

## Automated immunoassay analyzers

### Automated immunoassay analyzers: the latest lineup

Anne Ford

**I**n the quest to minimize the effect of laboratory labor shortages, automation seems like the Holy Grail. After all, it addresses so many aspects of the worker famine, from walkaway time to training. Plus, Bayer senior marketing manager Gary Allen says, it helps even understaffed laboratories accept new business: "Automation allows them to say, 'Bring it on!'"

The automated immunoassay analyzers in this month's survey provide a bouquet of ways for laboratories to increase their capabilities and efficiency. Chief among them, says Dade Behring chemistry marketing manager Joseph Meola, is consolidation. His company's Dimension family of analyzers combines chemistry and immunoassay testing. "For phlebotomy, it's fewer tubes to be drawn. For processing, it's less samples to be handled," he says.

Bayer's Advia CentraLink network solution system offers laboratories a chance at consolidation by connecting multiple instruments through a single server to the LIS. With CentraLink, says Allen, "you save money because you buy one interface instead of three or four."

Olympus' forthcoming AU connector will hop on the consolidation train by allowing laboratories to connect multiple Olympus AU instruments and use a single point for sample entry. "You put the samples in, and the connector then sorts the samples to the appropriate analyzer," says Bruce Gernaey, director of marketing for the diagnostic systems group.

Abbott is expanding on the benefits of consolidation with the Architect

ci8200, a combined chemistry and immunoassay analyzer. "We don't move samples in a linear fashion between the chemistry and immunoassay systems," says Chip Clark, director of U.S. marketing for immunochemistry. "We do it in bays, and that allows access to samples at any time." This feature is especially helpful for stat testing. "Let's say that you were in a car accident and you needed to be taken to the hospital," he says. "In the old days the ambulance would have to fight along the same routes as everyone else. The Architect acts more like a helicopter. We're able to pick up the sample and move it in front of everything else that's being done."

Other technological offerings in the market include a feature from DPC called RealTime Solutions, which is available on the company's Immulite 2000 instrument and will be available on the forthcoming Immulite 2500 SMS as well. "It harnesses the power of the Internet, allowing DPC to monitor the system's performance in real time," says senior marketing manager Mark Smith. "We can see when issues are happening and step in to take corrective action to prevent systems from going down. We can also use this to monitor QC." He stresses that this function is not the same thing as remote diagnostics—"because it uses the Internet to see a constant stream of information."

BioMérieux has made its own technological advancements with the Vitus DataStation, a PC-based data center introduced two months ago that provides improved reports and easier user interaction. Hycor, too, has made a technological improvement to

its Hy•Tec 288 instrument, which now features an external computer rather than an onboard computer for greater flexibility and ease of use. And Grifols-Quest is introducing an automatic self-test feature on its Triturus ELISA analyzer. "During start-up, the instrument will test all of the individual modules of the instrument—reader, washer, incubators, and dilutors—and generate a status report to give the operator complete assurance that everything is functioning optimally before they perform the first test," says John Medders, president. He says it should be available before the AACC meeting next month.

Meanwhile, Ortho-Clinical Diagnostics recently introduced the Vitros ECiQ system. The new system features enhancements to the company's proprietary Intellicheck technology, which "provides verification of sample and assay processing steps when you're running an assay," says Russ Potter, worldwide immunodiagnosics product manager. "There's now a facility onboard that allows you to review a report on those key verifications to ensure that each result reported is of appropriate quality." The Vitros ECiQ was launched in the United States at the end of April.

But the host of new offerings doesn't include just technological advancements. A slew of new assays was launched recently, and others are on the horizon. Nichols Institute Diagnostics' aldosterone assay, which has been available for a couple of months, "is the only automated chemiluminescent assay for aldosterone," says international marketing manager Bill Wilson. DiaSorin, meanwhile, is offering two initial assays on its recently introduced Liaison system, antibody-based vitamin D and PTH. The Binding Site just launched a full range of infectious disease ELISA kits for use on the DSX

system. And Roche's research and development team is working on many new assays, among them ischemia modified albumin, osteocalcin, and C-peptide. Just to round off the list, Beckman Coulter global marketing manager Jim Rigo says his company plans to launch dozens of new immunoassay tests within the next few years as well as update and improve many of its current immunoassay kits for use on its Uni-Cel DxI 800 and Access analyzers.

Laboratories can anticipate several new instruments as well, such as Diamedix's Parsec system, which will be launched at AACC. "It's a whole new concept in what we know today as microtiter automation," says senior product manager Pat Ahmad. "The Parsec is a modular system providing flexibility to handle your laboratory workflow. It can be customized to specific laboratory needs, and it offers multiplatform technology—EIA, chemiluminescence, histopathology—for workstation consolidation, all within one system." Other new instruments are Bayer's Advia Centaur CP, scheduled for release in 2005; the Olympus AU3000i, which will be available for preview at AACC; Pharmacia's random-access ImmunoCAP 1000 and 250 systems for labs seeking business development solutions and full automation for allergy testing, also to be displayed at AACC; and Roche's second generation of integrated systems, to be unveiled at AACC as well.

CAP TODAY's lineup of automated immunoassay analyzers includes products from the companies listed above and from Awareness Technology, Bio-Rad, Tosoh Bioscience, and Trinity Biotech. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities. □

Anne Ford is CAP TODAY senior editor.

# Automated immunoassay analyzers

Part 1 of 23

Abbott Diagnostics  
Peggy Reuck peggy.reuck@abbott.com  
100 Abbott Park Rd., Dept. Z22, AP6C-5  
Abbott Park, IL 60064-3500  
847-937-1718  
www.abbott.com

See accompanying article on page 18

Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet	AxSym Plus/1993 worldwide, 1994 U.S./U.S. U.S./U.S. 3,200/14,000 cont. random access/floor-standing/segment 59 x 63 x 33.5 in/22 sq ft
Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	hTSH II, TT <sub>3</sub> , TT <sub>4</sub> , FT <sub>3</sub> , FT <sub>4</sub> , T-uptake, total 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 met., methadone, opiates, PCP, acetamin., ethanol, salicylates, tricyc., anti-TPO, TG, cortisol, BNP  total PSA, free PSA, anti-HCV, anti-HAV, anti-HAV IgM, cyclosporine HBsAg/conf. ferr., fol., anti-HBs, HBsAg, anti-HBc, anti-HBc IgM, anti-HBe, HBe, HIV 1/2g0, HIV combo, HCV, anti-HAV, anti-HAV IgM none hepatitis, retrovirus, trop. I, B <sub>12</sub> , ferr., fol. none none
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no n/a n/a
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	FPIA, MEIA, ion capture, REA/heterogeneous, bead (microparticle), fiber matrix filter 20 20 0 20/100  onboard reagent stability: 48, 112, 224, 336/no no yes yes/assay name, reag. lot No., expir., pack No. ID no/<1 ppm 60/90/90 no/liquid yes/90 reaction vessels no — 10 μL/73 μL for sample cup, 450 μL for aliquot, 4.5 mL for primary yes (soft close of files only)/optional no/— 52-68 decibels no yes/100 & 75 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes/yes yes yes w/ AxSym Plus yes/no yes/yes no/no  seconds no 6 pt. or 2 pt. w/ master calib., index calib. no/4 weeks yes/yes (up to 4 curves/analyte) shortest interval: 8 hr, longest: 24 hr yes/yes no/no/1 min
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	13 min 30 sec from standby 68-120 tests/flexible platform—load list dependent (assay dependent)  yes/yes onboard/no all major LIS vendors yes yes — yes (broadcast download & host query) yes yes no/yes/yes  yes, AbbottLink 12 hr 5 months/within 12 hr per customer request yes daily: 5 min; weekly: 30 min; monthly: 30 min no/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/ purchase/Advanced operator training	\$124,000/0-200 patient tests per day \$16,800 extended hours coverage 5 days on site, 5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	menu, reliability, online exception help, pressure monitoring, clot detection, ratio calculation, stat TAT

# Automated immunoassay analyzers

<b>Part 2 of 23</b>	Abbott Diagnostics Suzanne Macaitis <a href="mailto:suzanne.macaitis@abbott.com">suzanne.macaitis@abbott.com</a> 100 Abbott Park Rd., Dept. OZZ2, AP6C-5 Abbott Park, IL 60064-3500 847-936-3323 <a href="http://www.abbott.com">www.abbott.com</a>	Abbott Diagnostics Suzanne Macaitis <a href="mailto:suzanne.macaitis@abbott.com">suzanne.macaitis@abbott.com</a> 100 Abbott Park Rd., Dept. OZZ2, AP6C-5 Abbott Park, IL 60064-3500 847-936-3323 <a href="http://www.abbott.com">www.abbott.com</a>
<i>See accompanying article on page 18</i>		
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet	Architect i2000; i4000/1999/U.S. U.S./U.S. 100+/1,200+ batch, random access, cont. random access/floor-standing/rack 48 x 44 x 68 in/23 sq ft per module	Architect i2000SR/2003/U.S. U.S./U.S.-worldwide 5/372 batch, random access, cont. random access/floor-standing/rack 48 x 61 x 49 in/23 sq ft per module
Tests available on instrument in U.S.	βhCG, FSH, LH, prolac., CEA, TSH, TT <sub>4</sub> , FT <sub>4</sub> , FT <sub>3</sub> , TT <sub>3</sub> , estradiol	stat βhCG, FSH, LH, prolac., progest., CEA, TSH, TT <sub>4</sub> , FT <sub>4</sub> , FT <sub>3</sub> , TT <sub>3</sub> , estradiol, βhCG
Tests cleared but not clinically released	total PSA, free PSA, AFP	AFP, total PSA, free PSA
Tests not available in U.S. but submitted for clearance	—	troponin
Tests not available in U.S. but available in other countries	AFP, fPSA, tPSA, CA 19-9, B2 micro, B <sub>12</sub> , folate, ferritin, testosterone, HCV, HBsAg, HBsAg confirm, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-HBe, HBe, HIV 1/2g0, anti-HBg	troponin, AFP, fPSA, tPSA, CA 19-9, B2 micro, B <sub>12</sub> , folate, ferritin, testosterone, HCV, HBsAg, HBsAg confirm, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-HBe, HBe, HIV 1/2g0
Research-use-only assays Tests in development	— T-uptake, CA 125, CA 15-3, CA 19-9, progesterone, anti-TPO, anti-Tg	none T-uptake, CA 125, CA 15-3, progesterone, CK-MB, CA 19-9, myoglobin, anti-TPO, anti-Tg
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none none	none none
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no n/a n/a	no n/a n/a
Methods supported/Separation methods No. of different measured assays onboard simultaneously	chemiluminescence w/ flexible protocols/magnetic microparticle 25 per module*, max. 4 modules=100 assays max.	chemiluminescence w/ flexible protocols/magnetic microparticle 25
No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	100+ n/a 25 per module*/100-test & 500-test kits 30 days/30 days/yes (2-12°C) yes yes yes/2D bar code, lot. No., No. tests, calib. data no/n/a 300/250/12,500 tests per module no/liquid yes/1,200 no — 150 μL/50 μL yes/no no/— 60-65 decibels yes/50 μL yes/10-16 mm, up to 75-100 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/no no/no yes/no — — yes 2-6 pt. curve no/30 days yes/yes 3 levels every 24 h yes/yes n/a/no/10 min	100+ n/a 25/100-test & 500-test kits 30 days/30 days/yes (2-12°C) yes yes yes/2D bar code, lot. No., No. tests, calib. data no/n/a 300/135/12,500 tests no/liquid yes/1,200 no — 150 μL/50 μL yes/no no/— 60-65 decibels yes/50 μL yes/10-16 mm, up to 75-100 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes — seconds yes 2-6 pt. curve no/30 days yes/yes 3 levels every 24 h yes/yes n/a/no/10 min
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	28 min seconds 67/200 per module yes/yes onboard/no all major LIS vendors yes — — yes (broadcast download & host query) yes yes yes/yes/yes no 12 h — yes daily: <15 min; weekly: <10 min; monthly: none yes (includes audit trail of who replaced parts)/yes	18 min seconds 67/200 per module yes/yes onboard/no Sunquest, Cerner, Skyclab, Per Se yes — — yes (broadcast download & host query) yes no yes/yes/yes no 12 h — yes daily: <15 min; weekly: <10 min; monthly: none yes (includes audit trail of who replaced parts)/yes
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/ purchase/Advanced operator training	\$169,500/500 immunoassays per day \$27,450 (list price) 5 days at vendor offices/yes (5 days on-site integration)	\$150,000/200-500 immunoassay tests per day — 5 days at vendor offices/yes (5 days on-site integration)
Distinguishing features (supplied by vendor)	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  * for kits with ≤3 reagent bottles	integration capability with c8000 chemistry analyzer; immediate stat processing through multi-dimensional sample handling, auto rerun, repeat and reflex testing; Chemiflex: advanced, patented chemiluminescence detection technology with flexible protocols delivers superior assay performance; high throughput up to 200 tests per hour, five-hour walkaway, superior capacity and ease of use

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

# Automated immunoassay analyzers

<p><b>Part 3 of 23</b></p> <p><i>See accompanying article on page 18</i></p>	<p>Abbott Diagnostics Suzanne Macaitis <a href="mailto:suzanne.macaitis@abbott.com">suzanne.macaitis@abbott.com</a> 100 Abbott Park Rd., Dept. OZZ2, AP6C-5 Abbott Park, IL 60064-3500 847-936-3323 <a href="http://www.abbott.com">www.abbott.com</a></p>	<p>Awareness Technology Inc. Mary Freeman <a href="mailto:info@awaretech.com">info@awaretech.com</a> 1935 SW Martin Hwy. Palm City, FL 34990 772-283-6540 <a href="http://www.awaretech.com">www.awaretech.com</a></p>
<p>Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>Architect ci8200/2003/U.S. U.S., Japan/U.S. 2/134 batch, random access, cont. random access/floor-standing/features a patented Retest Sample Handler that uses multi-dimensional sample handling 48 x 127 x 49 in/42 sq ft</p>	<p>ChemWell/1998/U.S. U.S./open system 6/350 batch, random access/benchttop/rack 16 x 34 x 20 in/4 sq ft</p>
<p>Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development User-defined methods implemented for what analytes  Tests not available on other manufacturers' analyzers</p>	<p>acid phosph., album., BCG &amp; BCP, alkaline phosphatase, ALT, ALT-Act, amylase, AST, AST-Act, bilirubin direct &amp; total, calcium, cholest., CK, CO<sub>2</sub>, creatin., GGT, gluc., iron, lactic acid, LDH, lipase, magnesium, neo. bilirubin, phosph., TIBC, total protein, triglyc., urea nitrogen, uric acid, amylase, chloride, potassium, sodium, urea acid, urine protein, protein, stat βhCG, estradiol, FSH, LH, prolac., free T3 &amp; T4, total T3 &amp; T4, TSH, CEA, digox., valp. acid, carb, phenytoin, theophylline, CRP, HbA1c, microalbum., RF, amphet/meth, barb., benzodiaz., cannab., cocaine, ethanol, meth., opiates, PCP, propoxyphene AFP, free PSA, total PSA troponin troponin, total &amp; free PSA, testost., B<sub>12</sub>, fol., ferr., AFP, CA 19-9, B2 micro, HCV, HBsAg, HBsAg confirm, anti-HAV IgM, anti-HBc, anti-HBc IgM, anti-HBe, HBe, alpha-1-glyco., ASLO, hsCRP, pancreatic amylase, digitox., IgE, HBDH, cholinest., HIV 1/2g0 n/a CK-MB, myoglob., CA 125, CA 15-3, CA 19-9, T-uptake, dir. LDL, DHEAS, testost. ammonia, C3, C4, cholinesterase, u-CRP, haptoglobin, ferritin, IgA/G/M, lithium, microalbumin, prealbumin, transferrin, progesterone, anti-TPO, anti-Tg —</p>	<p>unlimited—open system  — unlimited—open system  unlimited—open system — general biochemistries n/a</p>
<p>Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate</p>	<p>no — —</p>	<p>yes up to 12 min. strip, 8; max. full plate, 96</p>
<p>Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result &amp; reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time</p>	<p>chemiluminescence/magnetic particle 93 320 220 90/100–500 720 immunoassay; 720 clinical chemistry/yes (2–8°C) yes yes yes/2D bar code, lot No., No. of tests, calib. data if bar coded/&lt;0.1 ppm avg. 300/367/varies, &gt;81,000 yes, chemistry side no yes/1-yr guarantee 2 μL (clinical chemistry), 150 μL (immunoassay) 2 μL/50 μL yes/yes yes/25 L per hr 60–65 decibels yes/50 μL yes/10–16 mm, up to 75–100 mm/no yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes yes yes yes/yes yes yes/yes yes/yes yes/yes 20 seconds yes varies yes/immunoassay 30 days; clinical chemistry 28 days yes/yes 24 hr/every 24 hr no/yes yes/yes/10 min</p>	<p>EIA/coated microwell up to 12 unlimited unlimited 27/assay dependent assay dependent/assay dependent/yes (10°C below ambient) yes yes no no/none assay dependent/96/12 yes/liquid yes/96 yes/assay dependent 2 μL 2μL/— no/no no — no yes/12 x 75 mm/no no/— — yes no/no yes no/yes no/no yes/no yes/yes assay dependent no assay dependent yes/assay dependent yes/yes shortest interval: each run; longest: daily yes/yes yes/yes/2 min</p>
<p>Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module</p>	<p>18 min 20 sec immunoassay 67, clinical chemistry 400/1,400 (IA 18 sec; CC 4.5 sec) yes/yes n/a Sunquest, Cerner, Millenium, Per Se yes — — yes (broadcast download &amp; host query) yes no yes/yes/yes no 12 hr n/a/n/a yes daily: &lt;5 min; weekly: 32 min; monthly: 15 min yes/yes</p>	<p>assay dependent 30 sec assay dependent yes/yes onboard/yes (included) — no yes n/a yes (broadcast download &amp; host query) yes no yes/yes/yes no within 48 hr —/— yes daily: &lt;10 min; weekly: &lt;10 min; monthly: &lt;10 min no/no</p>
<p>List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/ purchase/Advanced operator training</p>	<p>\$375,000/200–500 immunoassay tests per day n/a as needed on site; 8 days at vendor offices/no</p>	<p>\$25,000/up to 500 tests per day \$4,000 3 days on site/no</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>integration of chemistry and immunoassay without compromise to stat TAT and throughput through exceptional sample management (multi-dimensional retest sample handler) and &lt;0.1 ppm carryover, large reagent and sample capacity, patentent ICT Chip, extended linearities and lower sensitivities (Chemiflex)</p>	<p>ability to perform general biochemistries</p>

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

## Automated immunoassay analyzers

<p><b>Part 4 of 23</b></p> <p><i>See accompanying article on page 18</i></p>	<p>Bayer Health Care Diagnostics Division  <b>Jay Snyder</b> jay.snyder.b@bayer.com                      511 Benedict Ave.                      Tarrytown, NY 10591                      914-333-6134                      www.bayerdiag.com</p>	<p>Bayer Health Care Diagnostics Division  <b>Jay Snyder</b> jay.snyder.b@bayer.com                      511 Benedict Ave.                      Tarrytown, NY 10591                      914-333-6134                      www.bayerdiag.com</p>
<p>Name of instrument/First year sold/Where designed                      Country where manufactured/Where reagents manufactured                      No. of units in clinical use in U.S./Outside U.S.                      Operational type/Model type/Sample handling system                      Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>ACS: 180 SE/1997/U.S.                      U.S./U.S.                      &gt;800/&gt;2,000                      cont. random access/benchttop/ring                      24 x 59 x 23 in/9.5 sq ft</p>	<p>Bayer Immuno I Immunoassay System/1993/U.S.                      Ireland/U.S., U.K.                      400/~400                      cont. random access/floor standing/rack                      54 x 65 x 29 in/13.1 sq ft</p>
<p>Tests available on instrument in U.S.</p> <p>Tests cleared but not clinically released</p> <p>Tests not available in U.S. but submitted for clearance</p> <p>Tests not available in U.S. but available in other countries</p> <p>Research-use-only assays</p> <p>Tests in development</p>	<p>T<sub>3</sub>, T<sub>4</sub>, FT<sub>4</sub>, FT<sub>3</sub>, T-uptake, TSH, 3rd-gen. TSH, B<sub>12</sub>, fol., RBC fol., ferr., IgE, urine &amp; serum cortisol, deoxytyrid., 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, BNP</p> <p>none                      none                      none</p> <p>CA 19-9 (RUO), OV (RUO)</p> <p>—</p> <p>none                      none</p>	<p>T<sub>3</sub>, T<sub>4</sub>, T-uptake, FT<sub>4</sub>, FT<sub>3</sub>, TSH, 3rd-gen. TSH, digoxin, theoph., gentamicin, tobramycin, phenytoin, phenobarb., valp. acid, vancomycin, carbamazep., quini-dine, NAPA, procain., ferr., B<sub>12</sub>, fol., RBC fol., CK-MB, myogl., trop. I, rubella IgG, toxo IgG &amp; IgM, cortisol, β<sub>2</sub>-microgl., deoxytyrid., AFP, CA 15-3, CA 125 II, CEA, complexed PSA, PSA, hCG/extended range-100,000 mIU/mL, LH, FSH, prolac., progest., estradiol, testost., unconj. estriol, HER-2/<i>neu</i></p> <p>none                      none                      CA 19-9, CA 72-4, rubella IgM</p> <p>CA 19-9 (RUO)</p> <p>—</p> <p>none                      cPSA, HER-2/<i>neu</i></p>
<p>Fully automated microplate system</p> <p>No. of each analyte performed in separate disposable unit</p> <p>No. of wells in microplate</p>	<p>no                      n/a                      n/a</p>	<p>no                      n/a                      n/a</p>
<p>Methods supported/Separation methods</p> <p>No. of different measured assays onboard simultaneously</p> <p>No. of different assays programmed, calibrated at once</p> <p>No. of user-definable (open) channels</p> <p>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</p> <p>Shortest/Median onboard reagent stability/Refrigerated onboard</p> <p>Multiple reagent configurations supported</p> <p>Reagent container placed directly on system for use</p> <p>Reagents bar coded/Information in bar code</p> <p>Same capabilities when 3rd-party reagents used/Susceptibility to carryover</p> <p>Walkaway capacity in minutes/Specimens/Tests-assays</p> <p>System is open (home-brew methods can be used)/Liquid or dry system</p> <p>Uses disposable cuvettes/Max. No. stored</p> <p>Uses washable cuvettes/Replacement frequency</p> <p>Minimum specimen vol. required</p> <p>Minimum sample vol. aspirated precisely at once/Min. dead vol.</p> <p>Supplied with UPS (backup power)/Requires floor drain</p> <p>Requires dedicated water system/Water consumption</p> <p>Noise generated</p> <p>Has dedicated pediatric sample cup/Dead vol.</p> <p>Primary tube sampling/Tube sizes/Pierces caps on primary tubes</p> <p>Sample bar-code reading capability/Autodiscrimination</p> <p>Bar-code placement per NCCLS standard Auto2A</p> <p>Onboard test auto inventory (determines vol. in container)</p> <p>Measures No. of tests remaining/Short sample detection</p> <p>Auto detection of adequate reagent or specimen</p> <p>Clot detection/Reflex testing capability</p> <p>Hemolysis detection-quantitation/Turbidity detection-quantitation</p> <p>Dilution of patient samples onboard/Automatic rerun capability</p> <p>Sample vol. can be increased to rerun out-of-linear range high results/                      Increased to rerun out-of-linear range low results</p> <p>Time between initial result &amp; reaspiration of sample for rerun</p> <p>Autocalibration or autocalibration alert</p> <p>No. of calibrators required for each analyte</p> <p>Calibrants can be stored onboard/Avg. calibration frequency</p> <p>Multipoint calib. supported/Multiple calibs. stored for same assay</p> <p>How often QC required</p> <p>Onboard real-time QC/Support multiple QC lot Nos. per analyte</p> <p>Automatic shutdown/Startup is programmable/Startup time</p>	<p>chemiluminescence/magnetic particle</p> <p>13                      13                      0                      13/50</p> <p>40 hr/1.7 days/no</p> <p>yes                      yes                      yes/assay name, lot No., expir., pack ID                      n/a/—                      150/60/450                      no/liquid                      yes/450                      no                      60 µL, assay dependent                      10 µL/50 µL                      no/no                      no/~1.8 L per hr                      —                      no                      yes/multiple/no                      yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes                      yes                      yes                      yes/yes                      yes                      yes/no                      no/no                      yes/yes                      no/no</p> <p>20 sec                      no                      2                      no/varies by assay, generally 28 days                      yes/yes                      24 hr                      yes/yes                      no/no/&lt;5 min, generally remains on</p>	<p>EIA, rate turbidimetry (homogeneous latex agglut.)/magnetic particle</p> <p>22                      22                      0                      22/50-200, assay dependent</p> <p>21 hr/30 days/yes (4°-11°C)</p> <p>yes                      yes (T<sub>3</sub> &amp; cortisol require oper. prehandling, preparation)                      yes/test name, expir., No. of tests, lot No., pack ID                      n/a/&lt;5 ppm                      437/78/875                      no/liquid                      no                      yes/24 hr                      75 µL, assay dependent                      2 µL/75 µL w/ 1 mL sample cup                      yes/no                      no/n/a                      —                      yes/30 µL                      yes/multiple/no                      yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes                      yes                      yes                      yes (auto countdown)/yes                      yes                      yes/no                      no/no                      no/no                      no/no</p> <p>30 sec                      no                      6                      no/varies by assay, generally 60 days                      yes/yes                      shortest interval: each shift, longest: 24 hr                      yes/yes                      no/no/3 min, generally remains on</p>
<p>Stat time to completion of β-hCG test</p> <p>Time delay from ordering stat test to aspir. of sample</p> <p>Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)</p> <p>Can auto transfer QC results to LIS/Onboard capability to review QC</p> <p>Data management capability/Instrument vendor supplies LIS interface</p> <p>Interfaces up and running in active user sites with</p> <p>LIS interface operates simultaneously w/ running assays</p> <p>Uses LOINC to transmit orders and results</p> <p>How labs get LOINC codes for reagent kits</p> <p>Bidirectional interface capability</p> <p>Results transmitted to LIS as soon as test time complete</p> <p>Interface available (or will be) to auto specimen handling system</p> <p>Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component</p> <p>Can order (via modem) malfunctioning part(s) w/o operator</p> <p>On-site response time of service engineer</p> <p>Mean time between failures/To repair failures</p> <p>Onboard error codes to facilitate troubleshooting</p> <p>Avg. time to complete maintenance by lab personnel</p> <p>Onboard maintenance records/Maintenance training demo module</p>	<p>15 min                      &lt;60 sec                      60/180 (20 sec)</p> <p>yes/yes                      onboard/no                      Cerner, Soft, Meditech, Antrim, Misys, McKesson, Citation, Triple G, Dynamic Healthcare (all major vendors)</p> <p>yes                      yes                      customer definable via LIS                      yes (broadcast download &amp; host query)                      yes                      yes                      no/no/no</p> <p>no                      4 hr                      4 months/3 hr                      yes                      daily: 15 min; weekly: 15 min; monthly: 15 min                      yes (includes audit trail of who replaced parts)/yes</p>	<p>38 min                      30 sec                      40/120 (30 sec)</p> <p>yes/yes                      onboard/no                      Cerner, Misys, Meditech, McKesson, Citation, Soft, Dawning, Antrim, Dynamic Healthcare, Data Innovations (all major vendors)</p> <p>yes                      yes                      customer definable via LIS                      yes (broadcast download &amp; host query)                      yes                      yes (Advia LabCell, Lab Interlink)                      no/—/—</p> <p>—                      4 hr                      4 months/2 hr                      yes                      no daily maintenance                      no/no</p>
<p>List price/Targeted bed size or daily volume</p> <p>Annual service contract cost (24 hours/7 days)</p> <p>Training provided w/ purchase/Advanced operator training</p>	<p>\$130,000/≥50 immunoassays per day                      \$13,000                      varies on site, 4 days at vendor offices/yes</p>	<p>\$139,000/≥50 tests per day                      —                      varies on site, 5 days at vendor offices/yes</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>automatic dilutions, repeats performed onboard; clot detection and management; CD-ROM offers online operators manual and help</p>	<p>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</p>

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

# Automated immunoassay analyzers

<p><b>Part 5 of 23</b></p> <p><i>See accompanying article on page 18</i></p>	<p>Bayer Health Care Diagnostics Division Nancy McLean nancy.mclean.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6037 www.bayerdiag.com</p>	<p>Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822 714-993-8329 www.beckmancoulter.com</p>
<p>Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>Advia Centaur/1998/U.S. Ireland/U.S. &gt;700/&gt;2,000 cont. random access/floor standing/rack or direct track sampling 51.5 x 72.5 x 41.5 in/21 sq ft</p>	<p>Access Immunoassay System/1993/U.S., France U.S./U.S., France 1,200/2,200 Cont. random access/benchtop/rack 18.5 x 39 x 24 in/6.5 sq ft</p>
<p>Tests available on instrument in U.S.</p> <p>Tests cleared but not clinically released</p> <p>Tests not available in U.S. but submitted for clearance</p> <p>Tests not available in U.S. but available in other countries</p> <p>Research-use-only assays</p> <p>Tests in development</p> <p>User-defined methods implemented for what analytes</p> <p>Tests not available on other manufacturers' analyzers</p>	<p>TSH, 3rd-gen. TSH, T<sub>4</sub>, FT<sub>4</sub>, T-uptake, T<sub>3</sub>, FT<sub>3</sub>, B<sub>12</sub>, fol., RBC fol., ferr., LH, FSH, prolac., progest., testost., estradiol, hCG, CK-MB, myogl., trop. I, digoxin, digitoxin, urine &amp; serum cortisol, IgE, equimolar PSA, CEA, AFP, BR 27.29, tobramycin, carbamazep., phenobarb., cPSA, phenytoin, aTPO, gentamicin, theophylline, vancomycin, anti-TG, rubella IgG &amp; IgM, toxo IgG &amp; IgM, valporic acid, CA 15-3, iPTH, homocys., CA 125 II, C-peptide, insulin, BNP</p> <p>HER2/neu anti-HBC total, anti-HBs, HBsAg, HBsAg conf., anti-HBC IgM specific allergens, mixes, allergy screen, aHBs, HBsAg conf., HBCIgM, Hbc total HBsAg, HBsAb, HAV total, HAV-IgM, HIVI/0/2, HCV CA 19-9 HBeAb, HBeAg</p> <p>none cPSA, HER-2/neu</p>	<p>CEA, T<sub>3</sub>, T<sub>4</sub>, T-uptake, 3rd-gen. TSH, FT<sub>4</sub>, FT<sub>3</sub>, βhCG, prolac, FSH, LH, progest., estrad., unconj. estriol, B<sub>12</sub>, 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 &amp; fPSA, testosterone, ostase, toxo IgM, antithyroglob., hypersensitive human growth hormone, thyroglobulin, AccuTnl, OV monitor (CA 125 antigen), BR monitor (CA 15.3 antigen), GI monitor (CA 19.9 antigen), BNP</p> <p>— — HIV 1/2, HBsAg, HBsAg confirm., HBsAB, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM none CMV IgG &amp; IgM, rubella IgM, PTH, DHEAS, free T<sub>3</sub>, anti-TPO, anti-intrinsic factor</p> <p>none chlam. Ag &amp; confirm., AFP-ONTD, hybritech PSA &amp; fPSA</p>
<p>Fully automated microplate system</p> <p>No. of each analyte performed in separate disposable unit</p> <p>No. of wells in microplate</p>	<p>no n/a n/a</p>	<p>no n/a n/a</p>
<p>Methods supported/Separation methods</p> <p>No. of different measured assays onboard simultaneously</p> <p>No. of different assays programmed, calibrated at once</p> <p>No. of user-definable (open) channels</p> <p>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</p> <p>Shortest/Median onboard reagent stability/Refrigerated onboard</p> <p>Multiple reagent configurations supported</p> <p>Reagent container placed directly on system for use</p> <p>Reagents bar coded/Information in bar code</p> <p>Same capabilities when 3rd-party reagents used/Susceptibility to carryover</p> <p>Walkaway capacity in minutes/Specimens/Tests-assays</p> <p>System is open (home-brew methods can be used)/Liquid or dry system</p> <p>Uses disposable cuvettes/Max. No. stored</p> <p>Uses washable cuvettes/Replacement frequency</p> <p>Minimum specimen vol. required</p> <p>Minimum sample vol. aspirated precisely at once/Min. dead vol.</p> <p>Supplied with UPS (backup power)/Requires floor drain</p> <p>Requires dedicated water system/Water consumption</p> <p>Noise generated</p> <p>Has dedicated pediatric sample cup/Dead vol.</p> <p>Primary tube sampling/Tube sizes/Pierces caps on primary tubes</p> <p>Sample bar-code reading capability/Autodiscrimination</p> <p>Bar-code placement per NCCLS standard Auto2A</p> <p>Onboard test auto inventory (determines vol. in container)</p> <p>Measures No. of tests remaining/Short sample detection</p> <p>Auto detection of adequate reagent or specimen</p> <p>Clot detection/Reflex testing capability</p> <p>Hemolysis detection-quantitation/Turbidity detection-quantitation</p> <p>Dilution of patient samples onboard/Automatic rerun capability</p> <p>Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results</p> <p>Time between initial result &amp; reaspiration of sample for rerun</p> <p>Autocalibration or autocalibration alert</p> <p>No. of calibrators required for each analyte</p> <p>Calibrants can be stored onboard/Avg. calibration frequency</p> <p>Multipoint calib. supported/Multiple calibs. stored for same assay</p> <p>How often QC required</p> <p>Onboard real-time QC/Support multiple QC lot Nos. per analyte</p> <p>Automatic shutdown/Startup is programmable/Startup time</p>	<p>chemiluminescence/magnetic particle</p> <p>30</p> <p>30</p> <p>0</p> <p>30/50-100</p> <p>96 hr/28 days/yes (4°C)</p> <p>yes</p> <p>yes</p> <p>yes/assay name, lot No., expir., pack ID</p> <p>n/a/zero carryover</p> <p>230/180/840</p> <p>no/liquid</p> <p>yes/1,000</p> <p>no</p> <p>60 µL, assay dependent</p> <p>10 µL/50 µL</p> <p>yes/no</p> <p>no/~2.5 L per hr</p> <p>&lt;64 decibels w/in 1 meter</p> <p>no</p> <p>yes/multiple/no</p> <p>yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes</p> <p>yes</p> <p>yes</p> <p>yes/yes</p> <p>yes</p> <p>yes/yes</p> <p>no/no</p> <p>yes/yes</p> <p>no/no</p> <p>15 sec minimum</p> <p>no</p> <p>2</p> <p>no/varies, avg. 21 days</p> <p>yes/yes</p> <p>24 hr</p> <p>yes/yes</p> <p>no/no/none</p>	<p>chemiluminescence/magnetic particle</p> <p>24</p> <p>24</p> <p>0</p> <p>24/50 tests per cartridge, 100 tests per kit</p> <p>336 hr/28 days/yes (4°C)</p> <p>yes</p> <p>yes</p> <p>yes/assay No., lot No., expir., unique reag. pack ID No.</p> <p>no/≤ 10 ppm</p> <p>180/60/300-31</p> <p>no/liquid</p> <p>yes/294</p> <p>no</p> <p>specimen container dependent</p> <p>5 µL/100 µL</p> <p>no/no</p> <p>no/n/a</p> <p>&lt;70 dba</p> <p>no</p> <p>yes/13 x 75 &amp; 100, 16 x 75 &amp; 100, 2 mL &amp; 3 mL sample cups/no</p> <p>yes/yes</p> <p>yes</p> <p>yes</p> <p>yes/yes</p> <p>yes</p> <p>no/no</p> <p>no/no</p> <p>yes/no</p> <p>no/no</p> <p>n/a</p> <p>no</p> <p>6</p> <p>no/28 days</p> <p>yes/yes</p> <p>24 hr</p> <p>yes/yes</p> <p>no/no/remains in ready mode</p>
<p>Stat time to completion of β-hCG test</p> <p>Time delay from ordering stat test to aspir. of sample</p> <p>Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)</p> <p>Can auto transfer QC results to LIS/Onboard capability to review QC</p> <p>Data management capability/Instrument vendor supplies LIS interface</p> <p>Interfaces up and running in active user sites with</p> <p>LIS interface operates simultaneously w/ running assays</p> <p>Uses LOINC to transmit orders and results</p> <p>How labs get LOINC codes for reagent kits</p> <p>Bidirectional interface capability</p> <p>Results transmitted to LIS as soon as test time complete</p> <p>Interface available (or will be) to auto specimen handling system</p> <p>Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component</p> <p>Can order (via modem) malfunctioning part(s) w/o operator</p> <p>On-site response time of service engineer</p> <p>Mean time between failures/To repair failures</p> <p>Onboard error codes to facilitate troubleshooting</p> <p>Avg. time to complete maintenance by lab personnel</p> <p>Onboard maintenance records/Maintenance training demo module</p>	<p>18 min</p> <p>15 sec</p> <p>80/240 (15 sec)</p> <p>yes/yes</p> <p>onboard/—</p> <p>Cerner, Misys, Meditech, McKesson, Citation, Antrim, Soft, CCA, Dynamic Healthcare, Dawning, NLF, DI, Triple G, and most other major vendors</p> <p>yes</p> <p>—</p> <p>custom definable via LIS</p> <p>yes (broadcast download &amp; host query)</p> <p>yes</p> <p>yes (IDS, Lab InterLink, Labotix, CLIDS, PSS, Hitachi CLAS, A&amp;T)</p> <p>yes/yes/yes</p> <p>no</p> <p>4 hr, 24 hr max.</p> <p>n/a/n/a</p> <p>yes</p> <p>daily: 3 min; weekly: 20 min; monthly: 30 min</p> <p>yes/yes</p>	<p>15 min</p> <p>36 sec</p> <p>33/100 (36 sec)</p> <p>yes/yes</p> <p>onboard/yes (included or add'l cost—negotiable)</p> <p>all major LIS vendors</p> <p>yes</p> <p>no</p> <p>—</p> <p>yes (host query)</p> <p>yes</p> <p>no</p> <p>no/yes/yes</p> <p>no</p> <p>24 hr max., usually w/in 6 hr</p> <p>not available/not available</p> <p>yes</p> <p>daily: 15 min; weekly: 30 min; monthly: none</p> <p>yes/no</p>
<p>List price/Targeted bed size or daily volume</p> <p>Annual service contract cost (24 hours/7 days)</p> <p>Training provided w/ purchase/Advanced operator training</p>	<p>\$225,000/300+ beds or ≥400 tests per day</p> <p>\$21,500</p> <p>varies on site, 4 days at vendor offices/yes</p>	<p>\$129,800/all vols. &amp; hospital sizes</p> <p>\$14,800</p> <p>4 days at vendor offices/yes</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>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</p>	<p>continuous random access benchtop analyzer; state-of-the-art chemiluminescence methodology; ease of use: any test, any tech, any time; superior assays: TSH, FT<sub>4</sub>, UE<sub>3</sub>, hybritech PSA, fPSA, B<sub>12</sub>, fol., AccuTnl</p>

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

## Automated immunoassay analyzers

<b>Part 6 of 23</b>	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822 714-993-8329 www.beckmancoulter.com	Beckman Coulter Inc. Juan Carlos Yubero 200 S. Kraemer Blvd. Brea, CA 92822 714-993-8329 www.beckmancoulter.com
<i>See accompanying article on page 18</i>		
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet	Access 2 Immunoassay System/2001/U.S. U.S./U.S. & France 800/500 cont. random access/benchttop/rack 18.5 x 39 x 24 in/6.5 sq ft	Synchron LXI 725/2002/U.S. U.S./U.S. —/— cont. random access/floor standing/rack-closed tube 60 x 134.5 x 48 in/44.8 sq ft
Tests available on instrument in U.S.	same as Access	CEA, T <sub>3</sub> , T <sub>4</sub> , TU, 3rd gen TSH, FT <sub>4</sub> , FT <sub>3</sub> , βhCG, prolactin, FSH, LH, progesterone, estradiol, unconj. estriol, B <sub>12</sub> , 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, ostease, AccuTnl, C3, C4, haptoglobin, BNP, OV monitor (CA 125 antigen), BR monitor (CA 15.3 antigen), GI monitor (CA 19.9 antigen), plus >100 Synchron chem tests, including critical care, general, esoteric, urine & CSF chemistries, all current Synchron DATs, TDMs, proteins, serologies
Tests cleared but not clinically released	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	same as Access	—
Research-use-only assays	none	—
Tests in development	same as Access	same as Access/same as Synchron
User-defined methods implemented for what analytes	none	—
Tests not available on other manufacturers' analyzers	same as Access	only system to perform heterogeneous immunoassays & general chemistry on a single platform using closed tube sampling
Fully automated microplate system	no	no
No. of each analyte performed in separate disposable unit	n/a	—
No. of wells in microplate	n/a	—
Methods supported/Separation methods	chemiluminescence/magnetic particle	chemiluminescence/magnetic particle
No. of different measured assays onboard simultaneously	24	65
No. of different assays programmed, calibrated at once	24	65
No. of user-definable (open) channels	0	100
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	24/100 tests per kit, 50 tests per cartridge	65/50 tests per cartridge, 100 tests per kit (immuno), 300 tests per container set (general)
Shortest/Median onboard reagent stability/Refrigerated onboard	336 hr/28 days/yes (4°C)	336 hr/28 days/yes (4°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Reagents bar coded/Information in bar code	yes/assay No., lot No., expir., unique reagent pack ID No.	yes/assay No., lot No., expir., unique reagent pack ID
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/≤ 10 ppm	no/≤ 10 ppm
Walkaway capacity in minutes/Specimens/Tests-assays	180/60/300	180/132/5,280
System is open (home-brew methods can be used)/Liquid or dry system	no/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	yes/294	yes/294
Uses washable cuvettes/Replacement frequency	no	yes, 2 yr warranty (general chem.)
Minimum specimen vol. required	specimen container dependent	—
Minimum sample vol. aspirated precisely at once/Min. dead vol.	5 µL/100 µL	5 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	yes (when networked)/no	—/yes
Requires dedicated water system/Water consumption	no	yes/—
Noise generated	<70 dba	—
Has dedicated pediatric sample cup/Dead vol.	yes/100 µL	no/—
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/13x75 & 100, 16x75 & 100, 2 µL & 3 µL cups; 13x75, 13x100 aliquot tubes/no	yes/13x75 & 100, 16x75 & 100 mm/yes
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
Bar-code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	no/yes	yes/yes
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	yes for general chemistry/yes for general chemistry
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	36 sec	36 sec
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	6	6
Calibrants can be stored onboard/Avg. calibration frequency	no/28 days	no/28 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	24 hr	24 hr
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
Automatic shutdown/Startup is programmable/Startup time	no/no/remains in ready mode	no/no/remains in ready mode
Stat time to completion of β-hCG test	15 min	17 min
Time delay from ordering stat test to aspir. of sample	36 sec	36 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	33/100 (36 sec)	33/100 (36 sec)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/yes
Data management capability/Instrument vendor supplies LIS interface	onboard/yes (included or additional cost—negotiable)	onboard/yes (included or additional cost is negotiable)
Interfaces up and running in active user sites with	all major LIS vendors	n/a
LIS interface operates simultaneously w/ running assays	yes	yes
Uses LOINC to transmit orders and results	no	yes
How labs get LOINC codes for reagent kits	—	—
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	no	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	24 hr max., usually within 6 hr	24 hr max., usually within 6 hr
Mean time between failures/To repair failures	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	—
Onboard maintenance records/Maintenance training demo module	yes/no	yes/no
List price/Targeted bed size or daily volume	\$149,800/all volumes & hospital sizes	—/—
Annual service contract cost (24 hours/7 days)	\$15,800	—
Training provided w/ purchase/Advanced operator training	4 days at vendor offices/yes	yes/yes
Distinguishing features (supplied by vendor)	ability to network up to four Access 2s using a single LIS interface with remote diagnostics, fully automated user-defined reflex testing; onboard context sensitive help, aliquot tube capability; continuous random access benchtop analyzer; state-of-the-art chemiluminescence methodology; superior assays: TSH, FT <sub>4</sub> , UE <sub>3</sub> , hybritech PSA, fPSA, B <sub>12</sub> , fol., AccuTnl	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

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

# Automated immunoassay analyzers

<b>Part 7 of 23</b>	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822 714-993-8329 www.beckmancoulter.com	The Binding Site Inc. Anne Grainger 5889 Oberlin Dr., #101 San Diego, CA 92121 800-633-4484 www.bindingsite.co.uk
<i>See accompanying article on page 18</i>		
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet	UniCel DxI 800/2003/U.S. U.S./U.S., France 110/75 cont. random access/floor standing/rack, direct track sampling 66.7 x 67.5 x 37.7 in/17.7 sq ft	DSX Automated System/2000/Guernsey, U.K. U.S./U.K. >150/>500 batch/benchtop/rack 32 x 42 x 36 in/7 sq ft
Tests available on instrument in U.S.	same as Access/Access 2 (excluding chlamydia Ag)	Ana scr, ENA scr., SS-A, SS-B, Sm, Sm/RNP, Jo-1, Scl-70, dsDNA, GBM, MPO, PR3, TG, TPO, cardiolipin IgG/IgM/IgA & scr, B2GP1 IgG/IgM/IgA & scr, phosphatidylserine IgG/IgM/IgA, C1q CIC, gliadin IgG/IgA & scr, tTG IgA, RF, histone, EBV VCA IgG/IgM, EBV EA-D IgG, EBV EBNA-1 IgG/IgM, toxo IgG/IgM, rubella IgG/IgM, CMV IgG/IgM, IgM capture, HSV 1/2 IgG, measles IgG/IgM, mumps IgG, VZV IgG, IgM, Lyme IgM/IgG & scr, H. pylori, syphilis, chlamydia, mycoplasma, legionella IgG/IgM, legionella UA
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	— — same as Access/Access 2 — same as Access/Access 2	none t. tox, tTG IgG, ASCA IgG/IgA, HSV 1/2 IgG type specific open system—any ELISA open system phosphatidylinositol IgG/IgM/IgA, phosphatidylethanolamine IgG/IgM/IgA, phosphatidylglycerol IgG/IgM/IgA, phosphatidylcholine IgG/IgM/IgA, phosphatidic acid IgG/IgM/IgA, prothrombin, C3d CIC, SMA, LKM open system open system
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none none	open system open system
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no — —	yes n/a min. strip 1 x 8; max. full plate 96 x 4 plates
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	chemiluminescence/magnetic particle 50 50 0 50/50 tests per cartridge, 100 or 1,000 tests per kit 336 hr/28 days/yes (3–10°C) yes yes yes/assay No., lot No., expir., unique reagent pack ID No. n/a/< 10 ppm 288 (avg.—assay mix dependent)/120/1,200 (avg.) no/liquid yes/>1,000 no specimen container dependent 5 µL/160 µL yes (PC only)/optional no/— <60 dba yes/100 µL yes/12x75 to 16x100 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no <9 sec (min.) yes assay dependent no/28 days yes/yes 24 h yes/yes no/no/remains in ready mode	EIA/coated microwell 12 assays per plate unlimited unlimited 25/96 per 4 plates 24 hr/n/a/no yes requires operator prehandling/preparation no yes/0 assay dependent/92/assay dependent yes/liquid no no 200 µL 5 µL/200 µL (50 µL with microtubes) yes/no no — yes/50 µL yes/various/no yes (2 of 5 interl., codabar, codes 39 & 128)/— yes no no/yes yes yes/no no/no yes/no no/no n/a no assay specific yes/once per analyte per plate yes/yes per plate yes/no yes/—/1–2 min
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	15 min 18 sec min. 67, max. 133/min. 200, max. 400 (9 or 18 sec) yes/yes onboard/yes (included or additional cost is negotiable) all major LIS vendors yes no — yes (broadcast download & host query) yes yes (Beckman Coulter automation systems) yes/yes/yes no per negotiated contract —/— yes daily: <10 min; weekly: TBD; monthly: none yes/yes	n/a n/a assay dependent yes/yes onboard/yes (additional) Cerner, Misisys yes no n/a yes (host query) yes (manual transmission available) no no/yes/yes no within 24 hr n/a/<24 hr yes daily: 5 min; weekly: n/a; monthly: n/a no/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/ purchase/Advanced operator training	\$325,000/300+ beds or >400 tests per day \$29,900 5 days at vendor office for 2 employees/yes	\$49,000 (dependent on modules)/200+ beds \$7,950 3 days on site, 2 days at vendor offices/yes
Distinguishing features (supplied by vendor)	highest throughput immunoassay analyzer; uses proven chemiluminescent assay technology and reagent packs to deliver consistent results with other Access systems; allows operators to load consumables on the fly without interacting with system console; stores sample aliquot onboard	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

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



# Automated immunoassay analyzers

<p><b>Part 8 of 23</b></p> <p><i>See accompanying article on page 18</i></p>	<p>bioMérieux Inc. Vincent Tumminello vincent.tumminello@na.biomerieux.com 100 Rodolphe St. Durham, NC 27712 919-620-2000 www.biomerieux-usa.com</p>	<p>Bio-Rad Laboratories Clinical Diagnostics Group V. Susan Hutchinson susan_hutchinson@bio-rad.com 4000 Alfred Nobel Dr. Hercules, CA 94547 510-724-7000 www.bio-rad.com</p>
<p>Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>Vidas &amp; MiniVidas/1989/U.S. U.S., Italy/U.S., France 1,500/&gt;15,000 batch, random access/benchttop/n/a Vidas: 16 x 32 x 21 in; MiniVidas: 21 x 21 x 17 in/Vidas 4.5, MiniVidas 4 sq ft</p>	<p>Coda/outside U.S. 1996; in U.S. 1997/Japan Japan/U.S., U.K., France, Korea, Australia 6/550 batch/benchttop/rack 21.6 x 39.5 x 26 in/7.13 sq ft</p>
<p>Tests available on instrument in U.S.</p> <p>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</p> <p>Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers</p>	<p>same for both instruments: <i>C. diff.</i> toxin A, chlam. Ag, chlam. blocking, rotavirus, rubella IgG, measles IgG, mumps IgG, varicella IgG, Lyme (IgG/IgM), TSH, FT<sub>4</sub>, T<sub>4</sub>, T<sub>3</sub>, hCG, estradiol, FSH, LH, prolac., progest., ferr., cortisol (serum &amp; urine), total IgE, digoxin, theoph., <i>H. pylori</i> IgG, toxo IgG, toxo IgM, CMV IgG, CMV IgM., quant. D-dimer, tPSA, toxo IgG/IgM, toxo competition testosterone myoglobin, trop. I 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<sub>3</sub>, fPSA, CEA, AFP, CA 15.3, CA 19.9, CA 125, vWT, prot. C, B<sub>2</sub>, microglobulin, stallergy none EBV, HbA1c none all assays for use on Vidas instruments only</p>	<p>contact Bio-Rad representative</p> <p>contact Bio-Rad representative</p> <p>— biotinidase, leucine, IRT, TSH, PICU, TGAL, GALT, 170HP</p> <p>n/a</p> <p>— STC drugs of abuse, Ostex Ntx, DSL assays—contact companies represented</p> <p>—</p>
<p>Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate</p>	<p>no 1 test per strip n/a</p>	<p>yes — min. strip: 1 sample; max. full plate, 96</p>
<p>Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover</p> <p>Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result &amp; reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency</p> <p>Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time</p>	<p>fluorescence, EIA/coated solid phase receptacle (SPR)/pipetting device Vidas: 30, MiniVidas: 12 total menu 0 unit dose format/30 or 60</p> <p>n/a/n/a/no no yes yes/assay name, lot No., sequence No., expir. no/zero carryover</p> <p>assay dependent/12–30/12–30 no/dry no no 100 µL 100 µL/n/a yes/no no/no — no no/n/a/no yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes n/a n/a no/no no no/no no/no no/no no/no no/no no/no n/a yes 1 no/14 days</p> <p>no (mftr.-determined calib. curves)/yes shortest interval: 8 hr, longest: 24 hr yes/yes no/no/remains ready</p>	<p>EIA/coated microwell &amp; noncoated microwell 9 9 unlimited 9 assays, 24 containers/288 tests</p> <p>n/a/n/a/no yes requires operator prehandling/preparation no no/reduced w/software version 4.0 &amp; updated firmware, depends on amount of washing varies by assay/90–270/up to 9 yes/liquid, reconst. onboard no (yes for dils.) no 10 µL specimen out of 110 µL 10 µL/200 µL, 130 µL in microtubes optional/no no/— n/a yes/130 µL not claimed, but some users have validated for their own use/— yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes yes no no/yes no no/no no/no yes/no no/no</p> <p>— no 1–6 no/most assays require calib. w/ each run, some as long as 2 weeks w/ 1 &amp; 2 pt. updates yes/yes shortest interval: user determined, longest: w/in run recommended yes/yes (late 2000 through Unity QC program) for hardware/6 min</p>
<p>Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with</p> <p>LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module</p>	<p>30 min no delay Vidas: 20, MiniVidas: 8/Vidas: 60, MiniVidas: 24 (—)</p> <p>yes/yes onboard/yes (add'l cost) 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 yes no n/a yes (broadcast download) yes no no/yes/yes</p> <p>no w/in 24 hr Vidas: 350 days, MiniVidas: 1,000 days/&lt;2 hr yes daily: 10–15 min.; weekly: 10–15 min; monthly: 30 min yes/yes</p>	<p>n/a n/a ~90 tests per hr w/ all results in approx. 3 hr (assay dependent)/ (protocol specific) yes/yes (not yet tested) onboard/customer acquires through LIS company, can be added to contract homegrown systems, Cerner, Dawning, &amp; Sunquest in development</p> <p>not possible on batch analyzer can be customized www.bio-rad.com; susan_hutchinson@bio-rad.com yes (broadcast download) yes no no/no/no</p> <p>no 24 hr —/4 hr yes daily: 5 min; weekly: 20 min; monthly: 20 min no/no</p>
<p>List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/ purchase/Advanced operator training</p>	<p>Vidas: \$51,800, MiniVidas: \$28,100/&lt;400 beds \$2,340–\$4,680 (MiniVidas 30) as needed on site, 3 days at vendor offices/yes</p>	<p>\$48,000/50–350 beds, 4–6 plates per days \$4,800 as needed on site, 3 days at vendor offices/—</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>unique dual-function combination solid phase &amp; pipetting device (SPR); assay menu mix (antigen detection, serology, fertility, thyroid, endocrine, coagulation) makes Vidas the ideal instrument for routine batch testing as well as emergency stat testing</p>	<p>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</p>

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

# Automated immunoassay analyzers

Part 9 of 23

Bio-Rad Laboratories Clinical Diagnostics Group  
V. Susan Hutchinson susan\_hutchinson@bio-rad.com  
4000 Alfred Nobel Dr.  
Hercules, CA 94547  
510-724-7000  
www.bio-rad.com

See  
our ad on  
page 81

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

See accompanying article on page 18

Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet	PhD System/2000/Belgium Belgium/U.S. 100/100 batch/benchtop/rack 35 x 66 x 35 in/16 sq ft	Evolis/2001/Germany Germany/U.S. 5/175 batch/benchtop/rack 37 x 44 x 30 in/10 sq ft
Tests available on instrument in U.S.	ANA (EIA), anti-Centomere (EIA), anti-dsDNA (EIA), anti-ENA (EIA), anti-Jo-1 (EIA), anti-SS-A (EIA), anti-SS-B (EIA), anti-scl-70 (EIA), anti-Sm (EIA), anti-SmRNP (EIA), anti-ssDNA (EIA), aCL IgM, aCL IgG, aCL IgA, anti-β2GPI IgG, anti-β2GPI IgM, anti-β2GPI IgA, aPS IgG, aPS IgM, aPS IgA	contact Bio-Rad representative
Tests cleared but not clinically released	—	HIV Ab, HIV Ab/Ag, HIV Ag, HBsAg, HBe Ab, HCV Ab, HTLV-1, anti-HBs, toxo IgG, toxo IgM
Tests not available in U.S. but submitted for clearance	—	—
Tests not available in U.S. but available in other countries	—	HIV Ab, HIV Ab/Ag, HIV Ag, HBsAg, HBe Ab, HCV Ab, HTLV-1, anti-HBs, toxo IgG, toxo IgM, rubella IgG, EBV VCA IgG, EBV VCA IgM, EBV EAD, EBV EBNA, syphilis total Ab, CMV total Ab
Research-use-only assays	—	—
Tests in development	anti-thyroglobulin, anti-TPO, anti-MPO, anti-PR3, anti-GBM, anti-CCP	infectious disease & autoimmune panels
User-defined methods implemented for what analytes	—	none
Tests not available on other manufacturers' analyzers	—	none
Fully automated microplate system	no	yes
No. of each analyte performed in separate disposable unit	1	—
No. of wells in microplate	min. strip: 1; max. full plate: 96	min. strip, 1; max. full plate, 96
Methods supported/Separation methods	EIA/coated microwell	EIA/coated microwell
No. of different measured assays onboard simultaneously	8	4
No. of different assays programmed, calibrated at once	8	4
No. of user-definable (open) channels	no limit	closed in U.S. market
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	8/192	4/96
Shortest/Median onboard reagent stability/Refrigerated onboard	4 hr/—/no	30 min/assay dependent/n/a
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	requires operator prehandling/preparation	yes
Reagents bar coded/Information in bar code	no/n/a	no
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	yes/—	no/no (disposable tips)
Walkaway capacity in minutes/Specimens/Tests-assays	195/184/1	varies by assay/180/4
System is open (home-brew methods can be used)/Liquid or dry system	yes/liquid	no/liquid
Uses disposable cuvettes/Max. No. stored	no/n/a	no
Uses washable cuvettes/Replacement frequency	no/n/a	no
Minimum specimen vol. required	1 µL specimen	0.2 µL
Minimum sample vol. aspirated precisely at once/Min. dead vol.	1 µL/200 µL	10 µL/100 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no
Requires dedicated water system/Water consumption	no	no
Noise generated	—	60 dBA
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	no/—/no	yes/5, 7, 10 mL/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., codabar, codes 39 & 128)/no	yes (2 of 5 interl., codabar, codes 39 & 128)/no
Bar-code placement per NCCLS standard Auto2A	yes	no
Onboard test auto inventory (determines vol. in container)	no	no
Measures No. of tests remaining/Short sample detection	no/yes	no/no
Auto detection of adequate reagent or specimen	yes	no
Clot detection/Reflex testing capability	no/no	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results	no/no	no/no
Time between initial result & reaspiration of sample for rerun	n/a	n/a
Autocalibration or autocalibration alert	no	no
No. of calibrators required for each analyte	1-5	assay dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/each run	no/with each run
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/no	yes/no
How often QC required	each run	user determined
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/no	yes/yes (through Unity QC program)
Automatic shutdown/Startup is programmable/Startup time	no/no/5 min	no/no
Stat time to completion of β-hCG test	n/a	n/a
Time delay from ordering stat test to aspir. of sample	n/a	n/a
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	n/a/n/a	assay dependent
Can auto transfer QC results to LIS/Onboard capability to review QC	no/yes	yes/—
Data management capability/Instrument vendor supplies LIS interface	onboard/yes (included)	onboard/yes
Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays	—	in development
Uses LOINC to transmit orders and results	yes	no
How labs get LOINC codes for reagent kits	can be customized	no
Bidirectional interface capability	www.bio-rad.com; susan_hutchinson@bio-rad.com	n/a
Results transmitted to LIS as soon as test time complete	no	yes (broadcast download)
Interface available (or will be) to auto specimen handling system	yes	yes
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	no	no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	<24 hr	—
Mean time between failures/To repair failures	6 months/4 hr	—/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 15 min; weekly: 15 min; monthly: 30 min	daily: 5 min; weekly: 10 min; monthly: 30 min
Onboard maintenance records/Maintenance training demo module	no/no	no/no
List price/Targeted bed size or daily volume	\$38,000/>50 tests per day	\$65,000/50-400 tests per day
Annual service contract cost (24 hours/7 days)	\$6,000	inquire
Training provided w/ purchase/Advanced operator training	2 days on site/no	3 days in Redmond, Wash./no
Distinguishing features (supplied by vendor)	accurate pipetting at 1 µL; connection of 1-10 pipetting stations together through an ethernet hub, graphical user interface; added module for IFA slide processing	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)

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

# Automated immunoassay analyzers

<b>Part 10 of 23</b>	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
<i>See accompanying article on page 18</i>		
<b>Name of instrument/First year sold/Where designed</b>	Stratus CS Stat Fluorometric Analyzer/1998/U.S.	Dimension Xpand Integrated Chemistry System/2001/U.S.
<b>Country where manufactured/Where reagents manufactured</b>	U.S./U.S.	U.S./U.S.
<b>No. of units in clinical use in U.S./Outside U.S.</b>	700/700	>800/—
<b>Operational type/Model type/Sample handling system</b>	random access/benchtop/whole blood collection tube	random access, cont. random access/floor-standing/segmented sample wheel
<b>Dimensions in inches (H x W x D)/Instrument footprint in square feet</b>	18 x 27 x 22 in./4.1 sq. ft.	45 x 51 x 31 in (without monitor)/—
<b>Tests available on instrument in U.S.</b>	mass CK-MB, trop. I, myoglobin, $\beta$ -hCG, D-dimer	thyrox. uptake, total thyrox., hemoglobin A1c, acid phosphat., alanine amino-transferase, alkaline phosphatase, amylase, aspartate aminotransferase, CK, CK isoenzyme, glutamyl transferase, lactic dehydrogenase, lipase, pseudo-cholinesterase, ferr., free thyrox., HCG, mass CK-MB, myoglob., tPSA, fPSA, TSH, trop. I, C3, C4, CRP, high-sens. CRP, IgA, IgG, IgM, transferr., ammonia, urine CSF protein, lactic acid, prealbum., carbamazep., cyclosporine, digox., digitox., gentamicin, lithium, phenobarbital, phenytoin, theophy., tobramycin, van-comycin, valp. acid, acetaminophen, ethyl alcohol, salicylate; urine screens: amph., barbit., benzo., cannab., cocaine metab., methad., opiates, phencyc., procainamide, lidocaine, n-acetylprocainamide (see Dimension RxL Max for full general chemistry menu)
<b>Tests cleared but not clinically released</b>	none	—
<b>Tests not available in U.S. but submitted for clearance</b>	none	—
<b>Tests not available in U.S. but available in other countries</b>	none	—
<b>Research-use-only assays</b>	none	—
<b>Tests in development</b>	NT-proBNP	quinidine, triiodothyronine, tacrolimus, microalbumin, NT-proBNP
<b>User-defined methods implemented for what analytes</b>	none	—
<b>Tests not available on other manufacturers' analyzers</b>	none	system performs heterogeneous immunoassays and general assays on single platform—complete routine chemistry menu
<b>Fully automated microplate system</b>	no	no
<b>No. of each analyte performed in separate disposable unit</b>	n/a	—
<b>No. of wells in microplate</b>	n/a	—
<b>Methods supported/Separation methods</b>	fluorescence, EIA, dendrimer technology/fiber matrix filter	EIA/magnetic particle
<b>No. of different measured assays onboard simultaneously</b>	up to 4	47
<b>No. of different assays programmed, calibrated at once</b>	1	190
<b>No. of user-definable (open) channels</b>	0	10
<b>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</b>	n/a/unit dose test packs	47/avg. 80–120
<b>Shortest/Median onboard reagent stability/Refrigerated onboard</b>	n/a/n/a/no	72 hr/30 days/yes (2–8°C)
<b>Multiple reagent configurations supported</b>	yes	yes
<b>Reagent container placed directly on system for use</b>	yes	yes
<b>Reagents bar coded/Information in bar code</b>	yes/assay ID, lot No., expir., calib. param.	yes/lot No., unique flex ID, stability
<b>Same capabilities when 3rd-party reagents used/Susceptibility to carryover</b>	no/zero carryover	yes/n/a due to probe washing
<b>Walkaway capacity in minutes/Specimens/Tests-assays</b>	14 min to 1st result, subsequent results in 4 min intervals/1/up to 4	can be hours/60/>1,000
<b>System is open (home-brew methods can be used)/Liquid or dry system</b>	no/liquid	yes/reconstitutes onboard
<b>Uses disposable cuvettes/Max. No. stored</b>	no	yes/12,000
<b>Uses washable cuvettes/Replacement frequency</b>	no	no/—
<b>Minimum specimen vol. required</b>	2.5 mL whole blood	32 $\mu$ L
<b>Minimum sample vol. aspirated precisely at once/Min. dead vol.</b>	n/a	2 $\mu$ L/primary tube capable
<b>Supplied with UPS (backup power)/Requires floor drain</b>	no/no	yes/no
<b>Requires dedicated water system/Water consumption</b>	no/n/a	yes/up to 2 L per hr
<b>Noise generated</b>	<65	<70
<b>Has dedicated pediatric sample cup/Dead vol.</b>	no	yes/10–20 $\mu$ L
<b>Primary tube sampling/Tube sizes/Pierces caps on primary tubes</b>	yes/4 or 5 mL/yes	yes/5, 7, 10 mL/no
<b>Sample bar-code reading capability/Autodiscrimination</b>	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 of 5 interl., codabar, codes 39 & 128)/yes
<b>Bar-code placement per NCCLS standard Auto2A</b>	yes	yes
<b>Onboard test auto inventory (determines vol. in container)</b>	n/a	yes
<b>Measures No. of tests remaining/Short sample detection</b>	no/yes	yes/yes
<b>Auto detection of adequate reagent or specimen</b>	yes	yes
<b>Clot detection/Reflex testing capability</b>	yes/yes	yes (HM)/yes
<b>Hemolysis detection-quantitation/Turbidity detection-quantitation</b>	no/no	no/no
<b>Dilution of patient samples onboard/Automatic rerun capability</b>	yes/no	yes/yes
<b>Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results</b>	no/no	yes/yes
<b>Time between initial result &amp; reaspiration of sample for rerun</b>	n/a	<20 sec
<b>Autocalibration or autocalibration alert</b>	yes	no
<b>No. of calibrators required for each analyte</b>	1 cal pack	varies—3 levels for most assays
<b>Calibrants can be stored onboard/Avg. calibration frequency</b>	no/60–90 days same lot, new lot	no/30–90 days
<b>Multipoint calib. supported/Multiple calibs. stored for same assay</b>	yes/yes	yes/yes
<b>How often QC required</b>	shortest interval: daily system check, longest: every 30 days for liquid controls	24 h
<b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b>	yes/no	no/yes
<b>Automatic shutdown/Startup is programmable/Startup time</b>	no/no/30 min. to warm up	no/no/5 min
<b>Stat time to completion of <math>\beta</math>-hCG test</b>	14 min	16 min
<b>Time delay from ordering stat test to aspir. of sample</b>	instantly	24 sec
<b>Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)</b>	3/9	83/250 (14.4 sec)
<b>Can auto transfer QC results to LIS/Onboard capability to review QC</b>	yes/yes	yes/yes
<b>Data management capability/Instrument vendor supplies LIS interface</b>	yes/yes (included in price)	optional add-on/no (additional)
<b>Interfaces up and running in active user sites with</b>	Cerner, Sunquest	all major LIS vendors
<b>LIS interface operates simultaneously w/ running assays</b>	yes	yes
<b>Uses LOINC to transmit orders and results</b>	no	no
<b>How labs get LOINC codes for reagent kits</b>	n/a	—
<b>Bidirectional interface capability</b>	no	yes (broadcast download & host query)
<b>Results transmitted to LIS as soon as test time complete</b>	yes	yes
<b>Interface available (or will be) to auto specimen handling system</b>	no	yes
<b>Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component</b>	no/yes/yes	yes/yes/yes
<b>Can order (via modem) malfunctioning part(s) w/o operator</b>	no	no
<b>On-site response time of service engineer</b>	—	2–8 hr
<b>Mean time between failures/To repair failures</b>	>200 days/2.5 hr	—/—
<b>Onboard error codes to facilitate troubleshooting</b>	yes	yes
<b>Avg. time to complete maintenance by lab personnel</b>	daily: 5 min; weekly: none; monthly: 10 min	daily: <10 min; weekly: 10 min; monthly: 20–30 min
<b>Onboard maintenance records/Maintenance training demo module</b>	no/—	yes/no
<b>List price/Targeted bed size or daily volume</b>	—/—	—/—
<b>Annual service contract cost (24 hours/7 days)</b>	multiple types	multiple types
<b>Training provided w/ purchase/Advanced operator training</b>	3 days on site/no	5 days on site; 4 days at vendor offices/no
<b>Distinguishing features (supplied by vendor)</b>	whole blood collection tubes (heparin) or precentrifuged plasma (heparin); onboard centrifugation; unit-dose test packs; color-coded calibrators packaged on Calpaks; diluent packs for dilutions; self-contained system (no waste lines, etc.); closed container sampling; electronic QC; POCT1-A compliant when interfaced to Data Manager	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

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

# Automated immunoassay analyzers

<p><b>Part 11 of 23</b></p> <p>See accompanying article on page 18</p>	<p>Dade Behring Inc. P.O. Box 6101, Newark, DE 19714-6101 800-242-3233 www.dadebehring.com</p>	<p>Diagnostic Products Corp. Joe Kelly jkelly@dpconline.com 5700 W. 96th St., Los Angeles, CA 90045-5597 310-642-5180 www.dpcweb.com</p>
<p>Name of instrument/First year sold/Where designed</p> <p>Country where manufactured/Where reagents manufactured</p> <p>No. of units in clinical use in U.S./Outside U.S.</p> <p>Operational type/Model type/Sample handling system</p> <p>Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>Dimension RxL Max Integrated Chemistry System/2003/U.S.; Dimension RxL Integrated Chemistry System/1997/U.S. U.S./U.S. RxL Max: &gt;600/—; RxL: &gt;1,500/— batch, random access, cont. random access/floor-standing/segmented sample wheel 44 x 62.5 x 30.5 in./13.2 sq. ft.</p>	<p>Immulite/1993; Immulite Turbo/1999; Immulite 1000/2002/U.S. U.S./U.S., U.K. 5,000 worldwide cont. random access/benchttop/loading platform 16 x 42 x 24.75 in (w/o computer)/7.2 sq ft</p>
<p>Tests available on instrument in U.S.</p> <p>Tests cleared but not clinically released</p> <p>Tests not available in U.S. but submitted for clearance</p> <p>Tests not available in U.S. but available in other countries</p> <p>Research-use-only assays</p> <p>Tests in development</p> <p>User-defined methods implemented for what analytes</p> <p>Tests not available on other manufacturers' analyzers</p>	<p>See Dimension Xpand test menu for endocrinology, enzymes, heterogeneous immunoassays, specialty, immunology, TDM &amp; toxicology. General chemistry test menu: album., calcium, cholest., creatinine, dir. &amp; total bili., enzymatic CO<sub>2</sub>, glucose, HDLC, automated HDL, automated LDL, iron, magnes., phosphorus, total iron-binding capacity (&amp; no pretreat), total protein, triglyc., urea nitrogen, uric acid, carbon dioxide, chloride, potassium, sodium</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>NT-proBNP, plus all those listed on Xpand</p> <p>—</p> <p>system performs heterogeneous immunoassays and general assays on a single platform—complete routine chemistry menu</p>	<p>AlaTOP allergy scr., allergy food panel FP5E, total IgE, EPO, ferr., fol. acid, B<sub>12</sub>, intact PTH, PTH, PTHrP, carbamazep., phenytoin, valp. acid, phenobarb., CMV IgG, herpes I &amp; II IgG, rubella IgG quant., toxo IgG quant., DHEA-SO<sub>4</sub>, estrad., unconj. estriol, FSH, hCG, LH, progest., prolac., testost., digitox., digox., theoph., anti-TG Ab, anti-TPO Ab, FT<sub>3</sub>, FT<sub>4</sub>, rapid TSH, TBG, 3rd-gen. TSH, T-uptake, TT<sub>3</sub>, TT<sub>4</sub>, thyroglob., AFP, CEA, OM-MA, PAP, PSA, 3rd-gen. PSA, canine TT<sub>4</sub> &amp; TSH, C-pep., insul., CK-MB, myoglo., trop. I, ACTH, B<sub>2</sub>-microgl., cortisol, HsCRP, hGH, rubella IgM, toxo IgM, SHBG, urinary albumin, homocysteine, <i>H. pylori</i> 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) none none</p> <p>—</p> <p>GI-MA (CA 19-9), free PSA, TPS, Lyme screen, ECP osteocalcin, nicotine metabolite, cytokines, free βHCG</p> <p>ANA scr., <i>C. diff.</i>, calcitonin, chagas, CMV IgM, dsDNA Ab, hep. A, IGF BP3, IGF-1, Lyme IgG &amp; IgG/IgM, Hbe, Hbe IgM, androstenedione, cryptosporidium Ag, D-dimer, EBV, gastrin giardia Ag, <i>H. pylori</i> A, HSV IgM, IL10, NMP 22, NSE, PAPP-A none</p> <p>3rd-gen. PSA, AlaTOP allergy screen, allergy food panel FP5E, SHBG, TBG, EPO, canine TSH, thyroglob., intact PTH, ACTH. Turbo: intact PTH</p>
<p>Fully automated microplate system</p> <p>No. of each analyte performed in separate disposable unit</p> <p>No. of wells in microplate</p>	<p>no</p> <p>—</p> <p>—</p>	<p>no</p> <p>n/a</p> <p>n/a</p>
<p>Methods supported/Separation methods</p> <p>No. of different measured assays onboard simultaneously</p> <p>No. of different assays programmed, calibrated at once</p> <p>No. of user-definable (open) channels</p> <p>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</p> <p>Shortest/Median onboard reagent stability/Refrigerated onboard</p> <p>Multiple reagent configurations supported</p> <p>Reagent container placed directly on system for use</p> <p>Reagents bar coded/Information in bar code</p> <p>Same capabilities when 3rd-party reagents used/Susceptibility to carryover</p> <p>Walkaway capacity in minutes/Specimens/Tests-assays</p> <p>System is open (home-brew methods can be used)/Liquid or dry system</p> <p>Uses disposable cuvettes/Max. No. stored</p> <p>Uses washable cuvettes/Replacement frequency</p> <p>Minimum specimen vol. required</p> <p>Minimum sample vol. aspirated precisely at once/Min. dead vol.</p> <p>Supplied with UPS (backup power)/Requires floor drain</p> <p>Requires dedicated water system/Water consumption</p> <p>Noise generated</p> <p>Has dedicated pediatric sample cup/Dead vol.</p> <p>Primary tube sampling/Tube sizes/Pierces caps on primary tubes</p> <p>Sample bar-code reading capability/Autodiscrimination</p> <p>Bar-code placement per NCCLS standard Auto2A</p> <p>Onboard test auto inventory (determines vol. in container)</p> <p>Measures No. of tests remaining/Short sample detection</p> <p>Auto detection of adequate reagent or specimen</p> <p>Clot detection/Reflex testing capability</p> <p>Hemolysis detection-quantitation/Turbidity detection-quantitation</p> <p>Dilution of patient samples onboard/Automatic rerun capability</p> <p>Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results</p> <p>Time between initial result &amp; reaspiration of sample for rerun</p> <p>Autocalibration or autocalibration alert</p> <p>No. of calibrators required for each analyte</p> <p>Calibrants can be stored onboard/Avg. calibration frequency</p> <p>Multipoint calib. supported/Multiple calibs. stored for same assay</p> <p>How often QC required</p> <p>Onboard real-time QC/Support multiple QC lot Nos. per analyte</p> <p>Automatic shutdown/Startup is programmable/Startup time</p>	<p>EIA, latex particle turbidimetric, direct turbidimetric/heterogeneous, magnetic particles</p> <p>48 (92 with optional reagent management system)</p> <p>190</p> <p>10</p> <p>44–88/max. 240</p> <p>72 hr/30 days/yes (2–8°C)</p> <p>yes</p> <p>yes</p> <p>yes/lot No., unique flex ID, stability</p> <p>yes/n/a due to probe washing can be hours</p> <p>yes/reconstitutes onboard</p> <p>yes/12,000</p> <p>no/—</p> <p>52 µL</p> <p>2 µL/primary tube capable</p> <p>yes/no</p> <p>yes/3.2 L per hr</p> <p>&lt;70</p> <p>yes/10–20 µL</p> <p>yes/5, 7, 10 mL/no</p> <p>yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes</p> <p>yes</p> <p>yes</p> <p>yes/yes</p> <p>yes</p> <p>yes (HM)/yes</p> <p>yes/yes</p> <p>yes/yes</p> <p>yes/yes</p> <p>&lt;20 sec</p> <p>no</p> <p>varies—3 levels for most assays</p> <p>yes/30–90 days</p> <p>yes/yes</p> <p>24 hr</p> <p>no/yes</p> <p>no/no/2 min tech time, 5 min instrument time</p>	<p>chemiluminescence/bead, centrifugation</p> <p>12; Turbo: 5</p> <p>unlimited; Turbo: 5</p> <p>0</p> <p>12/100 or 500; Turbo: 50 for intact PTH only</p> <p>n/a/30 days/yes (15°C)</p> <p>yes</p> <p>yes</p> <p>yes/test, lot No., expir.</p> <p>no/&lt;10 ppm</p> <p>100/—/70</p> <p>no/liquid</p> <p>yes/n/a</p> <p>no</p> <p>5 µL</p> <p>5 µL/100 µL</p> <p>yes/no</p> <p>no/0.5 L per h</p> <p>55 min., max. 68</p> <p>no</p> <p>no/n/a/—</p> <p>yes (2 of 5 interl., codabar, codes 39 &amp; 128)/no</p> <p>—</p> <p>no</p> <p>yes/yes</p> <p>yes</p> <p>no/no</p> <p>no/no</p> <p>no/no</p> <p>n/a</p> <p>no</p> <p>2-level adjustors, supplied in kit</p> <p>no/1–4 weeks (assay dependent); Turbo: 2 weeks</p> <p>no/yes</p> <p>customer determined</p> <p>no/yes</p> <p>no/no/5 min</p>
<p>Stat time to completion of β-hCG test</p> <p>Time delay from ordering stat test to aspir. of sample</p> <p>Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)</p> <p>Can auto transfer QC results to LIS/Onboard capability to review QC</p> <p>Data management capability/Instrument vendor supplies LIS interface</p> <p>Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays</p> <p>Uses LOINC to transmit orders and results</p> <p>How labs get LOINC codes for reagent kits</p> <p>Bidirectional interface capability</p> <p>Results transmitted to LIS as soon as test time complete</p> <p>Interface available (or will be) to auto specimen handling system</p> <p>Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component</p> <p>Can order (via modem) malfunctioning part(s) w/o operator</p> <p>On-site response time of service engineer</p> <p>Mean time between failures/To repair failures</p> <p>Onboard error codes to facilitate troubleshooting</p> <p>Avg. time to complete maintenance by lab personnel</p> <p>Onboard maintenance records/Maintenance training demo module</p>	<p>16 min</p> <p>24 sec</p> <p>55–166/167–500 (7.2 sec.)</p> <p>yes/yes</p> <p>optional add-on (DBNet–Dade Behring)/yes (add'l cost)</p> <p>all major LIS vendors</p> <p>yes</p> <p>no</p> <p>—</p> <p>yes (broadcast download &amp; host query)</p> <p>yes</p> <p>yes</p> <p>yes/yes/yes</p> <p>no</p> <p>2–8 hr</p> <p>—/—</p> <p>yes</p> <p>daily: 5 min, weekly: 10 min, monthly: 15 min</p> <p>yes/no</p>	<p>42 min; Turbo: 15 min</p> <p>2.5 min</p> <p>40/120 (—)</p> <p>no/yes</p> <p>onboard/yes (add'l cost)</p> <p>Sunquest, Cerner, Citation, ALG, CHC, DynaMedix, Antrim, Antek, CSS</p> <p>yes</p> <p>no</p> <p>—</p> <p>yes (broadcast download &amp; host query)</p> <p>yes</p> <p>no</p> <p>no/yes/no</p> <p>no</p> <p>4 hr</p> <p>8 mos/4 hr</p> <p>yes</p> <p>daily: 5 min; weekly: 10 min; monthly: 20 min</p> <p>no/yes</p>
<p>List price/Targeted bed size or daily volume</p> <p>Annual service contract cost (24 hours/7 days)</p> <p>Training provided w/ purchase/Advanced operator training</p>	<p>—/—</p> <p>multiple types</p> <p>5 days on site, 4 days at vendor offices/yes</p>	<p>\$75,000; Turbo: \$77,500/&gt;1,000 tests per month</p> <p>\$7,500</p> <p>3.5 days at vendor offices/no, in development</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>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</p>	<p>system performance reliability; worldwide user satisfaction; breadth of immunoassay menu</p>

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

# Automated immunoassay analyzers

<b>Part 12 of 23</b>	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
<i>See accompanying article on page 18</i>		
<b>Name of instrument/First year sold/Where designed</b>	Immolute 2000/1998/U.S.	Immolute 2500 SMS/2004/U.S.
<b>Country where manufactured/Where reagents manufactured</b>	U.S./U.S.	U.S./U.S., U.K.
<b>No. of units in clinical use in U.S./Outside U.S.</b>	3,000 worldwide	—/—
<b>Operational type/Model type/Sample handling system</b>	Cont. random access/floor-standing/rack	continuous random access/floor standing/rack
<b>Dimensions in inches (H x W x D)/Instrument footprint in square feet</b>	79 x 60 x 30/12.5 sq ft	70 x 40 x 136 in/37.29 sq ft
<b>Tests available on instrument in U.S.</b>	AFP, CEA, OM-MA, PSA, 3rd-gen. PSA, FT <sub>3</sub> , TT <sub>3</sub> , FT <sub>4</sub> , TT <sub>4</sub> , TBG, thyrogl., anti-TG Ab, anti-TPO Ab, T-uptake, rapid TSH, 3rd-gen. TSH, DHEA-SO <sub>4</sub> , estrad., FSH, hCG, LH, progester., prolac., total testost., β-2-microgl., cortisol, ferr., total IgE, intact PTH, C-pep., folic acid, B <sub>12</sub> , insulin, unconj. estriol, carbamazep., phenytoin, valp. acid, HsCRP, hGH, ACTH, PAP, pheno, homocysteine, CMV IgG (qualit.), <i>H. pylori</i> 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)	cortisol, ACTH, AlaTOP, 3rd gen allergen-specific IgE, total IgE, ferritin, EPO, PTH, calcitonin, pyril. D, homocy., hsCRP, insulin, C peptide, urin. albumin, IGF 1 & 1 BP-3, hCG, CMV IgG, rubella IgG/IgM, toxoplasma IgG/IgM, <i>H. pylori</i> IgG, AFP, androstenedione, DHEA SO <sub>4</sub> , estrad., free estriol, FSH, LH, prolactin, progesterone, testosterone, SHBG, CK-MB, HCG, troponin I, myoglobin, carbamazepine, digoxin, digitoxin, gentamicin, phenytoin, pheonobarbital, theophylline, tobramycin, valp. acid, rapid TSH, 3rd gen TSH, FT <sub>4</sub> , FT <sub>3</sub> , TT <sub>4</sub> , TT <sub>3</sub> , CEA, PSA, 3rd gen PSA
<b>Tests cleared but not clinically released</b>	none	n/a
<b>Tests not available in U.S. but submitted for clearance</b>	none	none
<b>Tests not available in U.S. but available in other countries</b>	—	none
<b>Research-use-only assays</b>	fPSA, Lyme screen, nicotine metabolite, CA 19-9 (GIMA)	none
<b>Tests in development</b>	anti-HBe, HBeAg, ANA screen, Chagas, CMV IgG avidity, dsDNA, EBV, HAV total, HAV IgM, <i>H. pylori</i> 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	none
<b>User-defined methods implemented for what analytes</b>	none	none
<b>Tests not available on other manufacturers' analyzers</b>	TBG, thyrogl., SHBG, intact PTH, C-peptide, 3rd-gen. PSA	—
<b>Fully automated microplate system</b>	no	no
<b>No. of each analyte performed in separate disposable unit</b>	n/a	—
<b>No. of wells in microplate</b>	n/a	—
<b>Methods supported/Separation methods</b>	chemiluminescence/bead, centrifugation	chemiluminescence/bead, centrifugation
<b>No. of different measured assays onboard simultaneously</b>	24	24
<b>No. of different assays programmed, calibrated at once</b>	unlimited	unlimited
<b>No. of user-definable (open) channels</b>	n/a	0
<b>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</b>	24/200 or 600	24/200
<b>Shortest/Median onboard reagent stability/Refrigerated onboard</b>	n/a/90 days/yes (4°C)	n/a/90 days/yes (4°C)
<b>Multiple reagent configurations supported</b>	yes	yes
<b>Reagent container placed directly on system for use</b>	yes	yes
<b>Reagents bar coded/Information in bar code</b>	yes/test, lot No., expir.	yes/lot No., name, expir. date, assay parameters
<b>Same capabilities when 3rd-party reagents used/Susceptibility to carryover</b>	no/<10 ppm	no/3 ppm
<b>Walkaway capacity in minutes/Specimens/Tests-assays</b>	cycle dependent/90/1,000	300/200/1,000
<b>System is open (home-brew methods can be used)/Liquid or dry system</b>	no/liquid	no/liquid
<b>Uses disposable cuvettes/Max. No. stored</b>	yes/1,000	yes/1,000
<b>Uses washable cuvettes/Replacement frequency</b>	no	no
<b>Minimum specimen vol. required</b>	5 µL to 100 µL sample	250 µL + 5 µL to 100 µL sample
<b>Minimum sample vol. aspirated precisely at once/Min. dead vol.</b>	5 µL/50 µL	5 µL/250 µL
<b>Supplied with UPS (backup power)/Requires floor drain</b>	yes/no	yes/no
<b>Requires dedicated water system/Water consumption</b>	no/—	no/—
<b>Noise generated</b>	52 decibels	52 decibels
<b>Has dedicated pediatric sample cup/Dead vol.</b>	yes/50 µL	yes/50 µL
<b>Primary tube sampling/Tube sizes/Pierces caps on primary tubes</b>	yes/12 x 75 & 100; 13 x 75 & 100; 16 x 75 & 100 mm/no	yes/75–100 mm height; 12–16 mm width/no
<b>Sample bar-code reading capability/Autodiscrimination</b>	yes (2 of 5 interl., codabar, codes 39 & 128)/yes	yes (2 or 5 interl., codabar, codes 39 & 128)/yes
<b>Bar-code placement per NCCLS standard Auto2A</b>	yes	yes
<b>Onboard test auto inventory (determines vol. in container)</b>	yes	yes
<b>Measures No. of tests remaining/Short sample detection</b>	yes/yes	yes/yes
<b>Auto detection of adequate reagent or specimen</b>	yes	yes
<b>Clot detection/Reflex testing capability</b>	yes/yes	yes/yes
<b>Hemolysis detection-quantitation/Turbidity detection-quantitation</b>	no/no	no/no
<b>Dilution of patient samples onboard/Automatic rerun capability</b>	yes/yes	yes/yes
<b>Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results</b>	no/no	yes/no
<b>Time between initial result &amp; reaspiration of sample for rerun</b>	min. 18 sec	min. 18 sec
<b>Autocalibration or autocalibration alert</b>	yes	yes
<b>No. of calibrators required for each analyte</b>	2 level adjustors, supplied in kit	2 level adjustors, supplied in kit
<b>Calibrants can be stored onboard/Avg. calibration frequency</b>	no/1–4 weeks (assay dependent)	no/1–4 weeks (assay dependent)
<b>Multipoint calib. supported/Multiple calibs. stored for same assay</b>	yes/yes	yes/yes
<b>How often QC required</b>	customer determined	customer determined
<b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b>	yes/yes	yes/yes
<b>Automatic shutdown/Startup is programmable/Startup time</b>	yes/no/5 min	yes/no/4 min
<b>Stat time to completion of β-hCG test</b>	35 min	15 min
<b>Time delay from ordering stat test to aspir. of sample</b>	18 sec	18 sec
<b>Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)</b>	200/200 (18 sec)	200/200 (18 sec)
<b>Can auto transfer QC results to LIS/Onboard capability to review QC</b>	yes/yes	yes/yes
<b>Data management capability/Instrument vendor supplies LIS interface</b>	onboard/yes (additional cost)	onboard/yes (additional cost)
<b>Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays</b>	Sunquest, Cerner, McKesson, CCA, ALG	any LIS interface is supported
<b>Uses LOINC to transmit orders and results</b>	yes	yes
<b>How labs get LOINC codes for reagent kits</b>	no	no
<b>Bidirectional interface capability</b>	yes (broadcast download & host query)	yes (broadcast download & host query)
<b>Results transmitted to LIS as soon as test time complete</b>	yes	yes
<b>Interface available (or will be) to auto specimen handling system</b>	yes (universal interface)	yes (any track system)
<b>Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component</b>	yes/yes/yes	yes/yes/yes
<b>Can order (via modem) malfunctioning part(s) w/o operator</b>	no	no
<b>On-site response time of service engineer</b>	6 hr	4 hr
<b>Mean time between failures/To repair failures</b>	2 mos/5 hr	2 months/5 hr
<b>Onboard error codes to facilitate troubleshooting</b>	yes	yes
<b>Avg. time to complete maintenance by lab personnel</b>	daily: 5–10 min; weekly: none; monthly: 20–30 min	daily: 5 min; weekly: none; monthly: 20 min
<b>Onboard maintenance records/Maintenance training demo module</b>	no/yes	no/yes
<b>List price/Targeted bed size or daily volume</b>	\$124,500/>4,000 tests per month	\$200,000 includes SMS & RTS/200+ beds
<b>Annual service contract cost (24 hours/7 days)</b>	\$12,500	\$17,000
<b>Training provided w/ purchase/Advanced operator training</b>	3.5 days at vendor offices/no, in development	varies on site, 5 days at vendor offices/yes
<b>Distinguishing features (supplied by vendor)</b>	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	large automated immunoassay test menu available; flexible sample handling, user-definable testing; Internet based service support for system; remote diagnostics; auto reflex; auto dilute; RealTime Solutions (RTS)

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

# Automated immunoassay analyzers

<b>Part 13 of 23</b>	Diamedix Corp. Pat Ahmad pat_ahmad@ivaxdiagnostics.com 2140 North Miami Ave., Miami, FL 33127 305-324-2300 or 800-327-4565	DiaSorin Inc. Brian Lauber brian.lauber@diasorin.com 1951 Northwestern Ave., Stillwater, MN 55082 800-328-1482 www.diasorin.com
See accompanying article on page 18		
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet	Mago Plus Automated EIA Analyzer/1997/Italy Italy/U.S. —/— Batch, random access/benchttop/2 racks, 120 samples total 28 x 48 x 26 in/8.7 sq ft, incl. onboard computer, reagents, spectrophotometer	ETI-Max 3000/2002/Germany Germany/U.S., Italy 125/300 batch, random access/benchttop/rack 40 x 45 x 30 in/10 sq ft
Tests available on instrument in U.S.	Autoimmune: anti-SSA/Ro, anti-SSB/La, anti-Sm, anti-Sm/RNP, anti-Scl-70, anti-Jo-1, anti-dsDNA, RF, ENA-6 scr., ANA ELISA scr., anti-MPO, anti-PR-3, anti-TPO, anti-TG, anti-cardio. scr., anti-cardio. IgG, IgM, IgA, anti-β-2-glycop. IgG, IgM, anti-gliadin IgG & IgA; Infectious: toxo IgG, toxo IgM capture, rubella IgG, rubella IgM capture, CMV IgG, CMV IgM capture, HSV I & II IgG & IgM, measles IgG, VZV IgG, EBV-VCA IgG & IgM, EBNA-1 IgG & IgM, EBV-EA-D IgG & IgM, anti-B. burgdorferi IgG/IgM, mumps IgG, H. pylori IgG, legionella IgG/IgM/IgA, syphilis Trep-Chek, mycoplasma IgG & IgM, HSV 1 IgG, HSV 2 IgG	HBsAg, anti-HBs, HCV, anti-HBc, IgM anti-HBc, HBeAg, anti-HBe, anti-HAV, IgM anti-HAV, EA-IgG, EBNA-IgG, VCA-IgG, VCA-IgM, toxo-IgM, toxo-IgG, CMV-IgG, CMV-IgM, HSV I/II-IgG, measles IgG, mumps-IgG, VZV IgG, MP IgG/IgM, 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, anti-cardiolipin IgM, anti-cardiolipin IgA, total anti-cardiolipin, anti-CCP, rubella IgG, anti-TPO, anti-β2 glycoprotein
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries	none none 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	none none none
Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	none — varied programs by customer at customer location assays designed/FDA cleared for this analyzer; tests can be validated on other anal.	none none n/a n/a
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	yes usually 1 analyte per well; multiple analytes per well in screen tests min. strip: 8 or less (breakapart wells), max. full plate: 96, up to 4 plates simul.	yes — min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate up to 7 plates at a time
Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	EIA/microtiter 9 ~50 tests preprogrammed, ready for use 20 9/96 >16 h/6 days/no yes yes available/kit lot No., expir. date yes/not susceptible to carryover, has continuous internal cleaning varies from 150 min-240 min/9 tests & 384 results per run yes/liquid yes/120 no/n/a 50 µL in pediatric tube 4 µL/100 µL yes/no no/n/a insignificant possible—can use 1.5 mL vial/100 µL yes/up to 16 x 100/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes — yes yes/yes yes no/no no/no yes/no no/no n/a no varies: 2 (single point curve tests), 6 (6 pt. curve tests), 3 (3 pt. curve tests) yes/every run yes/no each run yes/yes yes/yes/<5 min	EIA/coated microplate open open unlimited volume dependent no/no/no yes yes yes/— yes/no assay dependent/180/variable yes/liquid no no 10 µL 10 µL/200 µL yes/no no/no — no yes/multiple/no yes/yes yes yes/yes yes yes/no no/no yes/no no/no n/a no varies per kit no/each run yes/no per run yes/yes no/yes/5 min
Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	n/a <15 min set-up time 120/360 (~4 h) yes/yes onboard/yes (add'l cost) Cerner, Misis, Sunquest, others no yes — yes (broadcast download & host query) yes no no/yes/yes no w/in 24 hr —/— yes daily: 3 min; weekly: 5 min; monthly: none no/no	n/a n/a assay dependent yes/yes yes/yes yes yes — yes yes no no/no/no no 24 hr n/a/n/a yes daily: 5 min; weekly: 30 min yes/no
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/ purchase/Advanced operator training	\$62,000/all bed sizes, all test volumes included in reagent rental 1-2 days at vendor's facility or on site/as needed	\$75,000/medium- and large-sized hospitals — 3 days/yes
Distinguishing features (supplied by vendor)	only system (reagents & instrument) FDA cleared; moderate complexity rating; automation-ready reagents; user friendly SW for rapid training	selectively open system; multiple assays on a plate; Windows 2000 software; continuous loading of samples, reagents, and microplates; primary tube sampling; bidirectional interface

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

# Automated immunoassay analyzers

<p><b>Part 14 of 23</b></p> <p><i>See accompanying article on page 18</i></p>	<p>DiaSorin Inc. Patricia Kilbo trish.kilbo@diasorin.com 1951 Northwestern Ave. Stillwater, MN 55082 800-328-1482 www.diasorin.com</p>	<p>Grifols-Quest Inc. John Medders john.medders@grifols.com 8880 NW 18th Terr. Miami, FL 33172 800-379-0957 www.grifols-quest.com</p>
<p>Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>Liaison/1997/Germany Germany/U.S., Italy 10/&gt;800 batch, continuous random access/benchtop/rack 63 x 136 x 66 cm/9.9 sq ft</p>	<p>Triturus/1999/Spain Spain/U.S., Germany 60/600 batch, random access &amp; cont. random access/benchtop/universal carousel 28.3 x 41.3 x 34.3 in/10 sq ft</p>
<p>Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development  User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers</p>	<p>25 hydroxyvitamin D, intact PTH  — EBV IgM, EBNA IgG, EA IgG, VCA IgG, CMV IgG, CMV IgM CEA, PSA, fPSA, CA 15-3, CA-125, CA 19-9, TPA-M, EBV IgM, EBNA IgG, EA IgG, VCA IgG, CMV IgG, CMV IgG avidity, CMV IgM, toxo IgG, toxo IgM, toxo IgG avidity, HSV 2 IgG, HSV I/II IgM, HSV I/II IgG, HCG, B2M, HAV, HAV IgM, prolactin, LH, FSH, Sangtec 100, AFP, HCG, ferritin, TSH, FT3, FT4, T3, T4, anti-TG, TG, anti-TPO, rubella IgG, rubella IgM, HBsAg, HBsAg confirmatory, anti-HBs, anti HBe, HBe IgM, HBe, anti-HBe, troponin I, CK-MB, myoglobin, cortisol, c-peptide, Brahms procalcitonin — ANA screen, dsDNA, borrelia, testosterone, estradiol, progesterone, cyclosporin, everolimus, HSV-I IgG n/a autoimmune, S-100, avidity tests</p>	<p>system is completely open, any EIA procedure can be programmed. Infectious diseases, autoimmune diseases, endocrinology, oncology markers, hepatitis and HIV profiles n/a n/a n/a  n/a n/a  n/a n/a</p>
<p>Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate</p>	<p>no n/a n/a/n/a</p>	<p>yes 8 min. strip: 1, 8 wells; max. full plate: 96 wells, can accommodate 4 plates at a time</p>
<p>Methods supported/Separation methods  No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result &amp; reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time</p>	<p>chemiluminescence/magnetic particle  15 15 0 15/100 8/28 days/yes (12°C) no yes yes/all lot information no/no 75/120/1,500 no/liquid yes/720 no assay dependent 5 µL/200 µL yes/no no — yes/75 µL yes/—/no yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes — yes yes/yes yes yes/yes no/no yes/yes yes/no 2 min no 2 yes/28 days yes/no no/yes no/no/2 min</p>	<p>EIA/coated microwell, onboard shaker, 4 individually temperature-controlled incubators 1–8 tests on 1–4 plates 8 assays unlimited 8/96  n/a/n/a/no yes requires operator prehandling/preparation no yes/&lt;5 ppm 180/92/8 yes/liquid no no 200 µL 2 µL/300 µL yes/no but has external waste port to drain into sink or floor drain no/n/a — yes/50 µL yes/12, 13, 14, 16 mm/no yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes yes yes yes/yes yes yes/yes no/no yes/yes yes/yes  n/a yes 1–14 no/check every month yes/yes each run no/no yes/yes/1–2 min</p>
<p>Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module</p>	<p>n/a 2 min — yes/yes no/yes (additional) — yes — — yes (host query) yes no no/no/no no 24 hr —/— yes daily: 10 min; weekly: 20 min; monthly: 30 min no/no</p>	<p>system is open, depends on reagent methodology n/a depends on reagent methodology  yes/yes onboard/yes (additional) all major LISs yes yes LIS—unidirectional or bidirectional yes (host query &amp; broadcast download) yes no yes/yes/yes  no 24–48 hr —/24–48 hr yes daily: 5–20 min; weekly: n/a; monthly: n/a yes (includes audit trail of who replaced parts)/yes</p>
<p>List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/ purchase/Advanced operator training</p>	<p>\$125,000/— inquire 3 days on site/yes</p>	<p>\$69,000/300+ or higher \$12,000 4 days on site/yes</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>benchtop analyzer with high throughput; unique menu offering</p>	<p>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</p>

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

# Automated immunoassay analyzers

<p><b>Part 15 of 23</b></p> <p>See accompanying article on page 18</p>	<p>Hycor Biomedical Inc. cs@hycorbiomedical.com 7272 Chapman Ave. Garden Grove, CA 92841 714-933-3000 www.hycorbiomedical.com</p> <p style="text-align: center;">See our ad on page 19</p>	<p>Hycor Biomedical Inc. cs@hycorbiomedical.com 7272 Chapman Ave. Garden Grove, CA 92841 714-933-3000 www.hycorbiomedical.com</p> <p style="text-align: center;">See our ad on page 19</p>
<p>Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>Hy•Tec 288/outside U.S. 1998, U.S. 1999/Netherlands Netherlands/U.S., Scotland 43/85 random batches/benchtop/rack-robotics 29.5 x 42.5 x 27.5 in/8 sq ft</p>	<p>Hy•Tec 480/1994/Switzerland Switzerland/U.S., Scotland 8/57 random batches/benchtop/rack-robotics 19.7 x 55 x 28 in/10.6 sq ft</p>
<p>Tests available on instrument in U.S.  Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries  Research-use-only assays Tests in development  User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers</p>	<p>specific IgE, total IgE, &gt;1,000 allergens; ANA scr., TG, TPO, dsDNA, RF IgG, RF IgM, PR-3 c-ANCA, MPO p-ANCA &amp; anti-mitochondrial, ENA-6 scr., SS-A, SS-B, gliadin IgG &amp; IgA, Sm, Sm/RNP, Scl-70, Jo-1, GPC, GBM, cardiolipin IgG &amp; IgM, cardiolipin scr.; anti-β-2 GPI; user-definable software</p> <p>anti-tissue transglutaminase IgA none specific IgG, cardiolipin IgA, cardiolipin IgA, ssDNA, total rheumatoid factor, anti-phosphatidyl serine scr., anti-phosphatidyl serine IgG, IgM, anti-tissue transglutaminase IgA none anti-tissue transglutaminase IgG</p> <p><i>H. pylori</i> allergy &amp; autoimmune testing on fully automated system</p>	<p>specific IgE, total IgE, &gt;1,000 allergens; ANA scr., TG, TPO, dsDNA, RF IgG &amp; IgM, PR-3 c-ANCA, ENA-6 scr., SS-A, SS-B, gliadin IgG &amp; IgA, Sm, Sm/RNP, Scl-70, Jo-1, GPC, GBM, MPO p-ANCA, mitochondrial, cardiolipin IgG &amp; IgM, cardiolipin scr.; anti-β-2 GPI, <i>H. pylori</i>; user-definable software</p> <p>anti-tissue transglutaminase IgA none IgG, cardiolipin IgA, ssDNA, total rheumatoid factor, anti-phosphatidyl serine scr., anti-phosphatidyl serine IgG &amp; IgM none anti-tissue transglutaminase IgG</p> <p><i>H. pylori</i> allergy &amp; autoimmune testing on fully automated system</p>
<p>Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate</p>	<p>yes 8 (1 analyte per well; multiple analytes per well/screens; up to 8 analytes per run) 96-min. strip: 1 strip/8 wells; max. full plate: 12 strips/96 wells</p>	<p>yes 8 (1 analyte per well; multiple analytes per well/screens) 96-min. strip: 8 wells/1 strip; max. full plate: 12 strips/96 wells</p>
<p>Methods supported/Separation methods  No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result &amp; reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time</p>	<p>EIA, tube-based &amp; microplate-based assays/cellulose disc &amp; coated well</p> <p>varies by assay, up to 288 allergens or 8 autoimmune multiple unlimited varies by assay, up to 288 allergens or 8 autoimmune</p> <p>8 hr/12 hr/no yes yes no yes/&lt;1 part in 10,000 assay dependent/100/288 yes/liquid no no 10 µL, 110 µL w/ dead vol. 10 µL-50 µL, assay dependent//100 µL yes/no no/— — no yes/—/no yes (2 of 5 interl., codabar, codes 39 &amp; 128)/n/a no yes yes/yes yes no/no no/no yes/no no/no n/a yes 1-5 no/monthly yes/yes every assay yes/yes yes/no/2-3 min</p>	<p>EIA, tube-based &amp; microplate-based assays/cellulose disc &amp; coated well</p> <p>varies by assay, up to 480 multiple multiple 1/200-allergy, 96-autoimmune</p> <p>8 hr/12 hr/no yes yes no yes/&lt;1 part in 10,000 assay dependent/100/480 yes/liquid no no 10 µL, 310 µL w/ dead vol. 10 µL-50 µL, assay dependent//300 µL yes/no no/— — no yes/—/no yes (2 of 5 interl., codabar, codes 39 &amp; 128)/n/a no yes yes/yes yes no/no no/no yes/no no/no n/a yes 1-5 no/monthly yes/yes every assay yes/yes yes/no/5 min</p>
<p>Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module</p>	<p>n/a n/a n/a yes/yes onboard/optional 25 no no n/a yes optional no yes/yes/no no 48 hr 7 months/4 hr yes daily: 10-15 min; weekly: 20-25 min; monthly: 20-25 min yes (includes audit trail of who replaced parts)/yes</p>	<p>n/a n/a n/a yes/yes onboard/no 30 no no n/a yes yes no no 48 hr 10 months/4 hr yes daily: 10-15 min; weekly: 20-25 min; monthly: 20-25 min no/no</p>
<p>List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/ purchase/Advanced operator training</p>	<p>\$55,000/all sites, variable test vols. \$5,500 3 days on site/yes</p>	<p>\$75,000/all sites, variable test vols. \$7,500 3 days on site, 3 days at vendor offices/yes</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>fully automated allergy and autoimmune testing; &gt;1,000 allergens; user-definable software</p>	<p>fully automated allergy and autoimmune testing; &gt;1,000 allergens; open software</p>

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



# Automated immunoassay analyzers

<p><b>Part 16 of 23</b></p> <p><i>See accompanying article on page 18</i></p>	<p>Nichols Institute Diagnostics  <b>Bill Wilson</b> wilsonb@nicholsdiag.com          1311 Calle Batido, San Clemente, CA 92673          800-286-4NID (4643)          nicholsdiag.com</p>	<p>Olympus America Inc.  <b>Susan Watanabe</b> susan.watanabe@olympus.com          Two Corporate Center Dr., Melville, NY 11747          800-223-0125          www.olympus.com</p>
<p>Name of instrument/First year sold/Where designed          Country where manufactured/Where reagents manufactured          No. of units in clinical use in U.S./Outside U.S.          Operational type/Model type/Sample handling system          Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>Nichols Advantage Specialty System/1997/Germany          U.S./U.S.          &gt;120/&gt;160          batch, cont. random access/benchtot/rack          44 x 45 x 26 in/8 sq ft</p>	<p>AU400e/2002; AU400/1999/Japan          Japan/U.S., Ireland          &gt;500/&gt;1,500          cont. random access/floor-standing/rack &amp; turntable          47.6 x 57.1 x 29.9 in/70 x 129 in</p>
<p>Tests available on instrument in U.S.</p> <p>Tests cleared but not clinically released          Tests not available in U.S. but submitted for clearance          Tests not available in U.S. but available in other countries          Research-use-only assays          Tests in development          User-defined methods implemented for what analytes          Tests not available on other manufacturers' analyzers</p>	<p>ACTH, cortisol, urinary cortisol, EPO, ferritin, sTfR, CT, intact PTH, hGH, IGF-1, FT<sub>3</sub>, FT<sub>4</sub>, 3rd-gen. TSH, TG, anti-TG, anti-TPO, DHEAS, Bio-Intact PTH (1-84), 25 hydroxyvit D, direct renin, IGF BP-3, aldosterone, <i>H. pylori</i> IgG, Quick-IntraOperative Bio-Intact PTH (1-84)</p> <p>none          —          ITA          osteocalcin          1,25 dihydroxyvit D, <i>H. pylori</i> IgA, total hCG, AFP, UE3, C-peptide, insulin          none          IGF-1, calcitonin, Bio-Intact PTH (1-84), 25 hydroxyvit D, direct renin, aldosterone          sTfR, Quick-IntraOperative Bio-Intact PTH (1-84)</p>	<p>α1-acid glycoprotein, α1-antitrypsin, anti-streptolysin O, apolipo. A1 &amp; B, β-2-microglobulin, CRP, high-sensitivity CRP, CRP for pediatrics, C3 &amp; C4 complement, ferr., haptoglobin, immunogl. A, G, M, microalbumin, prealb., rheum. factor, transferrin, acetamin., amikacin, caffeine, carbamaz., digoxin, disopyramide, ethosux., gentamicin, lidocaine, methotrexate, N-acetylprocain., phenobarb., phenytoin, primidone, procain., quinidine, salicylate, theoph., tobramycin, valp. acid, vancomycin, amphet., barb., benzodiazep., cannab., cocaine metab., ethanol, LSD, methadone, methaqa., opiate, PCP, propoxyphene, tox barb., tox benzo., tox tricyc., T<sub>4</sub> thyrox. Also, general chemistries, enzymes, direct HDL &amp; direct LDL ceruloplasmin, HbA1c, lithium, cholinesterase, urinary protein</p> <p>none          cotinine          none          none          fructosamine          none</p>
<p>Fully automated microplate system          No. of each analyte performed in separate disposable unit          No. of wells in microplate</p>	<p>no          n/a          n/a</p>	<p>no          n/a          n/a</p>
<p>Methods supported/Separation methods          No. of different measured assays onboard simultaneously          No. of different assays programmed, calibrated at once          No. of user-definable (open) channels          No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set          Shortest/Median onboard reagent stability/Refrigerated onboard          Multiple reagent configurations supported          Reagent container placed directly on system for use          Reagents bar coded/Information in bar code          Same capabilities when 3rd-party reagents used/Susceptibility to carryover          Walkaway capacity in minutes/Specimens/Tests-assays          System is open (home-brew methods can be used)/Liquid or dry system          Uses disposable cuvettes/Max. No. stored          Uses washable cuvettes/Replacement frequency          Minimum specimen vol. required          Minimum sample vol. aspirated precisely at once/Min. dead vol.          Supplied with UPS (backup power)/Requires floor drain          Requires dedicated water system/Water consumption          Noise generated          Has dedicated pediatric sample cup/Dead vol.          Primary tube sampling/Tube sizes/Pierces caps on primary tubes          Sample bar-code reading capability/Autodiscrimination          Bar-code placement per NCCLS standard Auto2A          Onboard test auto inventory (determines vol. in container)          Measures No. of tests remaining/Short sample detection          Auto detection of adequate reagent or specimen          Clot detection/Reflex testing capability          Hemolysis detection-quantitation/Turbidity detection-quantitation          Dilution of patient samples onboard/Automatic rerun capability          Sample vol. can be increased to rerun out-of-linear range high results/            Increased to rerun out-of-linear range low results          Time between initial result &amp; reaspiration of sample for rerun          Autocalibration or autocalibration alert          No. of calibrators required for each analyte          Calibrants can be stored onboard/Avg. calibration frequency          Multipoint calib. supported/Multiple calibs. stored for same assay          How often QC required          Onboard real-time QC/Support multiple QC lot Nos. per analyte          Automatic shutdown/Startup is programmable/Startup time</p>	<p>chemiluminescence/magnetic particle          15          15          0          15/varies, typically 100          8 h/—/yes (17°C)          no          no, requires operator prehandling, preparation          yes/assay ID, lot No., serial No., expir.          no/≤5x10<sup>-5</sup>          up to 480/120/15 x 100=1,500          no/liquid          yes/120          no          assay dependent          10 µL/200 µL          yes/no          no/—          67          yes/100 µL          yes/10 x 75, 16 x 100 mm/no          yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes          no          yes          yes/yes          yes          yes/yes          no/no          yes/yes          no/no          37 min          no          2          no/7 days          yes/no          shortest interval: 4 hr, longest: 8 hr          no/no          no/no/10 min</p>	<p>EIA, photometric, potentiometric, calc. results/none (all homogeneous)          &gt;40          99          95          76/100-6,160          168 h/60 days/yes (4-12°C)          yes          yes          yes/reag. ID, lot No., bottle No., expir.          yes/n/a          variable/up to 102/8,058          yes/liquid          no          yes/permanent          2 µL per test          2 µL/25 µL          optional/yes          yes/20 L per h @ peak consump.          &lt;65          no          yes/pediatric, 5 mL, 7 mL, 10 mL/no          yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes          yes          yes          yes/yes          yes          yes/yes          yes/yes          yes/yes          yes/yes          varies by run size          yes          1-6          yes/14 days          yes/yes          lab-defined          yes/yes          yes/yes/24 h availability</p>
<p>Stat time to completion of β-hCG test          Time delay from ordering stat test to aspir. of sample          Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)          Can auto transfer QC results to LIS/Onboard capability to review QC          Data management capability/Instrument vendor supplies LIS interface          Interfaces up and running in active user sites with</p> <p>LIS interface operates simultaneously w/ running assays          Uses LOINC to transmit orders and results          How labs get LOINC codes for reagent kits          Bidirectional interface capability          Results transmitted to LIS as soon as test time complete          Interface available (or will be) to auto specimen handling system          Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component          Can order (via modem) malfunctioning part(s) w/o operator          On-site response time of service engineer          Mean time between failures/To repair failures          Onboard error codes to facilitate troubleshooting          Avg. time to complete maintenance by lab personnel          Onboard maintenance records/Maintenance training demo module</p>	<p>n/a          n/a          up to 55/up to 165 (—)          yes/yes          onboard/yes (included in price)          all commercially available LISs</p> <p>yes          yes          —          yes (broadcast download &amp; host query)          yes          no          no/yes/yes          no          24 hr          90 days/24 hr          yes          daily: 10 min; weekly: 30-45 min; monthly: 5 min          no/no</p>	<p>n/a          &lt;1 min          133.3/400 (9 sec)          yes/yes          onboard/yes (add'l cost)          Cerner, Antrim, CCA, Chemware, Dawning, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSi, Mediatech, Misis, Orchard, Citation</p> <p>yes          no          n/a          yes (broadcast download &amp; host query)          yes          yes          yes/yes/yes          no          &lt;24 hr          &gt;30 weeks/&lt;24 hr          yes          daily: 3 min; weekly: 7 min; monthly: 45 min          yes (incl. audit trail of who replaced parts)/yes</p>
<p>List price/Targeted bed size or daily volume          Annual service contract cost (24 hours/7 days)          Training provided w/ purchase/Advanced operator training</p>	<p>\$125,000/300+ beds          inquire          4 days at vendor offices/yes</p>	<p>\$130,000/200-2,000 tests per day (depending on menu)          inquire          5 days on site, 5 days at vendor offices/yes</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>the fully automated continuous random access chemiluminescence system can run specialty assays as if they are routine; bar coding of primary sample tubes, reagents, stored master curve and two-point calib.; assures ease of use and minimizes hands-on time; onboard refrigeration</p>	<p>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</p>

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

# Automated immunoassay analyzers

<b>Part 17 of 23</b>	<p>Ortho-Clinical Diagnostics, a Johnson &amp; Johnson Company                  Sean O'Connor soconnor@ocdus.jnj.com                  1001 U.S. Highway 202, Raritan, NJ 08869                  800-828-6316 or 908-218-1300                  www.orthoclinical.com</p>	<p>Ortho-Clinical Diagnostics, a Johnson &amp; Johnson Company                  Sean O'Connor soconnor@ocdus.jnj.com                  1001 U.S. Highway 202, Raritan, NJ 08869                  800-828-6316 or 908-218-8674                  www.orthoclinical.com</p>
<i>See accompanying article on page 18</i>		
<p>Name of instrument/First year sold/Where designed                  Country where manufactured/Where reagents manufactured                  No. of units in clinical use in U.S./Outside U.S.                  Operational type/Model type/Sample handling system</p>	<p>Vitros ECI Immunodiagnostic System/1997/U.S.                  U.S./U.K.                  &gt;2,000 worldwide                  cont. random access/floor standing/universal sample racks (circular) accommodate primary &amp; secondary containers without need for adapters</p>	<p>Vitros ECIQ Immunodiagnostic System/2004/U.S.                  U.S./U.K.                  n/a/n/a                  cont. random access/floor standing/circular universal sample trays accommodate primary &amp; secondary containers without need for adapters</p>
<p>Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>51 x 44 x 29 in/8.9 sq ft</p>	<p>51 x 44 x 29 in/8.9 sq ft</p>
<p>Tests available on instrument in U.S.</p>	<p>3rd-gen. TSH, TT<sub>3</sub>, TT<sub>4</sub>, FT<sub>3</sub>, FT<sub>4</sub>, T<sub>3</sub>-uptake, total β-hCG, estradiol, progesterone, LH, FSH, prolactin, N-telopeptide, CEA, AFP, CA 125 II, CA 15-3, ferritin, cortisol (serum and urine), CK-MB, troponin I, aHBs, B<sub>12</sub>, folate, RBC folate, equimolar PSA, HBsAg, aHCV, HBsAg (conf.), myoglobin, aHbC, aHbC IgM</p>	<p>3rd-gen. TSH, TT<sub>3</sub>, TT<sub>4</sub>, FT<sub>3</sub>, FT<sub>4</sub>, T<sub>3</sub>-uptake, total β-hCG, estradiol, progesterone, LH, FSH, prolactin, N-telopeptide, CEA, AFP, CA 125 II, CA 15-3, equimolar PSA, ferritin, B<sub>12</sub>, folate, RBC folate, cortisol (serum and urine), CK-MB, troponin I, myoglobin, HBsAg, aHBs, aHCV, HBsAg (conf.), aHbC, aHbC IgM</p>
<p>Tests cleared but not clinically released                  Tests not available in U.S. but submitted for clearance                  Tests not available in U.S. but available in other countries                  Research-use-only assays                  Tests in development                  User-defined methods implemented for what analytes                  Tests not available on other manufacturers' analyzers</p>	<p>none                  none                  CA 19-9, fβ-hCG, a-HbC IgM, a-HbC, a-HAV IgM, a-HBe, HBeAg, a-HIV I&amp;II, aHAV total                  none                  HIV 1/2, BNP, rubella IgG, rubella IgM, toxo. IgG, toxo. IgM, CMV IgG, CMV IgM                  none                  NTx</p>	<p>none                  none                  a-HAV IgM, a-HBe, HBeAg, a-HIV I&amp;II, CA 19-9, free β-hCG, aHAV total                  none                  rubella IgG, rubella IgM, toxo. IgG, toxo. IgM, CMV IgG, CMV IgM                  none                  N-telopeptide</p>
<p>Fully automated microplate system                  No. of each analyte performed in separate disposable unit                  No. of wells in microplate</p>	<p>no                  n/a                  n/a</p>	<p>no                  n/a                  n/a</p>
<p>Methods supported/Separation methods                  No. of different measured assays onboard simultaneously                  No. of different assays programmed, calibrated at once                  No. of user-definable (open) channels                  No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set                  Shortest/Median onboard reagent stability/Refrigerated onboard                  Multiple reagent configurations supported                  Reagent container placed directly on system for use                  Reagents bar coded/Information in bar code                  Same capabilities when 3rd-party reagents used/Susceptibility to carryover                  Walkaway capacity in minutes/Specimens/Tests-assays                  System is open (home-brew methods can be used)/Liquid or dry system                  Uses disposable cuvettes/Max. No. stored                  Uses washable cuvettes/Replacement frequency                  Minimum specimen vol. required                  Minimum sample vol. aspirated precisely at once/Min. dead vol.                  Supplied with UPS (backup power)/Requires floor drain                  Requires dedicated water system/Water consumption                  Noise generated                  Has dedicated pediatric sample cup/Dead vol.                  Primary tube sampling/Tube sizes/Pierces caps on primary tubes                  Sample bar-code reading capability/Autodiscrimination                  Bar-code placement per NCCLS standard Auto2A                  Onboard test auto inventory (determines vol. in container)                  Measures No. of tests remaining/Short sample detection                  Auto detection of adequate reagent or specimen                  Clot detection/Reflex testing capability                  Hemolysis detection-quantitation/Turbidity detection-quantitation                  Dilution of patient samples onboard/Automatic rerun capability                  Sample vol. can be increased to rerun out-of-linear range high results/                  Increased to rerun out-of-linear range low results                  Time between initial result &amp; reaspiration of sample for rerun                  Autocalibration or autocalibration alert                  No. of calibrators required for each analyte                  Calibrants can be stored onboard/Avg. calibration frequency                  Multipoint calib. supported/Multiple calibs. stored for same assay                  How often QC required                  Onboard real-time QC/Support multiple QC lot Nos. per analyte                  Automatic shutdown/Startup is programmable/Startup time</p>	<p>chemiluminescence (enhanced)/individual coated microwell                  20                  20 programmed &amp; calibrated at once; up to 25 lots calibrated per assay                  0                  20/100                  56 days/56 days/yes (2°-8°C)                  yes                  yes                  yes/test ID, expir., lot No., pack ID                  —/zero carryover                  360/60/400                  no/liquid                  —                  yes/2,000                  no                  10 μL/60 μL                  available/—                  no/—                  60 decibels                  no                  yes/mult. ped., microtainers &amp; cups, 5mL, 7mL, 10mL on same univ. sample tray/no                  yes (2 of 5 interl., codabar, codes 39 &amp; 128, &amp; ISBT 128)/yes                  yes                  yes                  yes/yes                  yes                  yes/yes                  no/no                  yes/yes                  no/—                  assay dependent                  yes                  1-3                  no/28 days                  yes/yes                  1 per day                  yes/yes                  yes/yes/24 hr availability</p>	<p>chemiluminescence (enhanced)/individual coated microwell                  20                  20; up to 25 lots calibrated per assay                  0                  20/100                  56 days/56 days/yes (2°-8°C)                  yes                  yes                  yes/test ID, expir., lot No., pack ID                  yes/zero carryover                  360/60/400                  no/liquid                  no                  10 μL                  10 μL/60 μL                  no, but it is available/no                  no/—                  60 decibels                  no                  yes/mult. ped., microtainers &amp; cups, 5mL, 7mL, 10mL on same univ. sample tray/no                  yes (2 of 5 interl., codabar, codes 39 &amp; 128, &amp; ISBT 128)/yes                  yes                  yes                  yes/yes                  yes                  yes/yes                  no/no                  yes/yes                  no/no                  —                  yes                  1-3                  no/28 days                  yes/yes                  once per day                  yes/yes                  yes/yes/immediate upon completion of last sample metering</p>
<p>Stat time to completion of β-hCG test                  Time delay from ordering stat test to aspir. of sample                  Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)                  Can auto transfer QC results to LIS/Onboard capability to review QC                  Data management capability/Instrument vendor supplies LIS interface                  Interfaces up and running in active user sites with                    LIS interface operates simultaneously w/ running assays                  Uses LOINC to transmit orders and results                  How labs get LOINC codes for reagent kits                  Bidirectional interface capability                  Results transmitted to LIS as soon as test time complete                  Interface available (or will be) to auto specimen handling system                  Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component                  Can order (via modem) malfunctioning part(s) w/o operator                  On-site response time of service engineer                  Mean time between failures/To repair failures                  Onboard error codes to facilitate troubleshooting                  Avg. time to complete maintenance by lab personnel                  Onboard maintenance records/Maintenance training demo module</p>	<p>24 min                  upon completion of last sample metering                  30/90 (40 sec)                  yes/yes                  onboard/no                  Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, PHCP, INS, Siemens, Dawning                  yes                  yes                  —                  yes (broadcast download)                  yes                  yes (all systems)                  yes/yes/yes                  no                  &lt;4 hr (contract dependent)                  —/dependent on corrective action                  yes                  daily: &lt;5 min; weekly: &lt;30 min; monthly: &lt;10 min                  no/yes</p>	<p>24 min                  immediate upon completion of last sample metering                  30/90 (40 sec)                  yes/yes                  onboard/no                  Cerner, Misys, Meditech, CHCS, Antrim, PathLab 2, RPNS VA, Citation, DHCP, Unisys, McKesson, PathLab 3, Soft, LabForce, DynaMedix, Dynacore, Psyche, Ascent, PHCP, INS, Siemens, Dawning, others                  yes                  yes                  —                  yes (broadcast download)                  yes                  yes (all systems)                  yes/yes/yes                  no                  &lt;4 hr (contract dependent)                  dependent on corrective action/dependent on corrective action                  yes                  daily: &lt;5 min; weekly: &lt;30 min; monthly: &lt;10 min                  no/yes</p>
<p>List price/Targeted bed size or daily volume                  Annual service contract cost (24 hours/7 days)                  Training provided w/ purchase/Advanced operator training</p>	<p>\$140,000/flexible for majority of customer demand                  varies w/ service level choices                  3.5 days at vendor offices/yes, as needed on site</p>	<p>\$150,000/flexible for majority of customer demand                  varies w/ service level choices                  as needed on site, 3.5 days at vendor offices/—</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>provides simple to use, fully automated, true random access testing for routine and specialty immunodiagnostic testing; uses Intellicheck technology to verify diagnostic checks throughout sample and assay processing, significantly reducing misreported results</p>	<p>provides simple to use, fully automated, true random access testing for routine and specialty immunodiagnostic testing; new Intellicheck Technology enhancements are included to verify all sample and assay processing steps to significantly reduce the potential of misreported results along with an IntelliReport for traceability; enhanced ergonomics with adjustable flat, low-glare touchscreen monitor and keyboard platform with a multi-position support arm</p>

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

# Automated immunoassay analyzers

<b>Part 18 of 23</b>	Pharmacia Diagnostics AB Lorraine Damico lorraine.damico@pharmacia.com 7000 Portage Road, 248-DIA Kalamazoo, MI 49001-0199 800-346-4364 www.us.diagnostics.com	Pharmacia Diagnostics AB Lorraine Damico lorraine.damico@pharmacia.com 7000 Portage Road, 248-DIA Kalamazoo, MI 49001-0199 800-346-4364 www.us.diagnostics.com
<i>See accompanying article on page 18</i>		
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system	ImmunoCap 250 system/2004/Japan, Sweden Japan, Sweden/Sweden —/— random access/floor standing/racks	ImmunoCap 1000 system/2003/Japan, Sweden Japan, Sweden/Sweden ~10/~200 continuous random access/floor standing/racks
Dimensions in inches (H x W x D)/Instrument footprint in square feet	73 x 50 x 30 in + 26 in wide computer stand/—	83 x 71 x 40 in + 26 in wide computer stand/—
Tests available on instrument in U.S.	greater than 550 ImmunoCap specific IgE tests, ImmunoCAP total IgE, and ImmunoCap specific IgG* tests	greater than 550 ImmunoCap specific IgE tests, ImmunoCap total IgE, and ImmunoCap specific IgG* tests
Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	— — — *specific IgG is for investigational use only —	— — — *specific IgG is for investigational use only —
User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers	— Pharmacia Diagnostics AB ImmunoCap assays	— Pharmacia Diagnostics AB ImmunoCap assays
Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate	no — —	no — —
Methods supported/Separation methods No. of different measured assays onboard simultaneously	fluoroenzyme immunoassay (FEIA)/ImmunoCap cellulose polymer matrix reaction wells 3 methods	fluoroenzyme immunoassay (FEIA)/ImmunoCap cellulose polymer matrix reaction wells 3 methods
No. of different assays programmed, calibrated at once	not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory	not limited, though inventory manager software will instruct operator of reagent insufficiencies in the onboard inventory
No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	0, closed system 3/400 or 100 depending on the conjugate type	0, closed system 3/400 or 100 depending on the conjugate type
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result & reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time	5 days/1 yr/yes (2-8°C) yes yes (wash solution requires preparation) yes/product name, lot No., expiration date no/— —/50 simultaneously/370 per run no/liquid no n/a 40 µL 40 µL/40-200 µL (varies with tube type) yes/no no/10 L 65 dBA no yes/10-17 mm x 50-105 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes no yes yes/yes yes yes/yes no/no no/yes no/no 100 min yes 6 per analyte for calibration run, and 2 per analyte when using stored curve yes/28 days or sooner if conjugate lots change yes/yes once per work shift (user defined) yes/yes yes/yes/30 minutes unattended	5 days/1 yr/yes (2-8°C) yes yes (wash solution requires preparation) yes/product name, lot No., expiration date no/zero carryover (disposable sample tips) —/200 simultaneously/depends on shift length & No. no/liquid no n/a 40 µL per test 40 µL/40-200 µL (varies with tube type) yes/no no/10 L 68 dBA no yes/10-17 mm x 50-105 mm/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes no yes yes/yes yes yes/yes no/no no/yes no/no 100 min yes 6 per analyte for calibration run, and 2 per analyte when using stored curve yes/28 days or sooner if conjugate lots change yes/yes once per work shift (user defined) yes/yes yes/yes/30 minutes unattended
Stat time to completion of B-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with  LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module	n/a 6 min 20 specimens/60 (100 minutes to first result, then 1 result per 60 seconds) yes/yes onboard/yes (instrument side only) Mitsys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others yes no n/a yes (broadcast download & host query) yes yes yes/yes/yes no <24 hr —/ yes daily: 1 min; weekly: 10 min; monthly: 15 min yes/—	n/a 6 min 80 specimens/240 (100 minutes to first result, then 1 result per 15 seconds) yes/yes onboard/yes (instrument side only) Mitsys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others yes no n/a yes (broadcast download & host query) yes yes yes/yes/yes no <24 hr —/ yes daily: 1 min; weekly: 10 min; monthly: 15 min yes/—
List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/ purchase/Advanced operator training	\$75,000/>20,000-95,000 tests per year \$7,200 (24/7) or \$5,400 (business hours only) 3.5 days at vendor offices/yes	\$235,000/>95,000 tests per year \$18,000 4.5 days at vendor offices/yes
Distinguishing features (supplied by vendor)	allergy diagnostics is our core business; these are not "add-on" tests; this system and reagents are designed to provide the most accurate specific allergy diagnostic results and use well documented ImmunoCap technology; supported by a dedicated sales force to drive business development programs that help labs increase the services they offer physicians and outreach revenue for lab	allergy diagnostics is our core business; these are not "add-on" tests; this system and reagents are designed to provide the most accurate specific allergy diagnostic results and use well documented ImmunoCap technology; supported by a dedicated sales force to drive business development programs that help labs increase the services they offer physicians and outreach revenue for lab

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

# Automated immunoassay analyzers

<p><b>Part 19 of 23</b></p> <p><i>See accompanying article on page 18</i></p>	<p>Pharmacia Diagnostics AB Lorraine Damico lorraine.damico@pharmacia.com 7000 Portage Road, 248-DIA Kalamazoo, MI 49001-0199 800-346-4364 www.us.diagnostics.com</p>	<p>Roche Diagnostics Todd Atkinson todd.atkinson@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us</p>
<p>Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>UniCap 100E system/1995/Sweden Sweden/Sweden 400/4,000 batch/benchtop/carousel 18 x 28 x 24 in + computer/—</p>	<p>Elecsys 2010/1996/— Japan/Germany &gt;600/&gt;4,000 cont. random access/benchtop/rack or disk 22.1 x 47.2 x 28.7 in/9.4 sq ft</p>
<p>Tests available on instrument in U.S.</p> <p>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</p> <p>Research-use-only assays Tests in development</p> <p>User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers</p>	<p>greater than 550 ImmunoCap specific IgE tests, ImmunoCap total IgE, gliadin IgA, gliadin IgG are FDA-cleared; and ImmunoCap specific IgG tests*, ECP*, tryptase* are IUO</p> <p>— — ELIA, autoimmune products (available in U.S. through Scimedix); Celikey tTg (tissue transglutaminase) IgA, IgG *ImmunoCap specific IgG tests, ECP, tryptase are investigational use only (IUO)</p> <p>— Pharmacia Diagnostics AB ImmunoCap assays</p>	<p>TSH, FT<sub>4</sub>, T<sub>4</sub>, T<sub>3</sub>, FT<sub>3</sub>, T-uptake, LH, FSH, progesterone, estradiol, prolactin, testosterone, CK-MB, TNT, myoglobin, digoxin, PSA (screen), CEA, CA 125, AFP, ferritin, B<sub>12</sub>, folate, RBC folate, IgE, intact PTH, hCG, cortisol, insulin, fPSA, DHEAS, β-hCG, CA 15-3, anti-TPO, serum β crosslaps, HBsAg, HBeAg (conf), pro BNP, cortisol urine, anti-HBs, SHBG</p> <p>C-peptide</p> <p>— osteocalcin, CA 19-9, anti-HBc, cyfra 21-1, anti-HBs, anti Hbc IgM, anti-HBe, HBeAg, CA 72-4, NSE, anti-TG, infec. diseases, TG, PINP none</p> <p>— none TNT</p>
<p>Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate</p>	<p>no n/a n/a</p>	<p>no n/a n/a</p>
<p>Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once</p> <p>No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result &amp; reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time</p>	<p>fluoroenzyme immunoassay (FEIA)/ImmunoCap cellulose polymer matrix reaction wells 4 7</p> <p>0, closed system 48-96 depending on the conjugate type</p> <p>n/a yes yes (wash solution requires preparation) yes/product name, lot No., expiration date no/— 180 min/varies with analyte/48 no/liquid no n/a 40 µL per test 40 µL/40-200 µL (varies with tube type) yes/no no/1 L per run — no yes/10-16 mm x 50-105 mm/no yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes no no no/yes yes yes/yes no/no yes/yes no/no 2.5 hr-batch run yes 6 per analyte for calibration run, and 2 per analyte when using stored curve yes/28 days or sooner if conjugate lots change yes/yes once per work shift (user defined) yes/yes yes/yes/20 min including request entry or downloading</p>	<p>electrochemiluminescence/magnetic particle 15 60</p> <p>0 15/100-200</p> <p>56 days/56 days/yes (20°C) yes yes yes/calib. curve, application params., lot No., expir., reagent name no/zero carryover (disposable sample tips) 120/disk: 30, rack: 100/180 no/liquid yes/— no 10 µL 10 µL/100 µL —/no no/— — no yes/13-16 mm diam./no yes (2 of 5 interl., codabar, codes 39 &amp; 128)/yes — yes yes/yes yes yes/no no/no yes/no no/no</p> <p>— yes 2 no/monthly yes/yes once per 24 hr yes/yes no/no/4 min</p>
<p>Stat time to completion of β-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with</p> <p>LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module</p>	<p>n/a n/a batch analyzer/48/180 min processing time for batch to finish</p> <p>yes/yes onboard/yes, instrument side only (included) Mitsys, Cerner, SCC, Orchard, Antek, Triple-G, Tandem, American Health Net, Antrim, others</p> <p>yes no — yes (broadcast download &amp; host query) yes yes yes/yes/yes no n/a, swap —/— yes daily: 5 min; weekly: 10 min; monthly: 15 min yes/no</p>	<p>9 min (hCG intact) 42 sec 30/88 (42 sec)</p> <p>yes/yes onboard/yes (add'l cost) all major LISs</p> <p>yes no — yes (broadcast download &amp; host query) yes yes (CLAS &amp; Roche task targeted automation) no/yes/no no &lt;24 hr —/— yes daily: 1 min; weekly: 5 min; biweekly: 25 min; monthly: none no/no (training CD-ROM)</p>
<p>List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/ purchase/Advanced operator training</p>	<p>\$22,000/&gt;7,000-20,000 tests per year \$2,500 (swap contract only) 3.5 days at vendor offices/yes</p>	<p>disk: \$120,000, rack: \$135,000/various included w/ reagent rental 3 days at Indianapolis offices/yes</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>allergy diagnostics is our core business; these are not "add-on" tests; this system and reagents are designed to provide the most accurate specific allergy diagnostic results and use well documented ImmunoCap technology; supported by a dedicated sales force to drive business development programs that help labs increase the services they offer physicians and outreach revenue for the lab</p>	<p>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 reagent storage; minimal maintenance</p>

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

# Automated immunoassay analyzers

<b>Part 20 of 23</b>	Roche Diagnostics Todd Atkinson todd.atkinson@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us	Roche Diagnostics Todd Atkinson todd.atkinson@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.roche.com/labsystems/us
<i>See accompanying article on page 18</i>		
<b>Name of instrument/First year sold/Where designed</b> <b>Country where manufactured/Where reagents manufactured</b> <b>No. of units in clinical use in U.S./Outside U.S.</b>	Elecsys 1010/1997/— Switzerland/Germany >200/>2,000	Modular Analytics E170/2001/Japan Japan/Germany >50/>300 (combination of E and EE systems) and >25 Integrated Modular Systems (U.S. only)
<b>Operational type/Model type/Sample handling system</b> <b>Dimensions in inches (H x W x D)/Instrument footprint in square feet</b>	random access/benchtop/sample disk 25.6 x 37 x 25.2 in/6.5 sq ft	continuous random access/floor-standing/rack 96.25 (W) x 43.25 (D) in (Modular E configuration)/approx. 60 sq ft (one module system)
<b>Tests available on instrument in U.S.</b>	TSH, T <sub>3</sub> , T <sub>4</sub> , T-uptake, FT <sub>3</sub> , FT <sub>4</sub> , FSH, LH, prolac., progest., estradiol, testost., CK-MB, TNT, myogl., digoxin, CEA, AFP, PSA (screen), CA 125, ferr., IgE, intact PTH, hCG, cortisol, insulin, fPSA, DHEAS, β-hCG, CA 15-3, anti-TPO, serum β crosslaps, pro BNP, cortisol urine, SHBG, 9-minute PTH	TNT, CK-MB, digoxin, myoglobin, T <sub>4</sub> , T-uptake, TSH 3rd gen, FT <sub>4</sub> , T <sub>3</sub> , FT <sub>3</sub> , ATPO, β-hCG, FSH, LH, progesterone, prolactin, estradiol, DHEA-S, testosterone, CEA, AFP, PSA (screen), fPSA, CA 125, CA 15-3, ferritin, B <sub>12</sub> , folate, RBC folate, intact PTH, β crosslaps, cortisol, insulin, IGE, pro BNP, cortisol urine, SHBG
<b>Tests cleared but not clinically released</b> <b>Tests not available in U.S. but submitted for clearance</b> <b>Tests not available in U.S. but available in other countries</b>	C-peptide — osteocalcin, CA 19-9, cyfra 21-1, CA 72.4, NSE, anti-TG, TG, PINP	C-peptide HBsAg, HBsAg (conf.), anti-HBs 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, PINP
<b>Research-use-only assays</b> <b>Tests in development</b>	none —	none —
<b>User-defined methods implemented for what analytes</b> <b>Tests not available on other manufacturers' analyzers</b>	none TNT	none TNT
<b>Fully automated microplate system</b> <b>No. of each analyte performed in separate disposable unit</b> <b>No. of wells in microplate</b>	no n/a n/a	no — —
<b>Methods supported/Separation methods</b> <b>No. of different measured assays onboard simultaneously</b> <b>No. of different assays programmed, calibrated at once</b> <b>No. of user-definable (open) channels</b> <b>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</b> <b>Shortest/Median onboard reagent stability/Refrigerated onboard</b> <b>Multiple reagent configurations supported</b> <b>Reagent container placed directly on system for use</b> <b>Reagents bar coded/Information in bar code</b> <b>Same capabilities when 3rd-party reagents used/Susceptibility to carryover</b> <b>Walkaway capacity in minutes/Specimens/Tests-assays</b> <b>System is open (home-brew methods can be used)/Liquid or dry system</b> <b>Uses disposable cuvettes/Max. No. stored</b> <b>Uses washable cuvettes/Replacement frequency</b> <b>Minimum specimen vol. required</b> <b>Minimum sample vol. aspirated precisely at once/Min. dead vol.</b> <b>Supplied with UPS (backup power)/Requires floor drain</b> <b>Requires dedicated water system/Water consumption</b> <b>Noise generated</b> <b>Has dedicated pediatric sample cup/Dead vol.</b> <b>Primary tube sampling/Tube sizes/Pierces caps on primary tubes</b> <b>Sample bar-code reading capability/Autodiscrimination</b> <b>Bar-code placement per NCCLS standard Auto2A</b> <b>Onboard test auto inventory (determines vol. in container)</b> <b>Measures No. of tests remaining/Short sample detection</b> <b>Auto detection of adequate reagent or specimen</b> <b>Clot detection/Reflex testing capability</b> <b>Hemolysis detection-quantitation/Turbidity detection-quantitation</b> <b>Dilution of patient samples onboard/Automatic rerun capability</b> <b>Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results</b> <b>Time between initial result &amp; reaspiration of sample for rerun</b> <b>Autocalibration or autocalibration alert</b> <b>No. of calibrators required for each analyte</b> <b>Calibrants can be stored onboard/Avg. calibration frequency</b> <b>Multipoint calib. supported/Multiple calibs. stored for same assay</b> <b>How often QC required</b> <b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b> <b>Automatic shutdown/Startup is programmable/Startup time</b>	electrochemiluminescence IA/ magnetic particle 6 — 0 6/100-200 28 days/28 days/no yes yes yes/calib. curve, application params., lot No., expir., reag. name no/<8 ppm 150/42 1° tube + 24 sample cups/128 no/liquid yes/128 no 10 µL 10 µL/100 µL no/no no/— — yes/— yes/13-16 mm diam./no yes (2 of 5 interl., codabar, codes 39 & 128)/yes — yes yes/yes yes yes/no no/no yes/no no/no — yes 2 no/7 days yes/yes once per 24 hr yes/yes no/no/5 min	electrochemiluminescence/magnetic particle, electrochemiluminescence 25 per E module, maximum of 60 25 per module n/a 25 per module/100-200 56 days/56 days/yes (20°C) yes yes yes/calib. curve, application params., lot No., expir., reag. name n/a/zero, uses disposable sample tips 360/—/1,006 no/liquid yes/— no 10 µL —/100 µL no/no yes/18 per module in full operation — yes/100 µL yes/13 x 75 to 16 x 100/no yes (2 of 5 interl., codabar, codes 39 & 128)/yes — yes yes/yes yes yes/no no/no yes/yes yes/yes — yes 2 no/monthly yes/yes 24 hr yes/yes yes/yes/11 min
<b>Stat time to completion of β-hCG test</b> <b>Time delay from ordering stat test to aspir. of sample</b> <b>Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)</b> <b>Can auto transfer QC results to LIS/Onboard capability to review QC</b> <b>Data management capability/Instrument vendor supplies LIS interface</b> <b>Interfaces up and running in active user sites with</b> <b>LIS interface operates simultaneously w/ running assays</b> <b>Uses LOINC to transmit orders and results</b> <b>How labs get LOINC codes for reagent kits</b> <b>Bidirectional interface capability</b> <b>Results transmitted to LIS as soon as test time complete</b> <b>Interface available (or will be) to auto specimen handling system</b> <b>Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component</b> <b>Can order (via modem) malfunctioning part(s) w/o operator</b> <b>On-site response time of service engineer</b> <b>Mean time between failures/To repair failures</b> <b>Onboard error codes to facilitate troubleshooting</b> <b>Avg. time to complete maintenance by lab personnel</b> <b>Onboard maintenance records/Maintenance training demo module</b>	9 min (hCG intact) 65 sec 20/55 (65 sec) yes/yes onboard/yes (add'l cost) all major LISs yes no — yes (broadcast download & host query) yes no no/yes/no no <24 hr —/— yes daily: 1 min; biweekly: 5 min; monthly: 5 min no/—	18 min — 56/176 (21 sec) yes/yes onboard/yes (add'l cost) all major LISs yes no — yes (broadcast download & host query) yes yes (Roche Modular Pre-Analytical Systems and task targeted automation) yes/yes/no no <24 hr —/— yes daily: 5 min; weekly: 10 min; monthly: 15 min yes/yes
<b>List price/Targeted bed size or daily volume</b> <b>Annual service contract cost (24 hours/7 days)</b> <b>Training provided w/ purchase/Advanced operator training</b>	\$59,000/various included w/ reagent rental 3 days at Indianapolis offices/yes	\$295,000 Modular E; \$470,000 Modular EE; \$645,000 Modular EEE/various incl. w/ reagent rental 5 days at vendor offices/yes
<b>Distinguishing features (supplied by vendor)</b>	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	expandable liquid ready-to-use reagents that are compatible with other Elecsys systems, compatible with Pre-Analytical Automation; ECL technology provides broad measuring range and market, best low-end sensitivity, troponin T, auto-rerun and dilute

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

## Automated immunoassay analyzers

<b>Part 21 of 23</b>	Tosoh Bioscience Inc. Susan Kolarik susan.kolarik@tosohbioscience.com 347 Oyster Point Blvd., #201 South San Francisco, CA 94080 650-615-4970 www.tosohbioscience.com	Tosoh Bioscience Inc. Jane Merschen jane.merschen@tosohbioscience.com 347 Oyster Point Blvd., #201 South San Francisco, CA 94080 650-615-4970 www.tosohbioscience.com
See accompanying article on page 18		
Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet	AIA Nex•IA/1997/Japan Japan/Japan 40/300 cont. random access/floor standing/rack, carousel, TLA 47 x 35 x 26 in/6.3 sq ft	AIA-600 II/2000/Japan Japan/Japan 300/400 cont. random access/benchttop/chain 19.8 x 31.6 x 29.1 in/2.5 sq ft
Tests available on instrument in U.S.	TSH, 3rd-gen. TSH, FT <sub>4</sub> , T <sub>3</sub> , T <sub>4</sub> , T-uptake, FT <sub>3</sub> , 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 <sub>12</sub> , ST-testosterone, CA 19-9	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, HBeAb, HbcAb, toxo IgG & IgM, rubella IgG, CMV IgG	HBsAg, HBsAb, HBeAg, HbcAb, HbeAb, toxo IgG & IgM, rubella IgG, CMV IgG
Research-use-only assays	—	—
Tests in development	RBC folate	RBC folate
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	fluorescence, EIA/bead	fluorescence, EIA/bead
No. of different measured assays onboard simultaneously	>42	26
No. of different assays programmed, calibrated at once	entire menu	entire menu
No. of user-definable (open) channels	0	0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	n/a/unitized test cup	n/a/unitized test cup
Shortest/Median onboard reagent stability/Refrigerated onboard	72 hr/72 hr/n/a	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/lot No., test code	yes/lot No., test code
Same capabilities when 3rd-party reagents used/Susceptibility to carryover	no/zero carryover	no/zero carryover
Walkaway capacity in minutes/Specimens/Tests-assays	52/75-200/400 for the standard model	52/26/26
System is open (home-brew methods can be used)/Liquid or dry system	no/dry	no/dry
Uses disposable cuvettes/Max. No. stored	n/a/unitized test cup	n/a/unitized test cup
Uses washable cuvettes/Replacement frequency	n/a	n/a
Minimum specimen vol. required	500 μL tube, 100 μL cup	500 μL tube, 100 μL cup
Minimum sample vol. aspirated precisely at once/Min. dead vol.	10 μL/50 μL	10 μL/100 μL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption	no/n/a	no/n/a
Noise generated	—	—
Has dedicated pediatric sample cup/Dead vol.	no	no
Primary tube sampling/Tube sizes/Pierces caps on primary tubes	yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100, 13 x 75 & 100/no	yes/primary draw tubes: 7 mL & 10 mL or 15 x 75 & 100, 13 x 75 & 100/no
Sample bar-code reading capability/Autodiscrimination	yes/yes	yes/yes
Bar-code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines vol. in container)	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Auto detection of adequate reagent or specimen	yes	yes
Clot detection/Reflex testing capability	yes/no	yes/no
Hemolysis detection-quantitation/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample vol. can be increased to rerun out-of-linear range high results/Increased to rerun out-of-linear range low results	no/yes	no/yes
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	2 or 6—analyte dependent	2 or 6—analyte dependent
Calibrants can be stored onboard/Avg. calibration frequency	no/60-90 days	no/60-90 days
Multipoint calib. supported/Multiple calibs. stored for same assay	yes/yes	yes/yes
How often QC required	24 hr	24 hr
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	no/no
Automatic shutdown/Startup is programmable/Startup time	no/no/5-8 min	no/no/5 min
Stat time to completion of β-hCG test	~18 min	~18 min
Time delay from ordering stat test to aspir. of sample	90 sec	60 sec
Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)	40/120 (30 sec)	20/60 (1 min)
Can auto transfer QC results to LIS/Onboard capability to review QC	yes/yes	yes/no
Data management capability/Instrument vendor supplies LIS interface	optional add-on (all major LIS vendors—Schuyler House, Misys, LabForce, McKesson, Antrim, Data Innovations)/yes (add'l cost)	optional add-on (all major LIS vendors—Schuyler House, Misys, LabForce, McKesson, Antrim, Data Innovations)/yes (add'l cost)
Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays	Schuyler House, Fletcher Flora	Schuyler House, Fletcher Flora
Uses LOINC to transmit orders and results	yes	yes
How labs get LOINC codes for reagent kits	package insert	package insert
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transmitted to LIS as soon as test time complete	yes	yes
Interface available (or will be) to auto specimen handling system	yes (Hitachi, Lab Interlink, A&T)	no
Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component	no/no/no	no/no/no
Can order (via modem) malfunctioning part(s) w/o operator	no	no
On-site response time of service engineer	24 hr	24 hr
Mean time between failures/To repair failures	98% uptime/—	98% uptime/—
Onboard error codes to facilitate troubleshooting	yes	yes
Avg. time to complete maintenance by lab personnel	daily: 5-8 min; weekly: none; monthly: none	daily: 5 min; weekly: 5 min; monthly: none
Onboard maintenance records/Maintenance training demo module	yes (includes audit trail of who replaced parts)/no	no/no
List price/Targeted bed size or daily volume	\$135,000/65+ beds, 1,500-2,000+ tests	\$70,000/500-2,500 tests per month
Annual service contract cost (24 hours/7 days)	\$10,800	\$5,600
Training provided w/ purchase/Advanced operator training	4 days at vendor offices/no	3 days at vendor offices/no
Distinguishing features (supplied by vendor)	three sample loading options on single system: 200 sample rack loader, TLA adaptable, standard carousel model; unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use	unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use

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

## Automated immunoassay analyzers

<p><b>Part 22 of 23</b></p> <p><i>See accompanying article on page 18</i></p>	<p>Tosoh Bioscience Inc. Eric Yen eric.yen@tosohbioscience.com 347 Oyster Point Blvd., #201 South San Francisco, CA 94080 800-695-6550 ext. 5396 www.tosohbioscience.com</p>	<p>Tosoh Bioscience Inc. Susan Kolarik susan.kolarik@tosohbioscience.com 347 Oyster Point Blvd., #201 South San Francisco, CA 94080 800-695-6550 ext. 5396 www.tosohbioscience.com</p>
<p>Name of instrument/First year sold/Where designed Country where manufactured/Where reagents manufactured No. of units in clinical use in U.S./Outside U.S. Operational type/Model type/Sample handling system Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>AIA 360/2004/Japan Japan/Japan n/a continuous random access/benchtop/carousel 15.75 x 15.75 x 19.69 in/—</p>	<p>AIA 1800/2003/Japan Japan/Japan n/a continuous random access/floor standing/rack, sort drawer, standard and LA 65 x 50 x 37 in/6.3 sq ft</p>
<p>Tests available on instrument in U.S.</p>	<p>ST assays: <math>\beta</math>HCG, BMG, CK-MB, estradiol (E2), FER, FSH, FT<sub>4</sub>, HCG, LH, PRL, testosterone, cortisol, IgEII, CA 125, TSH, T<sub>4</sub>, T-uptake (TU), 27.29, CA 19-9, PROG, CEA, AFP, HGH, insulin (IRI), PAP, MYO, troponin I 2nd gen, PSA, CA 125, C-peptide, TT<sub>3</sub>, FT<sub>3</sub></p>	<p><math>\beta</math>HCG, BMG, CK-MB, estradiol (E2), FER, FSH, FT<sub>4</sub>, HCG, LH, PRL, testosterone, cortisol, IgEII, CA 125, TSH, T<sub>4</sub>, T-uptake (TU), 27.29, CA 19-9, PROG, CEA, AFP, HGH, insulin (IRI), PAP, MYO, troponin I 2nd gen, PSA, CA 125, C-peptide, TT<sub>3</sub>, FT<sub>3</sub>, B<sub>12</sub>, folate, TPOAb, TgAb</p>
<p>Tests cleared but not clinically released Tests not available in U.S. but submitted for clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Tests not available on other manufacturers' analyzers</p>	<p>— — BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, rubella, toxo, CMV — PTH, HbA1c — CA 19-9</p>	<p>— — BNP, HBsAg, HBsAb, HBcAg, HBcAb, HBeAg, rubella, toxo, CMV — PTH, HbA1c — CA 19-9</p>
<p>Fully automated microplate system No. of each analyte performed in separate disposable unit No. of wells in microplate</p>	<p>n/a n/a n/a</p>	<p>n/a n/a n/a</p>
<p>Methods supported/Separation methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Reagents bar coded/Information in bar code Same capabilities when 3rd-party reagents used/Susceptibility to carryover Walkaway capacity in minutes/Specimens/Tests-assays System is open (home-brew methods can be used)/Liquid or dry system Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum specimen vol. required Minimum sample vol. aspirated precisely at once/Min. dead vol. Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption Noise generated Has dedicated pediatric sample cup/Dead vol. Primary tube sampling/Tube sizes/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines vol. in container) Measures No. of tests remaining/Short sample detection Auto detection of adequate reagent or specimen Clot detection/Reflex testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-linear range high results/ Increased to rerun out-of-linear range low results Time between initial result &amp; reaspiration of sample for rerun Autocalibration or autocalibration alert No. of calibrators required for each analyte Calibrants can be stored onboard/Avg. calibration frequency Multipoint calib. supported/Multiple calibs. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot Nos. per analyte Automatic shutdown/Startup is programmable/Startup time</p>	<p>fluorescence, EIA/bead 25 entire menu 0 n/a/unitized test cup 72hr/72hr/n/a yes yes yes/lot No., test code no/zero carryover 58/25/25 no/dry no no 500 <math>\mu</math>L tube, 100 <math>\mu</math>L cup 10–100 <math>\mu</math>L no/no no/n/a — no yes/primary draw tubes: 13 x 75 &amp; 100; 16 x 75 &amp; 100/no yes/yes yes yes yes/yes yes yes/no no/no no/no no/no n/a no 2 or 6-analyte dependent no/30–90 days yes/yes 24 hr no/no yes/no/5 min</p>	<p>fluorescence, EIA/bead 31 trays entire menu 0 n/a/unitized test cup 72hr/72hr/n/a yes yes yes/lot No., test code no/zero carryover 58/170/640 no/dry n/a/unitized test cup n/a 500 <math>\mu</math>L tube, 100 <math>\mu</math>L cup 10 <math>\mu</math>L/50 <math>\mu</math>L yes/no no/n/a — no yes/primary draw tubes: 7 mL &amp; 10 mL or 15 x 75 &amp; 100; 13 x 75 &amp; 100/no yes/yes yes yes yes/yes yes yes/yes no/no yes/yes no/no varies no 2 or 6-analyte dependent no/30–90 days yes/yes 24 hr yes/yes no/no/5–8 min</p>
<p>Stat time to completion of <math>\beta</math>-hCG test Time delay from ordering stat test to aspir. of sample Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time) Can auto transfer QC results to LIS/Onboard capability to review QC Data management capability/Instrument vendor supplies LIS interface</p>	<p>~18 min 60 sec 12/36 (1 min) yes/no Antek, Schuyler House, more</p>	<p>~18 min 40 sec 60/180 (20 sec) yes/yes yes/no</p>
<p>Interfaces up and running in active user sites with LIS interface operates simultaneously w/ running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits Bidirectional interface capability Results transmitted to LIS as soon as test time complete Interface available (or will be) to auto specimen handling system Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component Can order (via modem) malfunctioning part(s) w/o operator On-site response time of service engineer Mean time between failures/To repair failures Onboard error codes to facilitate troubleshooting Avg. time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module</p>	<p>n/a — yes package insert yes yes no no/no/no no n/a &gt;6 months yes daily: 5 min no/no</p>	<p>yes yes yes package insert yes (broadcast download &amp; host query) yes yes (Hitachi, Lab Interlink, A&amp;T) no/no/no no 24 hr n/a yes daily: 5–8 min; weekly: 5 min; monthly: none yes (includes audit trail of who replaced parts)/no</p>
<p>List price/Targeted bed size or daily volume Annual service contract cost (24 hours/7 days) Training provided w/ purchase/Advanced operator training</p>	<p>\$25,000/200–1,000 tests per month \$2,000 training DVD and DVD player</p>	<p>TBD/65+ beds, 1,500–2,000 tests TBD 4 days at vendor offices/no</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>unitized test cups; primary tube sampling; no reagent preparation, room temp. stability for five days; third-generation TSH sensitivity; second-generation trop. I; appropriate from stat and routine use</p>	<p>two models: standard and LA; unitized test cups; primary tube sampling; no reagent preparation; dual clot detection; room temp. stability for five days; automated sample dilution and pretreatment; third-generation TSH sensitivity; second-generation trop. I; appropriate for stat and routine use</p>

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

# Automated immunoassay analyzers

<p><b>Part 23 of 23</b></p> <p>See accompanying article on page 18</p>	<p>Trinity Biotech                  Elaine Soltes elaine.soltes@trinityusa.com                  1930 Innerbelt Business Center Dr.                  St. Louis, MO 63114                  800-325-3424                  www.trinitybiotech.com</p>	<p style="text-align: center;">See our ad on page 21</p>	<p>Trinity Biotech                  Elaine Soltes elaine.soltes@trinityusa.com                  1930 Innerbelt Business Center Dr.                  St. Louis, MO 63114                  800-325-3424                  www.trinitybiotech.com</p>
<p>Name of instrument/First year sold/Where designed                  Country where manufactured/Where reagents manufactured                  No. of units in clinical use in U.S./Outside U.S.                  Operational type/Model type/Sample handling system                  Dimensions in inches (H x W x D)/Instrument footprint in square feet</p>	<p>PersonLab/1998/Italy                  Italy/n/a (open system)                  200/&gt;400 worldwide                  batch/benchtop/rack                  24 x 26 x 25.6 in/4.6 sq ft</p>		<p>Nexgen Four/2003/Italy                  Italy/U.S., Italy, Ireland, Germany                  &lt;10/&lt;10                  batch, random access, continuous random access/benchtop/ring (carousel)                  28 x 53.2 x 29.5 in (includes carousel)/—</p>
<p>Tests available on instrument in U.S.</p>	<p>open system—any microplate assay</p>		<p>open system—any microplate assay</p>
<p>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</p>	<p>open system                  open system                  open system</p>		<p>open system—any microplate assay                  open system—any microplate assay                  open system—any microplate assay</p>
<p>Research-use-only assays                  Tests in development</p>	<p>open system                  open system</p>		<p>open system—any microplate assay                  open system—any microplate assay</p>
<p>User-defined methods implemented for what analytes                  Tests not available on other manufacturers' analyzers</p>	<p>open platform                  n/a (open platform)</p>		<p>open system—any microplate assay                  open system—any microplate assay</p>
<p>Fully automated microplate system                  No. of each analyte performed in separate disposable unit                  No. of wells in microplate</p>	<p>yes                  n/a                  min. strip: 8; max. full plate: 96</p>		<p>yes                  n/a                  min. strip: 1; max. full plate: 96 x 4 plates</p>
<p>Methods supported/Separation methods                  No. of different measured assays onboard simultaneously                  No. of different assays programmed, calibrated at once                  No. of user-definable (open) channels                  No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set                  Shortest/Median onboard reagent stability/Refrigerated onboard                  Multiple reagent configurations supported                  Reagent container placed directly on system for use                  Reagents bar coded/Information in bar code                  Same capabilities when 3rd-party reagents used/Susceptibility to carryover                  Walkaway capacity in minutes/Specimens/Tests-assays                  System is open (home-brew methods can be used)/Liquid or dry system                  Uses disposable cuvettes/Max. No. stored                  Uses washable cuvettes/Replacement frequency                  Minimum specimen vol. required                  Minimum sample vol. aspirated precisely at once/Min. dead vol.                  Supplied with UPS (backup power)/Requires floor drain                  Requires dedicated water system/Water consumption                  Noise generated                  Has dedicated pediatric sample cup/Dead vol.                  Primary tube sampling/Tube sizes/Pierces caps on primary tubes                  Sample bar-code reading capability/Autodiscrimination                  Bar-code placement per NCCLS standard Auto2A                  Onboard test auto inventory (determines vol. in container)                  Measures No. of tests remaining/Short sample detection                  Auto detection of adequate reagent or specimen                  Clot detection/Reflex testing capability                  Hemolysis detection-quantitation/Turbidity detection-quantitation                  Dilution of patient samples onboard/Automatic rerun capability                  Sample vol. can be increased to rerun out-of-linear range high results/                  Increased to rerun out-of-linear range low results                  Time between initial result &amp; reaspiration of sample for rerun                  Autocalibration or autocalibration alert                  No. of calibrators required for each analyte                  Calibrants can be stored onboard/Avg. calibration frequency                  Multipoint calib. supported/Multiple calibs. stored for same assay                  How often QC required                  Onboard real-time QC/Support multiple QC lot Nos. per analyte                  Automatic shutdown/Startup is programmable/Startup time</p>	<p>EIA/coated microplate, varies acc. to kit mfr.                  6 (2 plates)                  500                  500                  6/96 (2 plates)                  mfr. dependent/no                  yes                  no, requires operator prehandling/preparation                  no                  yes/zero carryover option                  —/96-6/6                  yes/—                  yes/192-2 plates                  no                  200 µL plus amount required by mfr.                  10 µL/200 µL                  yes/no                  no/n/a                  —                  no                  yes/16 x 100–11 x 55 mm/no                  yes (2 of 5 interl., codabar, codes 39 &amp; 128)/—                  —                  yes                  yes/yes                  yes                  no/yes                  no/no                  yes/no                  yes/yes (mfr. &amp; assay dependent)                  n/a                  n/a                  mfr. &amp; assay dependent                  —/mfr. &amp; assay dependent                  yes/—                  mfr. &amp; assay dependent                  no/n/a                  no/no/5 min</p>		<p>EIA/coated microwell                  500+                  500+                  500+                  16/manufacturer defined                  —/—/no                  yes                  requires operator prehandling, preparation                  yes/—                  yes/zero carryover with plastic tips                  varies/varies/varies                  yes/liquid                  yes/—                  yes/—                  200 µL dead vol. plus amount required by test                  10 µL/200 µL                  yes/no                  no/—                  —                  no/—                  yes/—/no                  yes (2 or 5 interl., codabar, codes 39 &amp; 128)/—                  yes                  yes                  no/yes                  yes                  yes/yes                  no/no                  yes/no                  no/no                  —                  n/a                  manufacturer dependent                  manufacturer dependent/manufacturer dependent                  yes/manufacturer dependent                  manufacturer dependent                  —/—                  no/no/10 min</p>
<p>Stat time to completion of β-hCG test                  Time delay from ordering stat test to aspir. of sample                  Throughput per hr for three analytes on each specimen, in No. of specimens/No. of tests (cycle time)                  Can auto transfer QC results to LIS/Onboard capability to review QC                  Data management capability/Instrument vendor supplies LIS interface                  Interfaces up and running in active user sites with                  LIS interface operates simultaneously w/ running assays                  Uses LOINC to transmit orders and results                  How labs get LOINC codes for reagent kits                  Bidirectional interface capability                  Results transmitted to LIS as soon as test time complete                  Interface available (or will be) to auto specimen handling system                  Modem servicing/Can diagnose own malfunctions/Determine malfunctioning component                  Can order (via modem) malfunctioning part(s) w/o operator                  On-site response time of service engineer                  Mean time between failures/To repair failures                  Onboard error codes to facilitate troubleshooting                  Avg. time to complete maintenance by lab personnel                  Onboard maintenance records/Maintenance training demo module</p>	<p>n/a                  n/a                  n/a                  yes/yes                  onboard/yes (included in price)                  —                  yes                  —                  —                  yes (broadcast download &amp; host query)                  yes                  no                  yes/yes/yes                  no                  within 24 hr                  —/&lt;24 hr                  yes                  daily: 6–10 min; weekly: 10 min; monthly: 15 min                  yes/no</p>		<p>manufacturer dependent                  n/a                  —/open system—depends on kit                  yes/yes                  onboard/yes                  —                  —                  —                  yes                  yes                  no                  yes/yes/yes                  no                  by contract                  —/—                  yes                  daily: 5 min; weekly: 5–10 min; monthly: 10–15 min                  —/no</p>
<p>List price/Targeted bed size or daily volume                  Annual service contract cost (24 hours/7 days)                  Training provided w/ purchase/Advanced operator training</p>	<p>\$38,000/&gt;100 beds                  depends on acquisition option                  3–5 days on site/yes</p>		<p>\$86,950/&gt;100                  varies                  3–4 days on site/no</p>
<p>Distinguishing features (supplied by vendor)</p>	<p>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</p>		<p>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</p>

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