IgM, toxo-IgG, rub-IgG, CMV-IgG, CMV-IgM, HSV I-IgG, HSV II-IgG, HSV I/II-IgG, rubeola-IgG, mumps-IgG, VZV IgG, MP IgG, *H. pylori* IgG, Lyme IgG & IgM, syphilis IgG, ENA scr., ANA scr., anti-dsDNA, anti-Sm, anti-RNP/Sm, anti-SSB, anti-SSA, anti-Scl-70, anti-Jo-1, anti-histone, anti-cardiolipin IgG & IgM, total anti-cardiolipin, CAE, CCP	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	none	n/a
Tests not available in U.S. but submitted for clearance	none	n/a
Tests not available in U.S. but available in other countries	none	n/a
Research-use-only assays	none	n/a
Tests in development	none	n/a
User-defined methods implemented for what analytes	n/a	n/a
Tests not available on other manufacturers' analyzers	n/a	n/a
Fully automated microplate system	yes	yes
No. of each analyte performed in separate disposable unit	—	8
No. of wells in microplate	min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate up to 7 plates at a time	min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate 4 plates at a time
Methods supported/separation methods	EIA/coated microplate	EIA/coated microwell, onboard shaker, 4 individually temperature-controlled incubators
No. of different measured assays onboard simultaneously	open	1–8 tests on 1–4 plates
No. of different assays programmed, calibrated at once	open	8 assays
No. of user-definable (open) channels	open	unlimited
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	n/a/—	8/96
Shortest/median onboard reagent stability/refrigerated onboard	—/—/no	n/a/n/a/no
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes, placed directly on system	requires operator prehandling/preparation
Reagents bar coded/information in bar code	yes/part Nos.	no
Same capabilities when 3rd-party reagents used/susceptibility to carryover	no/n/a	no/<5 ppm
Walkaway capacity in minutes/specimens/tests-assays	assay dependent/180/open	180/92/8
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	100 µL	300 µL
Minimum sample vol. aspirated precisely at once/min. dead vol.	10 µL/100 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.	no	yes/200 µL
Primary tube sampling/tube sizes/pierces caps on primary tubes	yes/multiple/no	yes/12 x 75 mm, 13 x 85 mm, 16 x 85, 16 x 100 mm/no
Sample bar-code reading capability/autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	yes	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/turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/increased to rerun out-of-linear range low results	—/—/—	no/no
Time between initial result & reaspiration of sample for rerun	n/a	n/a
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	varies per kit	1–14
Calibrants can be stored onboard/avg. calibration frequency	no/each run	no/n/a
Multipoint calib. supported/multiple calibs. stored for same assay	yes/no	yes/yes
How often QC required	per run	each run
Onboard real-time QC/support multiple QC lot Nos. per analyte	yes/yes	no/no
Automatic shutdown/startup is programmable/startup time	yes/yes/5 min	yes/no/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	—	n/a
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	assay dependent	depends on reagent methodology
Can auto transfer QC results to LIS/onboard capability to review QC	yes/no	yes/yes
Data management capability/instrument vendor supplies LIS interface	onboard/yes	onboard/yes (included)
Interfaces up and running in active user sites with	yes	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 (broadcast download)	yes (broadcast download)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	no/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 h	24–48 h
Mean time between failures/to repair failures	n/a/n/a	—/depends 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	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	$75,000/medium-sized hospital	$79,000/300+ or higher
Annual service contract cost (24 hours/7 days)	—	$16,000
Training provided w/ purchase/advanced operator training	3 days on site/no	4 d on-site/yes
Distinguishing features	instrument is easy to set up, continuous loading of patient samples	multibatch or continuous throughput EIA analyzer; user-defined menu, completely open system; easy color-coded worksheet and set up for operator; 2 probes for high-speed processing; unique cross-well washing; able to use fixed probes or disposable tips

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

Automated immunoassay analyzers

Part 16 of 21

See accompanying article on page 72

	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
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.	20/84	8/57
Operational type/model type/sample handling system	random batches/benchtop/rack-robotics	random batches/benchtop/rack-robotics
Dimensions (H x W x D)/instrument footprint	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, RFIgG & 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, *H. pylori;* user-definable software
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	specific IgG, cardiolipin IgA, cardiolipin IgA, ssDNA, total rheumatoid factor, anti-phosphatidyl serine scr., anti-phosphatidyl serine IgG, IgM	IgG, basophil histamine release, cardiolipin IgA, ssDNA, total rheumatoid factor, anti-phosphatidyl serine scr., anti-phosphatidyl serine IgG & IgM
Research-use-only assays	none	none
Tests in development	anti-tissue transglutaminase	anti-tissue transglutaminase
User-defined methods implemented for what analytes	*H. pylori*	*H. pylori*
Tests not available on other manufacturers' analyzers	allergy & autoimmune testing on fully automated system	allergy & autoimmune testing on fully automated system, basophil histamine release
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/cellulose disc & coated well	EIA, tube-based & microplate-based assays/cellulose disc & 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 h/12 h/no	8 h/12 h/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/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 h	48 h
Mean time between failures/to repair failures	6 mos/4 h	6 mos/4 h
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	—
Training provided w/ purchase/advanced operator training	3 days on site/yes	3 days on site, 3 days at vendor offices/yes
Distinguishing features	fully automated allergy and autoimmune testing; >1,000 allergens; user-definable software	fully automated allergy and autoimmune testing; >1,000 allergens; open software

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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 17 of 21

See accompanying article on page 72

	Nichols Institute Diagnostics Bill Wilson wilsonb@nicholsdiag.com 1311 Calle Batido San Clemente, CA 92673 800-286-4643 nicholsdiag.com	Nichols Institute Diagnostics Bill Wilson wilsonb@nicholsdiag.com 1311 Calle Batido San Clemente, CA 92673 800-286-4643 nicholsdiag.com
Name of instrument/first year sold/where designed	CLSystem ID/1993/Sweden	Nichols Advantage Specialty System/1997/Germany
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.	60+/—	>120/>160
Operational type/model type/sample handling system	batch/benchtop/rack	batch, cont. random access/benchtop/rack
Dimensions (H x W x D)/instrument footprint	processor: 17 x 48 x 26 in; washer: 15 x 27 x 20 in; luminometer: 16.5 x 32 x 25 in/15 sq ft	44 x 45 x 26 in/8 sq ft
Tests available on instrument in U.S.	hGH, TSH, intact PTH, anti-TPO, anti-TG, ACTH, calcitonin, thyroglobulin	ACTH, cortisol, urinary cortisol, EPO, ferritin, sTfR, CT, intact PTH, hGH, IGF-1, FT_3, FT_4, 3rd-gen. TSH, TG, anti-TG, anti-TPO, DHEAS, Bio-Intact PTH (I-84), 25 hydroxyvit D, direct renin, IGF BP-3
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for clearance	none	aldosterone
Tests not available in U.S. but available in other countries	none	ITA
Research-use-only assays	none	osteocalcin, *H. pylori* IgG
Tests in development	none	1,25 dihydroxyvit D, *H. pylori,* IgA, total hCG, AFP, UE3, C-peptide, insulin
User-defined methods implemented for what analytes	none	none
Tests not available on other manufacturers' analyzers	—	IGF-I, calcitonin, Bio-Intact PTH (I-84), 25 hydroxyvit D, direct renin
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	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	1	15
No. of different assays programmed, calibrated at once	1	15
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	1/100	15/varies, typically 100
Shortest/median onboard reagent stability/refrigerated onboard	8 h/1 day/no	8 h/—/yes (17°C)
Multiple reagent configurations supported	yes	no
Reagent container placed directly on system for use	no, requires operator prehandling, preparation	no, requires operator prehandling, preparation
Reagents bar coded/information in bar code	no	yes/assay ID, lot No., serial No., expir.
Same capabilities when 3rd-party reagents used/susceptibility to carryover	—/—	no/$\leq 5x10^{-5}$
Walkaway capacity in minutes/specimens/tests-assays	—/256/1	up to 480/120/15 x 100=1,500
System is open (home-brew methods can be used)/liquid or dry system	yes/liquid	no/liquid
Uses disposable cuvettes/max. No. stored	no	yes/120
Uses washable cuvettes/replacement frequency	no	no
Minimum specimen vol. required	assay dependent	assay dependent
Minimum sample vol. aspirated precisely at once/min. dead vol.	25 µL/150 µL	10 µL/200 µL
Supplied with UPS (backup power)/requires floor drain	no/no	yes/no
Requires dedicated water system/water consumption	no/—	no/—
Noise generated	—	67
Has dedicated pediatric sample cup/dead vol.	no	yes/100 µL
Primary tube sampling/tube sizes/pierces caps on primary tubes	yes/10 x 75/no	yes/10 x 75, 16 x 100 mm/no
Sample bar-code reading capability/autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	no	no
Onboard test auto inventory (determines vol. in container)	no	yes
Measures No. of tests remaining/short sample detection	no/no	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/reflex testing capability	yes/no	yes/yes
Hemolysis/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	—	37 min
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	2	2
Calibrants can be stored onboard/avg. calibration frequency	yes/once per run	no/7 days
Multipoint calib. supported/multiple calibs. stored for same assay	yes/no	yes/no
How often QC required	shortest interval: 4 h, longest: 8 h	shortest interval: 4 h, longest: 8 h
Onboard real-time QC/support multiple QC lot Nos. per analyte	no/no	no/no
Automatic shutdown/startup is programmable/startup time	no/no/10 min	no/no/10 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
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	—/—	up to 55/up to 165 (—)
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	onboard/yes (included in price)
Interfaces up and running in active user sites with	—	all commercially available LISs
LIS interface operates simultaneously w/ running assays	—	yes
Uses LOINC to transmit orders and results	no	yes
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	yes (broadcast download)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no	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	24 h	24 h
Mean time between failures/to repair failures	10 mos/48 h	90 days/24 h
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 10 min; weekly: 30 min; monthly: 60 min	daily: 10 min; weekly: 30–45 min; monthly: 5 min
Onboard maintenance records/maintenance training demo module	no/no	no/no
List price/targeted bed size or daily volume	component related/—	$125,000/300+ beds
Annual service contract cost (24 hours/7 days)	—	inquire
Training provided w/ purchase/advanced operator training	—	4 days at vendor offices/yes
Distinguishing features	a chemiluminescence sequence batch analyzer designed to provide results for specialized and routine immunoassays; continuous sample loader, bidirectional communication, pos. sample ID; 1,200 patient samples per eight-hour shift	the fully automated continuous random access chemiluminescence system that will run specialty assays as if they were 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

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

Automated immunoassay analyzers

Part 18 of 21

See accompanying article on page 72

Olympus America Inc.
Susan Watanabe susan.watanabe@olympus.com
Two Corporate Center Dr., Melville, NY 11747
800-223-0125
www.olympus.com

Ortho-Clinical Diagnostics, a Johnson & Johnson Company
David Manning dmannin1@ocdus.jnj.com
1001 U.S. Highway 202, Raritan, NJ 08869
800-828-6316 or 908-218-1300
www.orthoclinical.com

Name of instrument/first year sold/where designed	AU400e/2002; AU400/1999/Japan	Vitros ECi Immunodiagnostic System/1997/U.S.
Country where manufactured/where reagents manufactured	Japan/U.S., Ireland	U.S./U.K.
No. of units in clinical use in U.S./outside U.S.	>300/>1,100	>1,000 worldwide
Operational type/model type/sample handling system	cont. random access/floor-standing/rack & turntable	cont. random access/floor-standing/universal sample racks (circular) accommodate primary & secondary containers without need for adapters
Dimensions (H x W x D)/instrument footprint	47.6 x 57.1 x 29.9 in/70 x 129 in	51 x 44 x 29 in/8.9 sq ft
Tests available on instrument in U.S.	α1-acid glycoprotein, α1-antitrypsin, anti-streptolysin O, apolipo. A1 & B, β-2-microglobulin, CRP, high-sensitivity CRP, CRP for pediatrics, C3 & C4 complement, ferr., haptoglobin, immunogl. A, G, M, microalbumin, myogl., prealb., rheum. factor, transferrin, acetamin., amikacin, caffeine, carbamaz., digoxin, disopyramide, ethosux., gentamicin, lidocaine, methotrexate, N-acetylprocain., phenobarb., phenytoin, primidone, procain., quinidine, salicylate, theoph., tobramycin, valp. acid, vancomycin, amphet., barb., benzodiazep., cannab., cocaine metab., ethanol, LSD, methadone, methaq., opiate, PCP, propoxyphene, tox barb., tox benzo., tox tricyc., T-uptake, T_4 thyrox. Also, general chemistries, enzymes, direct HDL & direct LDL	3rd-gen. TSH, TT_3, TT_4, FT_3, FT_4, T_3-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, equimolar troponin I, aHBs, B_{12}, folate, RBC folate, equimolar PSA, HBsAg, aHCV, HBsAg (conf.)
Tests cleared but not clinically released	ceruloplasmin, HbA1c, lithium, cholinesterase, urinary protein	none
Tests not available in U.S. but submitted for clearance	none	aHBC, aHBc IgM
Tests not available in U.S. but available in other countries	cotinine	CA 19-9, fβ–hCG, a-HBc IgM, a-HBc, a-HAV IgM, a-HBe, HBeAg, a-HIV I&II
Research-use-only assays	none	HCV antigen
Tests in development	none	myoglobin, HAV total, HIV 1/2, BNP, b-GS, HCA, rubella IgG, rubella IgM, toxo. IgG, toxo. IgM, CMV IgG, CMV IgM
User-defined methods implemented for what analytes	HbA1c, fructosamine	none
Tests not available on other manufacturers' analyzers	none	hepatitis, HIV, NTx
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	EIA, photometric, potentiometric, calc. results/none (all homogeneous)	chemiluminescence (enhanced)/individual coated microwell
No. of different measured assays onboard simultaneously	>40	20
No. of different assays programmed, calibrated at once	99	29 programmed & calibrated at once; up to 25 lots calibrated per assay
No. of user-definable (open) channels	95	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	76/100–6,160	20/100
Shortest/median onboard reagent stability/refrigerated onboard	168 h/60 days/yes (4–12°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/reag. ID, lot No., bottle No., expir.	yes/test ID, expir., lot No., pack ID
Same capabilities when 3rd-party reagents used/susceptibility to carryover	yes/n/a	—/zero carryover
Walkaway capacity in minutes/specimens/tests-assays	variable/up to 102/8,058	360/60/400
System is open (home-brew methods can be used)/liquid or dry system	yes/liquid	no/liquid
Uses disposable cuvettes/max. No. stored	no	yes/2,000
Uses washable cuvettes/replacement frequency	yes/permanent	no
Minimum specimen vol. required	2 µL per test	
Minimum sample vol. aspirated precisely at once/min. dead vol.	2 µL/25 µL	10 µL/60 µL
Supplied with UPS (backup power)/requires floor drain	optional/yes	available/—
Requires dedicated water system/water consumption	yes/20 L per h @ peak consump.	no/—
Noise generated	<65	60 decibels
Has dedicated pediatric sample cup/dead vol.	no	no
Primary tube sampling/tube sizes/pierces caps on primary tubes	yes/pediatric, 5 mL, 7 mL, 10 mL/no	yes/mult. ped. tube capabilities, microtainers & cups on same univ. sample tray/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, & 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/turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/increased to rerun out-of-linear range low results	yes/yes	no
Time between initial result & reaspiration of sample for rerun	varies by run size	assay dependent
Autocalibration or autocalibration alert	yes	yes
No. of calibrators required for each analyte	1–6	1–3
Calibrants can be stored onboard/avg. calibration frequency	yes/14 days	no/28 days
Multipoint calib. supported/multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	lab-defined	1 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/24 h availability	yes/yes/5 min from power off
Stat time to completion of ß-hCG test	n/a	24 min
Time delay from ordering stat test to aspir. of sample	<1 min	upon completion of last sample metering
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	133.3/400 (9 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/yes (addt'l cost)	onboard/no
Interfaces up and running in active user sites with	Cerner, Antrim, CCA, Chemware, Dawning, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Orchard, Citation	Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, PHCP, INS, Siemens, Dawning
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	no	yes
How labs get LOINC codes for reagent kits	n/a	
Bidirectional interface capability	yes (broadcast download & host query)	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 (Olympus OLA 1500 Sorter, Labotix, Lab InterLink)	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	<24 h	<4 h (contract dependent)
Mean time between failures/to repair failures	>20 weeks/<24 h	—/dependent on corrective action
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 3 min; weekly: 7 min; monthly: 45 min	daily: <5 min; weekly: <30 min; monthly: <10 min
Onboard maintenance records/maintenance training demo module	yes (incl. audit trail of who replaced parts)/yes	no/yes
List price/targeted bed size or daily volume	$130,000/200–2,000 tests per day (depending on menu)	$140,000/flexible for majority of customer demand
Annual service contract cost (24 hours/7 days)	inquire	varies w/ service level choices
Training provided w/ purchase/advanced operator training	5 days on site, 5 days at vendor offices/yes	3.5 days at vendor offices/yes, as needed on site
Distinguishing features	open reagent system; 122-test menu includes general chemistry and homogeneous immunoassay; onboard automation to repeat, reflex, or predilute samples; true random access and fast throughput; family of standardized analyzers including AU640, AU640e, AU2700, and AU5400	immunoassay anal. provides fast and easy fully automated, random access hepatitis testing along with thyroid, cardiac, anemia, endocrin, bone, and oncology assays; Intellichek technology on the Vitros ECi system performs, monitors, and verifies all sample and assay processing steps to reduce the possibility of an erroneous result being reported out

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

Automated immunoassay analyzers

Part 19 of 21

See accompanying article on page 72

	Roche Diagnostics **Doug Felten** doug.felten@roche.com; **Michael Leuther** michael.leuther@roche.com **9115 Hague Rd.** **Indianapolis, IN 46250** **800-428-5074** www.roche.com/labsystems/us	**Roche Diagnostics** **Doug Felten** doug.felten@roche.com; **Michael Leuther** michael.leuther@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 (H x W x D)/instrument footprint	**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, FT_4, T_4, T_3, FT_3, T-uptake, LH, FSH, progest., estradiol, prolac., testost., CK-MB, trop. T, myglobin, digoxin, PSA (screen), CEA, CA 125, AFP, ferr., B_{12}, fol., RBC folate, IgE, intact PTH, hCG, cortisol, insulin, fPSA, DHEAS, β–hCG, CA 15-3, anti-TPO, serum β crosslaps, free PSA, HBsAg, HBsAg (conf), pro BNP, cortisol urine**	**TSH, T_3, T_4, T-uptake, FT_3, FT_4, FSH, LH, prolac., progest., estradiol, testost., CK-MB, trop. T, 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**
Tests cleared but not clinically released	**none**	**—**
Tests not available in U.S. but submitted for clearance	**anti-HBs (available April)**	**—**
Tests not available in U.S. but available in other countries	**osteocalcin, CA 19-9, anti-HBc, cyfra 21-1, anti-HBs, anti HBc IgM, anti-HBe, HBeAg, CA 72-4, NSE, anti-TG, SHBG, infec. diseases, TG, CA 19-9**	**osteocalcin, CA 19-9, cyfra 21-1, CA 72.4, NSE, anti-TG, SHBG, TG**
Research-use-only assays	**—**	**—**
Tests in development	**osteocalcin, CA 19-9, anti-HBc, anti-HBc IgM, anti HBe, HBcAg, SHBG, TG, anti-TG, NSE, cyfra 21-1**	**CA 72-4, NSE, anti-TG, TG, UCHBG, osteocalcin, CA 19-9, cyfra 21-1**
User-defined methods implemented for what analytes	**none**	**none**
Tests not available on other manufacturers' analyzers	**trop. T**	**trop. T**
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/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 h**	**once per 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/4 min**	**no/no/5 min**
Stat time to completion of ß-hCG test	**9 min**	**9 min**
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 h**	**<24 h**
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	**disk: $120,000, rack: $135,000/various**	**$59,000/various**
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 Indianapolis based/yes**	**3 days Indianapolis based/yes**
Distinguishing features	**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**

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

Automated immunoassay analyzers

Part 20 of 21

See accompanying article on page 72

Roche Diagnostics
Doug Felten doug.felten@roche.com; **Michael Leuther** michael.leuther@roche.com
9115 Hague Rd.
Indianapolis, IN 46250
800-428-5074
www.roche.com/labsystems/us

Tosoh Bioscience Inc.
Susan Kolarik skolarik@tosohm.com
347 Oyster Point Blvd., #201
South San Francisco, CA 94080
650-615-4970
www.tosohbioscience.com

Name of instrument/first year sold/where designed	Modular Analytics E170/2001/Japan	AIA Nex•IA/1997/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)	40/300
Operational type/model type/sample handling system	continuous random access/floor-standing/rack	cont. random access/floor-standing/rack, carousel, TLA
Dimensions (H x W x D)/instrument footprint	96.25 (W) x 43.25 (D) in (Modular E configuration)/approx. 60 sq ft (one module system)	47 x 35 x 26 in/6.3 sq ft
Tests available on instrument in U.S.	TNT, CK-MB, digoxin, myoglobin, T_4, T-uptake, TSH 3rd gen, FT_4, T_3, FT_3, ATPO, β–hCG, FSH, LH, progesterone, prolactin, estradiol, DHEA-S, testosterone, CEA, AFP, PSA (screen), fPSA, CA 125, CA 15-3, ferritin, B_{12}, folate, RBC folate, intact PTH, β crosslaps, cortisol, insulin, IGE, pro BNP, cortisol urine	TSH, 3rd-gen. TSH, FT_4, T_3, T_4, T-uptake, FT_3, TPO Ab, Tg Ab, βhCG, estradiol, FSH, hCG (intact), LH II, progesterone, prolactin, βHCG, estradiol, FSH, HCG (intact), LHII, 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, B_{12}, ST-testosterone, CA 19-9
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for clearance	anti-HBs	—
Tests not available in U.S. but available in other countries	osteocalcin, HBsAg, HBsAg (conf.), CA 19-9, CA 72-4, cyfra 21-1, NSE, anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, TG, anti-TG, digitoxin	HBsAg, HBsAb, HBeAg, HbeAb, HbcAb, toxo IgG & IgM, rubella IgG, CMV IgG
Research-use-only assays	none	—
Tests in development	osteocalcin, CA 19-9, anti-HBc, anti-HBc IgM, anti-HBe, HBeAg, SHBG, NSE, cyfra 21-1, TG, anti-TG	RBC folate
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	>42
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	52/75–200/400 for the standard model
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/50 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/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 h	24 h
Onboard real-time QC/support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/startup is programmable/startup time	yes/yes/11 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	—	90 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	56/176 (21 sec)	40/120 (30 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)	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)	yes (Hitachi, Lab Interlink, A&T)
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 h	24 h
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: 5–8 min; weekly: none; monthly: none
Onboard maintenance records/maintenance training demo module	yes/yes	yes (includes audit trail of who replaced parts)/no
List price/targeted bed size or daily volume	$295,000 Modular E; $470,000 Modular EE; $645,000 Modular EEE/various	$135,000/65+ beds, 1,500–2,000+ tests
Annual service contract cost (24 hours/7 days)	incl. w/ reagent rental	$10,800
Training provided w/ purchase/advanced operator training	5 d at vendor offices/yes	4 days at vendor offices/no
Distinguishing features	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	three sample loading options on single system: 200 sample rack loader, TLA adaptable, standard carousel model; unitized test cups; primary tube sampling; no reagent prep.; dual clot detection; room temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use

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

SURVEY OF INSTRUMENTS

Automated immunoassay analyzers

Part 21 of 21

See accompanying article on page 72

Tosoh Bioscience Inc.
Jane Merschen jane@tosohm.com
347 Oyster Point Blvd., #201
South San Francisco, CA 94080
650-615-4970
www.tosohbioscience.com

Name of instrument/first year sold/where designed	AIA-600 II/2000/Japan
Country where manufactured/where reagents manufactured	Japan/Japan
No. of units in clinical use in U.S./outside U.S.	300/400
Operational type/model type/sample handling system	cont. random access/benchtop/chain
Dimensions (H x W x D)/instrument footprint	19.8 x 31.6 x 29.1 in/2.5 sq ft
Tests available on instrument in U.S.	same menu as for AIA Nex•IA
Tests cleared but not clinically released	—
Tests not available in U.S. but submitted for clearance	—
Tests not available in U.S. but available in other countries	HBsAg, HBsAb, HBeAg, HbcAb, HbeAb, toxo IgG & IgM, rubella IgG, CMV IgG
Research-use-only assays	—
Tests in development	RBC folate
User-defined methods implemented for what analytes	none
Tests not available on other manufacturers' analyzers	none
Fully automated microplate system	no
No. of each analyte performed in separate disposable unit	n/a
No. of wells in microplate	n/a
Methods supported/separation methods	fluorescence, EIA/bead
No. of different measured assays onboard simultaneously	26
No. of different assays programmed, calibrated at once	entire menu
No. of user-definable (open) channels	0
No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set	n/a/unitized test cup
Shortest/median onboard reagent stability/refrigerated onboard	72 h/72 h/n/a
Multiple reagent configurations supported	yes
Reagent container placed directly on system for use	yes
Reagents bar coded/information in bar code	yes/lot No., test code
Same capabilities when 3rd-party reagents used/susceptibility to carryover	no/zero carryover
Walkaway capacity in minutes/specimens/tests-assays	52/26/26
System is open (home-brew methods can be used)/liquid or dry system	no/dry
Uses disposable cuvettes/max. No. stored	n/a/unitized test cup
Uses washable cuvettes/replacement frequency	n/a
Minimum specimen vol. required	500 µL tube, 100 µL cup
Minimum sample vol. aspirated precisely at once/min. dead vol.	10 µL/100 µL
Supplied with UPS (backup power)/requires floor drain	yes/no
Requires dedicated water system/water consumption	no/n/a
Noise generated	—
Has dedicated pediatric sample cup/dead vol.	no
Primary tube sampling/tube sizes/pierces caps on primary tubes	yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100, 13 x 75 & 100/no
Sample bar-code reading capability/autodiscrimination	yes/yes
Bar-code placement per NCCLS standard Auto2A	yes
Onboard test auto inventory (determines vol. in container)	yes
Measures No. of tests remaining/short sample detection	yes/yes
Auto detection of adequate reagent or specimen	yes
Clot detection/reflex testing capability	yes/no
Hemolysis/turbidity detection-quantitation	no/no
Dilution of patient samples onboard/automatic rerun capability	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/yes
Time between initial result & reaspiration of sample for rerun	n/a
Autocalibration or autocalibration alert	no
No. of calibrators required for each analyte	2 or 6—analyte dependent
Calibrants can be stored onboard/avg. calibration frequency	no/60–90 days
Multipoint calib. supported/multiple calibs. stored for same assay	yes/yes
How often QC required	24 h
Onboard real-time QC/support multiple QC lot Nos. per analyte	no/no
Automatic shutdown/startup is programmable/startup time	no/no/5 min
Stat time to completion of ß-hCG test	~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)	20/60 (1 min)
Can auto transfer QC results to LIS/onboard capability to review QC	yes/no
Data management capability/instrument vendor supplies LIS interface	optional add-on (all major LIS vendors—Schuyler House, Misys, LabForce, McKesson, Antrim, Data Innovations)/yes (addt'l cost)
Interfaces up and running in active user sites with	Schuyler House, Fletcher Flora
LIS interface operates simultaneously w/ running assays	yes
Uses LOINC to transmit orders and results	yes
How labs get LOINC codes for reagent kits	package insert
Bidirectional interface capability	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes
Interface available (or will be) to auto specimen handling system	no
Modem servicing/can diagnose own malfunctions/determine malfunctioning component	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no
On-site response time of service engineer	24 h
Mean time between failures/to repair failures	98% uptime/—
Onboard error codes to facilitate troubleshooting	yes
Avg. time to complete maintenance by lab personnel	daily: 5 min; weekly: 5 min; monthly: none
Onboard maintenance records/maintenance training demo module	no/no
List price/targeted bed size or daily volume	$70,000/500–2,500 tests per month
Annual service contract cost (24 hours/7 days)	$5,600
Training provided w/ purchase/advanced operator training	3 days at vendor offices/no
Distinguishing features	unitized test cups; primary tube sampling; no reagent prep.; dual clot detection; room temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use

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

ARCHIVES
of
Pathology & Laboratory Medicine
Reach for Worldwide Impact

The *Archives of Pathology & Laboratory Medicine*, the leading medical journal for pathologists worldwide, is seeking manuscripts for publication, especially in the established fields of anatomic and clinical pathology, as well as new technologies and laboratory management. Color figures are published free of charge. (Published articles also appear full-text and images on the World Wide Web.)

Visit www.cap.org and click on the *Archives* link for submission instructions, or request information on the reader service card. Mail completed manuscripts to:

Editorial Office
Archives of Pathology & Laboratory Medicine
Loyola University Medical Center
2160 S. First Ave., Building 102, Office 2649
Maywood, IL 60153

Questions?
Call Kenneth D. McClatchey, DDS, MD
Archives editor
at (708) 216-0885, or fax to (708) 216-3331