

# Chemistry analyzers—all that's new and more

Anne Ford

**A**s more laboratories demand analyzers that can perform both chemistry and immunoassay testing, these hybrid instruments are evolving from what Mark Steelman, Ortho-Clinical Diagnostics worldwide product manager for chemistry systems, calls "bolt-together" systems to "integrated systems with fully optimized testing and workflow capabilities." Jim Schwartz, spokesperson for Abbott Diagnostics, elaborates: "Successful integration goes beyond just hooking the systems together, but rather requires innovative approaches to numerous unique challenges—i.e., maintaining sample integrity and maximizing workflow and assay performance."

Many of the vendors in this month's instrumentation survey, which encompasses chemistry and chemistry-immunoassay analyzers for mid- to high-volume laboratories, are addressing these challenges with recently introduced and forthcoming products. Steelman says, "It will take a new generation of analyzers to fully deliver on the potential of such [integrated] systems," and while that new generation may not have fully arrived, it appears to be well on its way.

At CAP TODAY press time, at least three companies aimed to launch new analyzers at this month's American Association for Clinical

Chemistry meeting: Roche Diagnostics, Carolina Chemistries, and Bayer Diagnostics. Roche's Cobas 6000 analyzer series, which received FDA clearance in March, is designed for the mid-volume laboratory and represents Roche's second generation of integrated analyzers. Roche representative Peter Van Overwalle says the company will ultimately offer seven configurations; the first three consist of the Cobas c501 clinical chemistry analyzer, the Cobas e 601 immunoassay analyzer, and the integrated Cobas 6000 <501 | 601> analyzer series. The latter offers 88 clinical chemistry and immunoassay reagent channels, runs up to 1,170 tests per hour, features a stat interruption mode, and requires 33 square feet of floor space. All Cobas 6000 instruments will offer Cobas Link, which Van Overwalle calls "one of the most comprehensive connectivity solutions in the market" and which will offer "screen sharing, remote diagnostics, and reporting," among other features. To come in 2008, he adds, is the Cobas 8000 analyzer series, aimed at the high-volume market.

Meanwhile, AACC attendees can also check out Carolina Liquid Chemistries' A&T 504X chemistry analyzer. The A&T 504X performs up to 1,200 tests per hour and eliminates sample pretreatment of HbA1c by automatically lysing whole-blood samples. In addition, it can

automatically dilute specimens—meaning, company president Philip Shugart says, "that reruns for out-of-range tests, antigen excess checks, et cetera, can be done at the same speed, without slowing down the instrument." The A&T 504X can automatically dilute calibrators as well, so that only one calibrator is required to run a five-point calibration curve. Shugart adds, "HbA1c on this instrument does not require a total hemoglobin for calculating—it is a single-channel test. This feature makes HbA1c testing much easier, faster, and more economical." Also in the works at Carolina Chemistries are the CAT Workcell (a combination of the A&T 504X with Tosoh's

AIA 1800 instrument) for chemistry and immunochemistry testing and the CAT laboratory automation system, a fully automated platform for handling centrifugation, decapping, aliquotting, and chemistry and immunochemistry testing.

A third analyzer scheduled for launch at the AACC meeting: Bayer Diagnostics' Advia 1800. "With a throughput of 1,800 tests per hour, the Advia 1800 is an ideal solution for high-volume automated laboratories in addition to mid-volume stand-alone laboratories," says Eric LaFleche, North American associate marketing manager for clinical chemistry. "The Advia 1800, in addition to the Advia 1200 and the Ad-

Survey of chemistry analyzers (for mid- and high-volume labs), pages 19–55

## Letters

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GK, Collins DN. *Acta Cytologica*. 1991;35:3–7). In the 37-year-long practice of the New York State cytology proficiency test, we have seen examples of failures by internationally known cytopathologists whose expertise was absolutely beyond doubt.

Proficiency testing is a heavily statistical subject (Crocker L, Algina J. *Introduction to Classical*

*and Modern Test Theory*, New York: Holt, Rinehart and Winston; 1986). If this fact is disregarded, then a scientifically sound cytology proficiency test will never be available. Adjusting the superficial aspects of the cytology proficiency test, the scoring grids, the variable validation methods of the slides, and so on, will only marginally improve the test's validity and reliability. A more thorough overhaul of the system, based on rational statistical prin-

ciples, is needed. Lip service is paid frequently to the importance of statistics in medical science, but the use of non-descriptive statistics in the practice of anatomic pathology has generally remained wishful thinking. Now, when the cytopathology community is attempting to introduce a highly accurate system in cytology proficiency testing, a consideration of statistical principles is more important than ever.

The importance of statistical insights for a rational cytology proficiency test can be demonstrated with an example. Data from the National Cytology Proficiency Testing Update [Cheryl Wiseman, MPH, CT(ASCP), of CMS, published online Feb. 8, 2006] show that as of Jan. 31, 2006, among 12,786 examinees nine percent failed the test when attempting it for the first time. For the second attempt, the failure rate—among those who had failed the initial attempt—remained surprisingly similar, 10 percent, though common sense seems to dictate that the rate should be much higher among those who have already failed the test once and therefore supposedly have lower professional skills. Yet the passing rate at the second attempt is virtually identical to the passing rate of all participants at the first attempt.

It would be virtually impossible to conclude that the huge decrease in the failure rate from 100 percent to 10 percent is attrib-

utable to a vast improvement of skills of the "failed" cytologists during the few weeks that lapsed between the two tests. There is a far simpler explanation: What we are seeing is a statistical phenomenon, known as "regression toward the mean," which was first described by Sir Francis Galton in 1877. There are two groups of examinees who earn failing scores during proficiency testing: those whose skills are genuinely insufficient and those who are competent but who achieve low scores due to random variation in the test results, as Drs. Hughes, Young, and Wilbur assume. The latter "misclassified" examinees subsequently regress toward the mean during the second test, that is, their test results become more commensurate with their genuine skills. Since the failure rates of the participants during the first and second attempts are so similar, we have to infer that the majority of the failed examinees fall into the second, misclassified group, and only a minority have truly insufficient skills. The high frequency of misclassification, which is not only theoretically fully plausible but also supported by Cheryl Wiseman's data, also demonstrates that a "short" proficiency test based on a small number of test slides has this inherent weakness—the associated high misclassification rate. A long board-examination type test would therefore be far more efficacious in investigating com-



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via 2400, provide the market with a full range of standardized chemistry platforms." Also at AACC, Bayer plans to release a new software package for its Advia chemistry systems with improved calibration management, simplified user interface, and reagent loading "on the fly" capability. "In addition, the software will provide customers with improved results reporting and archiving capabilities," LaFleche says.

Another product intended for introduction at the AACC meeting is Olympus America's Olympus Partner Advantage personal computer workstation, or OPA. Michael Argentieri, vice president of sales and marketing in the company's diagnostic systems group, says the OPA "combines several key processes, programs, and services under one portal through a single workstation" and "enables our customers to have direct access to our technical library, training and educational materials, third-party QC peer review for their Olympus analyzers, technical updates, reagent updates, and service communications and other notices." Olympus America developed the OPA after discovering through a customer satisfaction survey that its clientele wanted to be able to access the company's programs and services, as well as those of third parties, through a single gateway. Olympus will also display the AU-Connector system, which allows Olympus clinical

chemistry and immunoassay systems to be integrated into a single workcell. "With intelligent sample management and a central data-management system, the AU-Connector is designed to maximize efficiency and throughput while preserving its flexibility with stat and offline operation as well as postanalytical sorting to third-party and archive racks," Argentieri says.

AACC's 2007 meeting may be a year away, but Ortho-Clinical Diagnostics is already planning to introduce its Vitros 4,3 FS integrated system then. "The system is being designed to integrate clinical chemistry and immunodiagnosics in a unique way that intelligently accounts for variable sample and test mixes," Steelman says. "This will allow the system to provide fast and consistent turnaround times in-

*continued on page 18*

## Quick Takes

*"It's like having three mosquitoes in the back yard and blanketing the entire county with DDT."*

—Neil Sandson, MD,  
on the clinical nonspecificity of all current drugs.  
("Chip shot—psychiatry puts targeted test in play," page 86)

*"How do we learn from that? Dr. Jones gets sued, and then there's this bunch of legal thrashing around followed by a confidential settlement."*

—Elliott Foucar, MD,  
on the lack of a systematic collection, analysis,  
and distribution of malpractice data by the courts  
that could be used to correct flawed medical practices.  
("Pathologists given new order in the courtroom," page 5)

petence than the federally mandated short test.

George K. Nagy, MD  
Cytopathology Laboratory  
Wadsworth Center  
New York State Department of Health  
Albany

### Molecular testing

In this age of genomics, microbiologists who have been in the profession for many years have to heed and act on the message of the best-selling book *Who Moved My Cheese?* by Spencer Johnson, MD. DNA technology is here to stay. The dramatic and revolutionary shift from phenotypic to genotypic methods was evident at the 2006 meeting of the American Society for Microbiology. Since all areas of the laboratory will be forced in the future to deal with some form of molecular testing, analyzing, or reporting or all three, we have found that the best approach is to familiarize ourselves with basic molecular principles through classes at local colleges. We cannot blame our employers or circumstances that have forced the changes that are upon us in this age in which we live and work. We have to be proactive, and the time to act is now.

Arthur P. Guruswamy,  
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## Chemistry analyzers

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dependent of sample and test mix." In the meantime, the company continues to offer the Vitros 5,1 FS chemistry system. Introduced in 2004, the Vitros 5,1 FS system was the first instrument to offer the Vitros Micro Tip technology, which allows users to process assays with disposable tips and cuvettes, and the first Vitros system with open-channel capability. In the next few months, Ortho-Clinical Diagnostics intends to add eight drugs of abuse, haptoglobin, and homocysteine to the menu of the Vitros 5,1 FS system; it has already added direct methods for HDL, TIBC, HbA1c,  $\alpha_1$ -antitrypsin, and antistreptolysin O. Also available from the company is the Vitros 350 chemistry system, a successor to the Vitros

250 system that features higher throughput and faster time to first result than its predecessor.

High-volume laboratories await Dade Behring's Dimension Vista intelligent laboratory system, expected to debut this year. "Dimension Vista provides the first-time integration of four technologies housed within one workstation, resulting in the most efficient sample and test consolidation available," says Bonita Kushnerick, director of Vista and field marketing. Those four technologies—nephelometric, photometric, and the company's proprietary Loci and V-Lyte multi-sensor technologies—will allow users to perform routine and specialty chemistry, electrolyte, plasma protein, and immunoassay testing. Kushnerick adds, "Dimension Vista will provide hands-off automatic processing of calibration and quality control

through programmable scheduling of these tasks with material stored refrigerated onboard the analyzer." This year Dade Behring also plans to introduce the QCC PowerPak, an "efficiency-enhancement package that brings new and exciting features to the Dimension RxL Max and Dimension Xpand chemistry analyzers," says Joseph Meola, MS, MT(ASCP), U.S. marketing manager for automation and Dimension systems.

Already available from Beckman Coulter: the UniCel DxC 600i integrated workstation, featuring a menu of more than 150 analytes and a throughput of up to 990 chemistry and 100 immunoassay tests per hour. The DxC 600i is the latest member of the UniCel family of systems, which includes the DxC 600 and DxC 800 chemistry systems, both launched last year. "It was one of the most successful launches for our company," says market manager Daniel Siegenthaler. "We placed almost 500 systems into the marketplace in the first year." Like other Beckman Coulter systems, the DxC 600i, DxC 600, and DxC 800 feature closed-tube aliquotting and closed-tube sampling. Siegenthaler says one of the UniCel family's strengths is its standardization of reagents and assays: "Standardization seems to be really important, especially here in North America where so many purchases are made within the group purchasing organization or integrated health network framework."

In 2007, Abbott intends to introduce three instruments to its existing Architect line: the c16000 chemistry analyzer, the i1000SR immunoassay analyzer, and the ci16200 integrated immunochemistry analyzer. "With the launch of these additional Architect analyzers," says Schwartz, "laboratories will be able to achieve standardization across entire hospital systems with respect to results, operations, and effectiveness." Abbott already offers the Architect ci8200 integrated platform, which combines the i2000SR immunoassay analyzer and c8000 chemistry analyzer to process up to 200 immunoassay tests and up to 1,200 clinical chemistry tests per hour. The Architect line features robotic sample handling, which, Schwartz says, "integrates immunoassay and clinical chemistry testing without compromising throughput or assay performance for optimized productivity," as well as the SmartWash washing system "for true immunoassay and chemistry testing on one platform due to the reduction in carry-over."

CAP TODAY's survey of chemistry analyzers for mid- and high-volume laboratories includes products from the aforementioned manufacturers and from Awareness Technology, Clinical Data, and Randox Laboratories. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm it has the stated features and capabilities. □

Anne Ford is a writer in Chicago.

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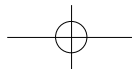
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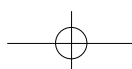
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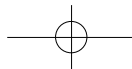
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## Chemistry analyzers (for mid/high volume laboratories)

Part 1 of 18	 <b>MID</b>	 <b>HIGH</b>
<b>See related comments, page 14</b>	<b>Abbott Diagnostics</b> Mike Wright michael.wright@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 800-323-9100 www.abbott.com	<b>Abbott Diagnostics</b> Mike Wright michael.wright@abbott.com 100 Abbott Park Road Abbott Park, IL 60064 800-323-9100 www.abbott.com
<b>Name of instrument/First year sold in U.S.</b>	Abbott Architect c8000/2003	Abbott Aeroset/1998
<b>List price/Total No. sold in 2005</b>	\$225,000/—	\$345,000/—
<b>No. units in clinical use in U.S./Outside U.S.</b>	210/1,270	276/650
<b>Country where designed/Manufactured/Where reagents mftd.</b>	U.S., Japan/U.S., Japan/U.S.	Japan/Japan/U.S.
<b>Operational type/Reagent type</b>	continuous random access/open reagent system	continuous random access/open reagent system
<b>Sample handling system/Model type</b>	multi-dimensional retest sample handler, carousel/floor standing	rack, carousel/floor standing
<b>Dimensions in inches (H x W x D)/Instrument footprint</b>	48 x 79 x 49/~26 sq ft	42.7 x 74.4 x 44.1/22.7 sq ft
<b>No. of tests for which analyzer has FDA-cleared applications</b>	83	82
<b>Tests clinically released in last 12 months</b>	amikacin, quinidine, UIBC, vancomycin, ammonia, ferritin, anti-streptolysin-O, $\alpha$ -1-antitrypsin, $\alpha$ -1-glycoprotein, Lp(a), myoglobin, IgE, CRP Vario, $\beta$ -2-microglobulin, ultra HDL, D-LDL, ecstasy (SQ), amphet/meth (SQ), barbiturate (SQ), benzodiazepine (SQ), cannabinoid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase	amikacin, quinidine, UIBC, vancomycin, ferritin, anti-streptolysin-O, $\alpha$ -1-antitrypsin, $\alpha$ -1-glycoprotein, Lp(a), myoglobin, IgE, CRP Vario, $\beta$ -2-microglobulin, ultra HDL, D-LDL, ecstasy (SQ), amphet/meth (SQ), barbiturate (SQ), benzodiazepine (SQ), cannabinoid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase
<b>Tests cleared but not clinically released</b>	copper, P amylase, CK-MB, enzymatic creatinine	copper, P amylase, CK-MB, enzymatic creatinine
<b>Tests not available in U.S. but submitted for 510(k) clearance</b>	tobramycin, gentamicin, lithium	tobramycin, gentamicin, lithium
<b>Tests not available in U.S. but available in other countries</b>	copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin	copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin
<b>Research-use-only assays</b>	—	—
<b>Tests in development</b>	acetaminophen, salicylate, tricyclics, barbs-serum, benzo-serum, PCP (SQ), propoxyphene (SQ)	acetaminophen, salicylate, tricyclics, barbs-serum, benzo-serum, PCP (SQ), propoxyphene (SQ)
<b>User-defined methods implemented for what analytes</b>	lithium, gentamicin, acetaminophen, salicylate, tobramycin, primidone, tricyclics, LSD, D-dimer	lithium, gentamicin, acetaminophen, salicylate, tobramycin, primidone, tricyclics, LSD, D-dimer
<b>Methods supported/immunoassay methods</b>	photometry, potentiometry, turbidimetric/—	photometry, potentiometry turbidimetric/—
<b>No. of direct ion selective electrode channels</b>	3	3
<b>No. of different measured assays onboard simultaneously</b>	68	59
<b>No. of different assays programmed, calibrated at once</b>	220	100
<b>No. of user-definable (open) channels/No. active simultaneously</b>	220/220	100/59
<b>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</b>	65/370	59/400
<b>Shortest/median onboard reagent stability/Refrigerated onboard</b>	7 days/28 days/yes (2–8°C)	7 days/28 days/yes
<b>Multiple reagent configurations supported</b>	yes	yes
<b>Reagent container placed directly on system for use</b>	yes	yes
<b>Instrument has same capabilities when 3rd-party reagent used</b>	yes	yes
<b>Walkaway capacity in minutes/Specimens/Tests-assays</b>	varies/215/69,000-68	60/231/50,000+
<b>System is liquid or dry</b>	liquid	liquid
<b>Uses disposable cuvettes/Max. No. stored</b>	no/—	no/n/a
<b>Uses washable cuvettes/Replacement frequency</b>	yes/minimum 1-yr guarantee	yes/minimum 1-yr guarantee
<b>Minimum sample volume aspirated precisely at one time</b>	2 $\mu$ L	2 $\mu$ L
<b>Supplied with UPS (backup power)/Requires floor drain</b>	yes/no	no/no
<b>Requires dedicated water system/Water consumption per hour</b>	yes/25 L	yes/45 L
<b>Noise generated in decibels</b>	—	—
<b>Dedicated pediatric sample cup/Dead volume</b>	yes/50 $\mu$ L	yes/50 $\mu$ L
<b>Primary tube sampling/Pierces caps on primary tubes</b>	yes/no	yes/no
<b>Sample bar-code reading capability</b>	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
<b>Reagent bar-code reading capability</b>	yes	yes
<b>Bar code placement per CLSI standard Auto2A</b>	yes	yes
<b>Onboard test auto inventory (determines volume in container)</b>	yes	yes
<b>Measures no. tests remaining/Short sample detection/Clot detection</b>	yes/yes/yes	yes/yes/yes
<b>Automatic detection of adequate reagent for aspir. &amp; analysis</b>	yes	yes
<b>Hemolysis/Turbidity detection-quantitation</b>	yes/yes	yes/yes
<b>Dilution of patient samples onboard/Automatic rerun capability</b>	yes/yes	yes/yes
<b>Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results</b>	yes/yes	yes/yes
<b>Autocalibration or autocalibration alert</b>	no	yes
<b>Calibrants stored onboard/Multipoint calibration supported</b>	yes/yes	yes/yes
<b>Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse</b>	8 hr/30 days/14 days/7–14 days	8 hr/30 days/14 days/7–14 days
<b>Automatic shutdown/Startup programmable</b>	no/no	yes/yes
<b>Stat time to completion of all analytes, throughput per hr. for:</b>		
• Sodium, potassium, chloride, TCO <sub>2</sub>	2.5 min, 200 specimens, 800 tests	10 min, 200+ specimens
• Sodium, potassium, chloride, TCO <sub>2</sub> , glucose, urea, creatinine	9.6 min, 160 specimens, 1,120 tests	10 min, 200+ specimens
• Album., bili. direct & total, AST, ALT, ALP	9.6 min, 133 specimens, 800 tests	10 min, 200+ specimens
<b>Typical time delay from ordering stat test to aspir. of sample</b>	<20 sec	<15 sec
<b>How often QC required/Onboard SW capability to review QC</b>	shortest interval: 8 hr; longest: 24 hr/yes	shortest interval: 8 hr (ISE); longest: 24 hr/yes
<b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b>	yes/yes	yes/yes
<b>QC results transferred automatically to LIS</b>	yes	yes
<b>Data mgmt. capability/Instrument vendor supplies LIS interface</b>	yes (add'l cost, SW mfr: Abbott)	no/yes (add'l cost)
<b>Interfaces up and running in active user sites with</b>	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Mediatech, Siemens, Triple G, CIS, others	all major vendors
<b>Bidirectional interface capability</b>	yes (broadcast download & host query)	yes (broadcast download & host query)
<b>Test results transmitted to LIS as soon as chem. time complete</b>	yes	yes
<b>LIS interface operates simultaneously with running assays</b>	yes	yes
<b>Uses LOINC to transmit orders &amp; results</b>	—	no
<b>How labs get LOINC codes for reagent kits</b>	package insert	—
<b>Interface avail. (or will be) to automated specimen handling system</b>	yes	in development
<b>Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component</b>	yes/yes/yes	no/no/no
<b>On-site time of svc. engineer/Onboard error codes for troubleshooting</b>	<24 hr/yes	<24 hr/yes
<b>Mean time between failures/To repair failures</b>	>2 months/varies	>2 months/varies
<b>Average time to complete maintenance by lab personnel</b>	daily: <15 min; weekly: <45 min; monthly: 15 min	daily: 5 min; weekly: 10 min; monthly: 30 min
<b>Onboard maintenance records/Maint. training demo module</b>	yes (includes audit trail of who replaced parts)/yes	no/no
<b>Training provided with purchase/Advanced oper. training avail.</b>	5 days on site, 5 days at vendor offices/yes	5 days on site, 5 days at vendor offices/no
<b>Annual service contract cost (24 h/7 d)</b>	\$18,500	\$18,500
<b>Distinguishing features</b>	unique multi-dimensional retest sample handler provides exceptional sample management and ensures stat TAT remains constant regardless of routine workload; large reagent and sample capacity; liquid ready-to-use reagents; maximizes ease of use with patented ICT chip; easy-to-use, intuitive software with state-of-the-art online operation manuals and troubleshooting	workstation consolidation; high throughput; large capacity; reliable; flexible system, extended assay linearity, open channel test capability, integrated chip technology for ISE (minimum 45,000 tests per ICT module), auto repeat and auto dilution capability, low sample volume (2–35 $\mu$ L)





## Chemistry analyzers (for mid/high volume laboratories)

**Part 2 of 18**
**MID**

**Abbott Diagnostics**  
**Mike Wright** michael.wright@abbott.com  
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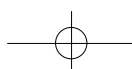
**HIGH**

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See related comments, page 14

<b>Name of instrument/First year sold in U.S.</b> <b>List price/Total No. sold in 2005</b> <b>No. units in clinical use in U.S./Outside U.S.</b> <b>Country where designed/Manufactured/Where reagents mftd.</b> <b>Operational type/Reagent type</b>	<b>Abbott Architect ci8200/2003</b> \$375,000/77 111/— U.S., Japan/U.S., Japan/U.S. continuous random access/self-contained multi-use cartridges, open reagent system	<b>Abbott Architect c16000/2007</b> n/a/0 0/2 U.S., Japan/U.S., Japan/U.S. continuous random access/open reagent system
<b>Sample handling system/Model type</b> <b>Dimensions in inches (H x W x D)/Instrument footprint</b>	multi-dimensional retest sample handler/floor standing 48 x 127 x 49/42 sq ft	multidimensional robotic sample handler and carousel/floor-standing 48 x 79 x 49/26 sq ft
<b>No. of tests for which analyzer has FDA-cleared applications</b> <b>Tests clinically released in last 12 months</b>  <b>Tests cleared but not clinically released</b> <b>Tests not available in U.S. but submitted for 510(k) clearance</b> <b>Tests not available in U.S. but available in other countries</b>  <b>Research-use-only assays</b> <b>Tests in development</b>  <b>User-defined methods implemented for what analytes</b>	107 amikacin, quinidine, UIBC, vancomycin, ammonia, ferritin, anti-streptolysin-O, $\alpha$ -1-antitrypsin, $\alpha$ -1-glycoprotein, Lp(a), myoglobin, IgE, CRP Vario, $\beta$ -2-microglobulin, ultra HDL, D-LDL, ecstasy (SQ), amphet/meth (SQ), barbiturate (SQ), benzodiazepine (SQ), cannabinoid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase copper, P amylase, CK-MB, enzymatic creatinine tobramycin, gentamicin, lithium copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin — acetaminophen, salicylate, tricyclics, barbs-serum, benzo-serum, PCP (SQ), propoxyphene (SQ) lithium, gentamicin, acetaminophen, salicylate, tobramycin, primidone, tricyclics, LSD, D-dimer	83 amikacin, quinidine, UIBC, vancomycin, ammonia, ferritin, anti-streptolysin-O, $\alpha$ -1-antitrypsin, $\alpha$ -1-glycoprotein, Lp(a), myoglobin, IgE, CRP Vario, $\beta$ -2-microglobulin, ultra HDL, D-LDL, ecstasy (SQ), amphet/meth (SQ), barbiturate (SQ), benzodiazepine (SQ), cannabinoid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase copper, P amylase, CK-MB, enzymatic creatinine tobramycin, gentamicin, lithium copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin — acetaminophen, salicylate, tricyclics, barbs-serum, benzo-serum, PCP (SQ), propoxyphene (SQ) lithium, gentamicin, acetaminophen, salicylate, tobramycin, primidone, tricyclics, LSD, D-dimer
<b>Methods supported/immunoassay methods</b>  <b>No. of direct ion selective electrode channels</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/No. active simultaneously</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>Instrument has same capabilities when 3rd-party reagent used</b> <b>Walkaway capacity in minutes/Specimens/Tests-assays</b> <b>System is liquid or dry</b> <b>Uses disposable cuvettes/Max. No. stored</b> <b>Uses washable cuvettes/Replacement frequency</b> <b>Minimum sample volume aspirated precisely at one time</b> <b>Supplied with UPS (backup power)/Requires floor drain</b> <b>Requires dedicated water system/Water consumption per hour</b> <b>Noise generated in decibels</b> <b>Dedicated pediatric sample cup/Dead volume</b> <b>Primary tube sampling/Pierces caps on primary tubes</b> <b>Sample bar-code reading capability</b>  <b>Reagent bar-code reading capability</b> <b>Bar code placement per CLSI standard Auto2A</b>	photometry, potentiometry, turbidimetric/chemiluminescence with flexible protocols 3 93 320 220/220 90/chem 370, immunoassay 100–500 144 hr/30 days/yes (2–8°C) yes yes yes varies >300/365/81,000-93,000 liquid yes, immunoassay/1,200 yes, chemistry/minimum 1-yr guarantee 2 $\mu$ L yes/no yes/30.5 L — yes/50 $\mu$ L yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes	photometry, potentiometry (ISE), turbidimetric/n/a 3 68 220 220/220 65/370 144 hr/28 days/yes (2–8°C) yes yes yes varies/215/69,000 + liquid no/330 yes/minimum 1-yr guarantee 2 $\mu$ L yes/yes yes/56 $\mu$ L — yes/50 $\mu$ L yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes
<b>Onboard test auto inventory (determines volume in container)</b> <b>Measures no. tests remaining/Short sample detection/Clot detection</b> <b>Automatic detection of adequate reagent for aspir. &amp; analysis</b> <b>Hemolysis/Turbidity detection-quantitation</b> <b>Dilution of patient samples onboard/Automatic rerun capability</b> <b>Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results</b> <b>Autocalibration or autocalibration alert</b> <b>Calibrants stored onboard/Multipoint calibration supported</b> <b>Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse</b> <b>Automatic shutdown/Startup programmable</b>	yes yes/yes/yes yes yes/yes yes/yes yes/yes (for chemistry) no yes, for chemistry only/yes 8 hr/30 days/14 days/7–14 days no/no	yes yes/yes/yes yes yes/yes yes/yes yes/yes no yes/yes 8 hr/30 days/14 days/7–13 days no/no
<b>Stat time to completion of all analytes, throughput per hr. for:</b> • Sodium, potassium, chloride, TCO <sub>2</sub> • Sodium, potassium, chloride, TCO <sub>2</sub> , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP  <b>Typical time delay from ordering stat test to aspir. of sample</b> <b>How often QC required/Onboard SW capability to review QC</b> <b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b> <b>QC results transferred automatically to LIS</b>	2.5 min, 200 specimens, 800 tests 9.6 min, 160 specimens, 1,120 tests 9.6 min, 133 specimens, 800 tests  <20 sec shortest interval: 8 hr; longest: 24 hr/yes yes/yes yes	2.5 min, 200 samples 9.6 min, 200 samples 9.6 min, 300 samples  3 sec shortest interval: 8 hr; longest: 24 hr yes/yes yes
<b>Data mgmt. capability/Instrument vendor supplies LIS interface</b> <b>Interfaces up and running in active user sites with</b>  <b>Bidirectional interface capability</b> <b>Test results transmitted to LIS as soon as chem. time complete</b> <b>LIS interface operates simultaneously with running assays</b> <b>Uses LOINC to transmit orders &amp; results</b> <b>How labs get LOINC codes for reagent kits</b>	yes (add'l cost, SW mfr: Abbott) Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Mediatech, Siemens, Triple G, CIS, others yes (broadcast download & host query) yes yes — —	optional add-on (add'l—price varies; SW mfr: Abbott) Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Mediatech, Siemens, Citation, CHCS, Antec, Orchard, others yes (broadcast download & host query) yes yes — package insert
<b>Interface avail. (or will be) to automated specimen handling system</b>	no	yes
<b>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component</b> <b>On-site time of svc. engineer/Onboard error codes for troubleshooting</b> <b>Mean time between failures/To repair failures</b> <b>Average time to complete maintenance by lab personnel</b> <b>Onboard maintenance records/Maint. training demo module</b> <b>Training provided with purchase/Advanced oper. training avail.</b> <b>Annual service contract cost (24 h/7 d)</b>	yes/yes/yes <24 hr/yes >2 months/varies daily: 23 min; weekly: <45 min; monthly: 15 min yes/yes 5 days on site, 5 days at vendor offices/yes \$28,500	yes/yes/yes <24 hr/yes —/— daily: 15 min; weekly: <45 min; monthly: 15 min yes (includes audit trail of who replaced parts)/yes 5 days on site, 5 days at vendor office/yes n/a
<b>Distinguishing features</b>	integration of CC and IA without compromising stat TAT, results, or throughput because of patented SmartWash technology, which minimizes carryover to <0.1 ppm; large reagent capacity of 93 assays, with sample load up to 365; efficiency provided via multiple patented technologies	<0.1 ppm carryover claim (SmartWash); workstation consolidation; true integration with immunoassay module; Integrated Chip Technology (ICT); FlexRate (extend linearities for enzymatic assays); in-line pressure monitoring that detects clots, bubbles, foam, and insufficient sample volume; reliability; low-sample volume requirements (2–35 $\mu$ L); automatic repeat/dilution/reflex protocols; universal sample racks

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



## SURVEY OF INSTRUMENTS

## Chemistry analyzers (for mid/high volume labs)

Part 3 of 18

HIGH

Abbott Diagnostics  
 Mike Wright michael.wright@abbott.com  
 100 Abbott Park Rd.  
 Abbott Park, IL 60064  
 800-323-9100 www.abbottdiagnostics.com

See related comments, page 14

Name of instrument/First year sold in U.S. List price/Total No. sold in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	Abbott Architect ci16200/2007 n/a/0 0/0 U.S., Japan/U.S., Japan/U.S. continuous random access/open reagent system multi-dimensional robotic sample handler and carousel/floor-standing 48 x 127 x 49/42 sq. ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months	— IA: DHEA-S, BNP, CA 19-9, anti-HCV, anti-HBs; clinical chem.: amikacin, quindine, UIBC, vancomycin, ammonia, ferritin, ASO, $\alpha$ -1-antitrypsin, $\alpha$ -1-glycoprotein, Lp(a), myoglobin, IgE, CRP Vario, $\beta$ -2-microglobulin, ultra HDL, D-LDL, ecstasy (SQ), amphet/meth (SQ), barbs (SQ), benzo (SQ), cannabinoid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance	anti-Tg, AFP, ferritin, insulin, copper anti-TPO, SHBG, P. amylase, CK-MB, enzymatic creatinine, tobramycin, gentamicin, lithium
Tests not available in U.S. but available in other countries	AFP, anti-HBc, anti-HBc IgM, anti-HBe, anti-HBs, anti-HCV, anti-Tg, anti-TPO, B12, ferritin, folate, HAVab-IgG, HAVab-IgM, HbsAg, HbsAg confirm, HIV Ag/Ab combo, insulin, SCC, SHBG, syphilis TP, testosterone, pepsinogen I/II, CMV IgG avidity, cortisol, PTH; clin chem.: copper, D-dimer, fructosamine, HBDH, kappa/lambda light chains, digitoxin, gentamicin
Research-use-only assays Tests in development	— MPO, anti-Tg, PTH, TG, SHBG, testosterone, cyclosporine, FK778, sirolimus, tacrolimus, anti-HBe, core, core-M, HAVAB-G, HAVAB-M, HbeAg, HbsAg, confirm, HIV Ag/AB combo, rubella IgG, AFP, others
User-defined methods implemented for what analytes	salicylate, tobramycin, primidone, tricyclics, LSD, D-dimer
Methods supported/immunoassay methods	photometry, potentiometry (ISE), turbidmetric chemiluminescence with flexible protocols (ChemiFlex)
No. of direct ion selective electrode channels	3
No. of different measured assays onboard simultaneously	93
No. of different assays programmed, calibrated at once	320
No. of user-definable (open) channels/No. active simultaneously	220/220
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	93/370 chemistry; 100-500 immunoassay
Shortest/median onboard reagent stability/Refrigerated onboard	144 hr/30 days/yes (2-8°C)
Multiple reagent configurations supported	yes
Reagent container placed directly on system for use	yes
Instrument has same capabilities when 3rd-party reagent used	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/365/81,000-93,000
System is liquid or dry	liquid
Uses disposable cuvettes/Max. No. stored	yes/1,200 (IA)
Uses washable cuvettes/Replacement frequency	yes/minimum 1-yr guarantee
Minimum sample volume aspirated precisely at one time	2 $\mu$ L
Supplied with UPS (backup power)/Requires floor drain	yes/yes
Requires dedicated water system/Water consumption per hour	yes/59 L
Noise generated in decibels	—
Dedicated pediatric sample cup/Dead volume	yes/50 $\mu$ L
Primary tube sampling/Pierces caps on primary tubes	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes
Bar code placement per CLSI standard Auto2A	yes
Onboard test auto inventory (determines volume in container)	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes
Automatic detection of adequate reagent for aspir. & analysis	yes
Hemolysis/Turbidity detection-quantitation	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes (for chemistry)
Autocalibration or autocalibration alert	no
Calibrants stored onboard/Multipoint calibration supported	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	8 hr/30 days/14 days/ 7-13 days
Automatic shutdown/Startup programmable	no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP	2.5 min, 200 samples 9.6 min, 200 samples 9.6 min, 300 samples
Typical time delay from ordering stat test to aspir. of sample	3 sec
How often QC required/Onboard SW capability to review QC	shortest interval: 8 hr; longest: 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes
QC results transferred automatically to LIS	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	optional add-on (add'l price varies; SW mfr: Abbott)
Interfaces up and running in active user sites with	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Mediatech, Siemens, Citation, CHCS, Antec, Orchard, others
Bidirectional interface capability	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes
LIS interface operates simultaneously with running assays	yes
Uses LOINC to transmit orders & results	—
How labs get LOINC codes for reagent kits	package insert
Interface avail. (or will be) to automated specimen handling system	yes
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes
Mean time between failures/To repair failures	—/—
Average time to complete maintenance by lab personnel	daily: 23 min; weekly: <45 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	n/a
Distinguishing features	uniquely multi-dimensional sample handler; <0.1 ppm carryover claim (SmartWash); large request and sample capacity; IA/CC testing integrated without compromise of stat TAT; ChemiFlex and FlexRate technologies deliver assay extended linearities and enhance sensitivities, others

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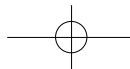
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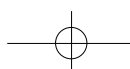


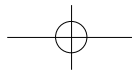
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## Chemistry analyzers (for mid/high volume laboratories)

Part 4 of 18	MID	MID
<p><b>Awareness Technology Inc.</b> Chris Schneider info@awaretech.com P.O. Box 1679 Palm City, FL 34991 772-283-6540 www.awaretech.com</p>		<p><b>Bayer Healthcare, Diagnostics Division</b> Eric LaFleche eric.lafleche.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6130 labnews.com</p>
<i>See related comments, page 14</i>		
<p>Name of instrument/First year sold in U.S. List price/Total No. sold in U.S. in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint</p>	<p>ChemWell/1999 \$25,000/— 10/800 U.S./U.S./open system continuous random access/open reagent system rack of 96 samples/benchtop 19 x 36 x 22 in/7 sq ft</p>	<p>ADVIA 1200/2005 \$189,000/— n/a/n/a Japan/Japan/Ireland random access/open reagent system carousel/floor standing 33.5 x 48 x 44 in/1.04 square meters</p>
<p>No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months</p>	<p>22 none</p>	<p>79 TIBC, ammonia, HbA1C, microalbumin, ASO, ApoA, ApoB, wrCRP, haptoglobin, IgA, IgG, IgM, carbamazepine, gentamicin, lithium, phenobarb, tobramycin, vancomycin, acetaminophen, ethanol, salicylate, DAUs, lactate</p>
<p>Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development</p>	<p>none 18 EIA kits manuf. by BioCheck have been submitted open system open system none</p>	<p>none none none none —</p>
<p>User-defined methods implemented for what analytes</p>	<p>all colorimetric biochemistry &amp; EIA that read between 340–700 nm</p>	<p>open system architecture, CK-MB, myoglobin, fructosamine, <math>\beta</math>-2 microglobulin, D-dimer, caffeine, TCA, Lp(a)</p>
<p>Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously 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 Instrument has same capabilities when 3rd-party reagent used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability</p>	<p>photometry/microwell assays 0 27 unlimited unlimited/27 27/reagent dependent reagent dependent/yes (15°C below ambient) optional yes reagent dependent yes not limited/96/not limited liquid yes (optional)/96 yes (optional)/weekly 2 <math>\mu</math>L no/no no/&lt;1 L 60 no no/no yes, by handheld scanner as tubes are loaded onto instrument (2 or 5 interl., UPC, Codabar, codes 39 &amp; 128)/autodiscrimination depends on handheld scanner models</p>	<p>photometry, potentiometry, turbidimetric/— 3 40 colorimetric, 3 ISE 100 62/62 43/700 7 days/45 days/yes yes yes yes 20,000 photometrics liquid no/231 yes/4 mos 1 <math>\mu</math>L yes/yes yes/20 L &lt;60 decibels yes/50 <math>\mu</math>L yes/no yes</p>
<p>Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A</p>	<p>no no</p>	<p>yes yes</p>
<p>Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. &amp; analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable</p>	<p>yes yes/yes/no yes no/no yes/yes yes/no yes yes/yes user defined for all yes/yes</p>	<p>yes yes/yes/yes yes yes/yes yes/yes yes/yes yes yes/yes daily/30 days/30 days/14 days yes/yes</p>
<p>Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO<sub>2</sub> • Sodium, potassium, chloride, TCO<sub>2</sub>, glucose, urea, creatinine • Album., bili. direct &amp; total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS</p>	<p>n/a n/a 5.5 min, 28 specimens 15 sec reagent dependent/yes yes/yes yes</p>	<p>2.5 min 10 min 10 min 10 sec per laboratory protocol/yes yes/yes yes</p>
<p>Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with</p>	<p>onboard/yes (included in price) not known</p>	<p>yes/n/a Soft, Misys, Cerner, Mediatech, Multidata, Seacoast, Triple G, CCA, Comp Service &amp; Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens, others yes (broadcast download &amp; host query)</p>
<p>Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders &amp; results How labs get LOINC codes for reagent kits</p>	<p>yes (broadcast download) yes yes no supplied by reagent manufacturer</p>	<p>yes yes yes yes yes</p>
<p>Interface avail. (or will be) to automated specimen handling system</p>	<p>no</p>	<p>n/a</p>
<p>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)</p>	<p>yes/yes/sometimes 48 hr/yes depends on user and varies/depends on problem and varies daily: &lt;5 min; weekly: about 15 min; monthly: about 30 min or less no/no 2 days on site, 3 days at vendor offices/yes \$4,000</p>	<p>yes/yes/yes varies by location, generally &lt;4 hr/yes —/— no/yes yes/no n/a</p>
<p>Distinguishing features</p>	<p>price; one instrument for EIA &amp; biochemistry; completely open and user programmable; special discounts for biochemistry only; calculates indices; very flexible formatting of reports</p>	<p>clot detection; serum indices; 1,200 tests per hour; auto reruns, dilutions, repeats, reflex testing; open-system for 3rd party assays; part of family of chemistry systems (ADVIA 2400 &amp; ADVIA 1650) and uses same reagents; short sample detection; liquid level sensing, refrigerated compartment for calibrators/QC; integration to Centralink</p>





## Chemistry analyzers (for mid/high volume laboratories)

Part 5 of 18



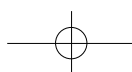
**Bayer HealthCare, Diagnostics Division**  
**Eric LaFleche** eric.lafleche.b@bayer.com  
 511 Benedict Ave.  
 Tarrytown, NY 10591  
 914-333-6162  
 labnews.com



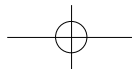
**Bayer HealthCare, Diagnostics Division**  
**Eric LaFleche** eric.lafleche.b@bayer.com  
 511 Benedict Ave.  
 Tarrytown, NY 10591  
 914-333-6162  
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<b>Name of instrument/First year sold in U.S.</b>	ADVIA 1650/1999	ADVIA 2400/2003
<b>List price/Total No. sold in U.S. in 2005</b>	\$279,000/—	\$305,000/—
<b>No. units in clinical use in U.S./Outside U.S.</b>	n/a/n/a	n/a/n/a
<b>Country where designed/Manufactured/Where reagents mftd.</b>	Japan/Japan/Ireland	Japan/Japan/Ireland
<b>Operational type/Reagent type</b>	random access/open reagent system	random access/open reagent system
<b>Sample handling system/Model type</b>	carousel rack handler option, automation option/floor standing	carousel, rack handler option, automation option/floor standing
<b>Dimensions in inches (H x W x D)/Instrument footprint</b>	45 x 59 x 34/14 sq ft	1,157 x 1,711 x 934 mm/—
<b>No. of tests for which analyzer has FDA-cleared applications</b>	80	79
<b>Tests clinically released in last 12 months</b>	lithium, vancomycin	lithium, vancomycin
<b>Tests cleared but not clinically released</b>	none	none
<b>Tests not available in U.S. but submitted for 510(k) clearance</b>	none	none
<b>Tests not available in U.S. but available in other countries</b>	none	none
<b>Research-use-only assays</b>	none	none
<b>Tests in development</b>	—	—
<b>User-defined methods implemented for what analytes</b>	open system architecture, CK-MB, myoglobin, fructosamine, caffeine, TCA, Lp(a), $\beta$ -2-microglobulin, D-dimer	open system architecture, CK-MB, myoglobin, fructosamine, caffeine, TCA, Lp(a), $\beta$ -2-microglobulin, D-dimer
<b>Methods supported/immunoassay methods</b>	photometry, potentiometry, turbidimetrics/—	photometry, potentiometry turbidimetric/—
<b>No. of direct ion selective electrode channels</b>	3	3
<b>No. of different measured assays onboard simultaneously</b>	46 colorimetric, 3 ISE	46 colorimetric, 3 ISE
<b>No. of different assays programmed, calibrated at once</b>	100	100
<b>No. of user-definable (open) channels/No. active simultaneously</b>	62/62	62/62
<b>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</b>	49/850	49/850
<b>Shortest/median onboard reagent stability/Refrigerated onboard</b>	7 days/45 days/yes	7 days/45 days/yes
<b>Multiple reagent configurations supported</b>	yes	yes
<b>Reagent container placed directly on system for use</b>	yes	yes
<b>Instrument has same capabilities when 3rd-party reagent used</b>	yes	yes
<b>Walkaway capacity in minutes/Specimens/Tests-assays</b>	32,000 photometrics	32,000 photometric
<b>System is liquid or dry</b>	liquid	liquid
<b>Uses disposable cuvettes/Max. No. stored</b>	no/221	no/340
<b>Uses washable cuvettes/Replacement frequency</b>	yes/4 months	yes/every 4 months
<b>Minimum sample volume aspirated precisely at one time</b>	2 $\mu$ L of diluted specimen	2 $\mu$ L of diluted specimen
<b>Supplied with UPS (backup power)/Requires floor drain</b>	yes/yes	yes/yes (or sink)
<b>Requires dedicated water system/Water consumption per hour</b>	yes/25 L	yes/40 L
<b>Noise generated in decibels</b>	<45 decibels	<50 decibels
<b>Dedicated pediatric sample cup/Dead volume</b>	yes/50 $\mu$ L	yes/~50 $\mu$ L
<b>Primary tube sampling/Pierces caps on primary tubes</b>	yes/no	yes/no
<b>Sample bar-code reading capability</b>	yes	yes
<b>Reagent bar-code reading capability</b>	yes	yes
<b>Bar code placement per CLSI standard Auto2A</b>	yes	yes
<b>Onboard test auto inventory (determines volume in container)</b>	yes	yes
<b>Measures no. tests remaining/Short sample detection/Clot detection</b>	yes/yes/yes	yes/yes/yes
<b>Automatic detection of adequate reagent for aspir. &amp; analysis</b>	yes	yes
<b>Hemolysis/Turbidity detection-quantitation</b>	yes/yes	yes/yes
<b>Dilution of patient samples onboard/Automatic rerun capability</b>	yes/yes	yes/yes
<b>Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results</b>	yes/yes	yes/yes
<b>Autocalibration or autocalibration alert</b>	yes	yes
<b>Calibrants stored onboard/Multipoint calibration supported</b>	yes/yes	yes/yes
<b>Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse</b>	daily/30 days/30 days/14 days	daily/30 days/30 days/14 days
<b>Automatic shutdown/Startup programmable</b>	yes/yes	yes/yes
<b>Stat time to completion of all analytes, throughput per hr. for:</b>		
• Sodium, potassium, chloride, TCO <sub>2</sub>	2.5 min	2.5 min
• Sodium, potassium, chloride, TCO <sub>2</sub> , glucose, urea, creatinine	10 min	10 min
• Album., bili. direct & total, AST, ALT, ALP	10 min	10 min
<b>Typical time delay from ordering stat test to aspir. of sample</b>	10 sec	10 sec
<b>How often QC required/Onboard SW capability to review QC</b>	per laboratory protocol/yes	per laboratory protocol/yes
<b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b>	yes/yes	yes/yes
<b>QC results transferred automatically to LIS</b>	yes	yes
<b>Data mgmt. capability/Instrument vendor supplies LIS interface</b>	yes/n/a	yes/n/a
<b>Interfaces up and running in active user sites with</b>	Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens	Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation
<b>Bidirectional interface capability</b>	yes (broadcast download & host query)	yes (broadcast download & host query)
<b>Test results transmitted to LIS as soon as chem. time complete</b>	yes	yes
<b>LIS interface operates simultaneously with running assays</b>	yes	yes
<b>Uses LOINC to transmit orders &amp; results</b>	yes	yes
<b>How labs get LOINC codes for reagent kits</b>	e-mail, software	via software
<b>Interface avail. (or will be) to automated specimen handling system</b>	yes (all systems)	yes (with ADVIA WorkCell as of October 2003)
<b>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component</b>	yes/yes/yes	yes/yes/yes
<b>On-site time of svc. engineer/Onboard error codes for troubleshooting</b>	varies by location, generally <4 hr/yes	varies by location, generally <4 hr/yes
<b>Mean time between failures/To repair failures</b>	—/—	—/—
<b>Average time to complete maintenance by lab personnel</b>	automated daily maintenance	automated daily maintenance
<b>Onboard maintenance records/Maint. training demo module</b>	no/yes	no/yes
<b>Training provided with purchase/Advanced oper. training avail.</b>	yes/yes	yes/yes
<b>Annual service contract cost (24 h/7 d)</b>	n/a	n/a
<b>Distinguishing features</b>	system will aspirate every three seconds and retain aliquot onboard; original sample is available to leave system; all testing performed with aliquot of sample remaining on ADVIA 1650; all reruns/repeats/ dilutions automatically performed without operator intervention; microvolume technology allows up to 840 tests from a 70-mL test wedge of reagent; reflex testing available; 98 percent uptime guarantee	system provides true workstation consolidation with more than 80 available chemistry and special chemistry methods and applications; also offers user-defined methods that equate to cost-effective consolidation; offers unrivaled walkaway capability with an onboard capacity of >450 specimens with the Universal Rack Handler option; 32,000 photometric tests and 90,000 ISE tests; sample saver technology allows automatic repeats, dilutions and reflex testing without operator intervention of having to return to the original specimen



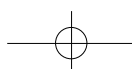


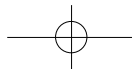


## Chemistry analyzers (for mid/high volume laboratories)

Part 6 of 18	<b>MID</b>	<b>MID</b>
<b>See related comments, page 14</b>	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com	Beckman Coulter Inc. Dan Siegenthaler dmsiegenthaler@beckman.com 200 South Kraemer Blvd., P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com
Name of instrument/First year sold in U.S. List price/Total No. sold in U.S. in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Synchron CX9 Pro/2001 \$220,600/not available >1,000/>600 U.S./U.S./U.S. & Ireland continuous random access/open reagent system	UniCel DxC 600/2004 \$340,000/not available >250/>100 U.S./U.S./U.S. & Ireland continuous random access/open reagent system
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	sectors, centrifugable/floor standing 69 x 74 x 30 in/15.4 sq ft	racks, centrifugable/floor standing 62 x 62 x 41 in/17.7 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released	>100 none none	>100 none none
Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	none none	none none
Research-use-only assays Tests in development User-defined methods implemented for what analytes	none sirolimus, tacrolimus, tricyclics, semiquantitative drugs of abuse UIBC, cyclosporine, homocysteine	none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay	photometry, potentiometry, near-infrared bidentate turbidimetric/particle enhanced turbidimetric, enzyme immunoassay, near infrared particle immunoassay
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously 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 Instrument has same capabilities when 3rd-party reagent used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	5 (indirect) 33 59 102/33 33/25-2,500 168 hr/30 days/yes (2-8°C) yes yes yes 100/63/2,079 liquid no/n/a yes/permanent-2-yr warranty (80 stored on instrument) 3 µL yes/yes yes/7 L 70 yes/40 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	5 65 100 100/65 65/about 3,500 modular; about 600 cartridge 168 hr/30 days/yes (2-8°C) yes yes no 83/132/5,280 liquid n/a yes/2-yr warranty, semi-permanent 3 µL optional/no yes/16 L 60 yes/40 µL yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes yes	yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation	yes yes/yes/yes yes yes/yes	yes yes/yes/yes yes yes/yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes/yes yes/yes yes no/yes 24 hr/up to 90 days/up to 60 days/14 days none required	yes/yes yes/yes yes no/yes 1 day/up to 90 days/up to 60 days/14 days none required
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP	52 sec, 75 specimens 52 sec, 75 specimens 10 min, 32 specimens	6:15 from standby, 96 specimens 6:15 from standby, 96 specimens 13:07 from standby, 57 specimens
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	45 sec 24 hr/yes yes/yes yes	16 sec 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	onboard & optional add-on (SW mfr: Beckman Coulter)/yes (add'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no customer request	onboard & optional add-on (SW mfr: Beckman Coulter)/yes (add'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps yes (broadcast download & host query) yes yes yes customer request
Interface avail. (or will be) to automated specimen handling system	yes (Power Processor)	yes (Beckman Coulter automation)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/no/no metro: same day, rural: same or next day/yes —/— daily: 5 min; weekly: 15 min; monthly: 25 min no/no 5 days at vendor offices/yes —	yes/yes/yes metro: same day, rural: same or next day/yes n/a/n/a daily: none; weekly: 7 min (tech time); monthly: 11 min (tech time) yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes —
Distinguishing features	serum indices; centrifugable sectors; clot detection; design optimized for automation; continuous random access for samples, controls, reagents, and results; no-maintenance glucose oxygen sensor; no-wait autoloader; polychromatic correction; thermal ring and semipermanent glass cuvettes; pulsed xenon lamp; advanced workflow and results mgmt.; liquid, ready-to-use reagents, calibrators, controls; DL2000 Workflow and Results Manager	closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks, no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; DL2000: stat notification, review by exception, reflex testing, add-on test notification

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





## Chemistry analyzers (for mid/high volume laboratories)

Part 7 of 18

**MID**

Beckman Coulter Inc.  
Katie Blount kjbount@beckman.com  
P.O. Box 8000  
Brea, CA 92822-8000  
800-526-3821  
www.beckmancoulter.com

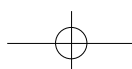
**HIGH**

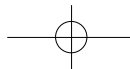
Beckman Coulter Inc.  
200 South Kraemer Blvd.  
P.O. Box 8000  
Brea, CA 92822-8000  
800-526-3821  
www.beckmancoulter.com

See related comments, page 14

Name of instrument/First year sold in U.S. List price/Total No. sold in U.S. in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Unicel DxC 600i/2006 —/0 6/2 U.S./U.S./U.S., Ireland continuous random access/open reagent system	Synchron LX20/1997 \$278,000/not available >800/>300 U.S./U.S./U.S. & Ireland continuous random access/open reagent system
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	racks, closed-tube/floor-standing 62 x 126.5 x 48/42.16	racks, centrifugable/floor standing LX20 60 x 70 x 41/19.9 sq ft; LX4201 60 x 140 x 41/39.8 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months	>150 intrinsic factor Ab	>100 n/a
Tests cleared but not clinically released	0	none
Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	DHEA-S, TPO Ab, iPTH IL-6, TPO Ab, EPO, iPTH	none none
Research-use-only assays Tests in development	IL-6 EPO, ANA Screen, ds DNA Ab, $\beta$ -2-glycoprotein 1 Ab, CMV IgG, CMV IgM, rubella IgM, Inhibin A, PIGF (pre-eclampsia), SVEGFRI (pre-eclampsia) BPH-A, [-2]proPSA, soluble transferrin receptor	none sirolimus, tacrolimus, tricyclics, semiquantitative drugs of abuse homocysteine
User-defined methods implemented for what analytes	UIBC, cyclosporine, homocysteine	UIBC, cyclosporine, homocysteine
Methods supported/immunoassay methods	photometry, potentiometry (ISE), turbidimetric, enzyme immunoassay/chemiluminescence	photometry, potentiometry, near infrared/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	5 89 >150 100/65 89/about 300 cartridge (chem), 50 per pack (immuno)	5 (indirect) 41 100 100/41 41/10,650
Shortest/median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	168 hr/28 days/yes (2–10°C) yes yes no 180/96/5,280 liquid yes/294 (immuno) yes/2-yr warranty (chem) 5 $\mu$ L optional/yes yes/16 L — yes/n/a yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	168 hr/30 days/yes (2–8°C) yes yes no 83/132/5,280 liquid no/n/a yes/semi-permanent—2-yr warranty (250 stored on instrument) 3 $\mu$ L yes/no yes/16 L 65 yes/40 $\mu$ L (samples directly from pediatric bullet) yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes yes	yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes/yes yes yes/yes yes/yes yes/no no no/yes 1 day/90 days/up to 60 days/14 days none required	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes no/yes 24 hr/up to 90 days/up to 60 days/14 days none required
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO <sub>2</sub> • Sodium, potassium, chloride, TCO <sub>2</sub> , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP	8:15 from standby, 96 specimens 8:15 from standby, 96 specimens 15:07 from standby, 57 specimens	38 sec, 90 specimens 38 sec, 90 specimens 8 min, 90 specimens
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	2:16 24 hr/— yes/yes yes/yes	16 sec 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	onboard & optional add-on (sw mfr: Beckman Coulter) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps yes (broadcast download & host query) yes yes yes customer request	onboard & optional add-on (Beckman Coulter DL2000)/yes (add'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no customer request
Interface avail. (or will be) to automated specimen handling system	no	yes (Power Processor, total lab automation)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes metro: same day; rural: same day or next n/a/n/a daily: <15 min, weekly: 36 min; monthly: 11 min yes (includes audit trail of who replaced parts)/no 10 days at vendor offices/yes n/a	yes/yes/yes metro: same day, rural: same or next day/yes —/— daily: none; weekly: 5 min; monthly: 25 min no/no 5 days at vendor offices/yes —
Distinguishing features	closed-tube aliquot and closed-tube sampling reduce manual processes and improve safety; parallel processing of chemistry and immunoassay helps eliminate bottle necks; one of the broadest menus available on a single workstation; consolidation of chemistry and immunoassay without compromise	serum indices; centrifugable racks; clot detection; no-wait autoloader/linear racks; multiple wavelength blanking; smart modules, fiber optics; advanced workflow and data management; thermal ring and semipermanent glass cuvettes; pulsed xenon lamp; electronic stat notification; review by exception; reflex testing; add-on test, DL2000 Workflow and Results Manager

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





## Chemistry analyzers (for mid/high volume laboratories)

Part 8 of 18



Beckman Coulter Inc.  
200 South Kraemer Blvd.  
P.O. Box 8000  
Brea, CA 92822-8000  
800-526-3821  
www.beckmancoulter.com

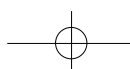


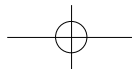
Beckman Coulter Inc.  
Kathleen Blount kjbblount@beckman.com  
200 South Kraemer Blvd.  
P.O. Box 8000  
Brea, CA 92822  
800-526-3821 www.beckmancoulter.com

See related comments, page 14

Name of instrument/First year sold in U.S. List price/Total No. sold in U.S. in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	Synchron LX20 Pro/2001 \$343,000/— >800/>300 U.S./U.S./U.S. & Ireland continuous random access/open reagent system racks, centrifugable/floor standing 60 x 70 x 41/19.9 sq ft	Synchron LXi725/2002 —/not available >400/>250 U.S./U.S./U.S. continuous random access/open reagent system racks, centrifugable/floor standing 60 x 134.5 x 48/44.8 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months  Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) 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	>100 n/a  none none none none sirolimus, tacrolimus, tricyclics, semiquantitative drugs of abuse  UIBC, cyclosporine, homocysteine	>135 n/a  none none none none intact PTH, EPO, IL-6, dsDNA, TNF- $\alpha$ , soluble transferrin receptor, $\beta$ -2-glycoprotein 1 Ab  UIBC, homocysteine, cyclosporine
Methods supported/immunoassay methods  No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously 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 Instrument has same capabilities when 3rd-party reagent used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability  Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	photometry, potentiometry, near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay 5 (indirect) 41 100 100/41 41/10,650  168 hr/30 days/yes (2–8°C) yes yes no 83/132/5,280 liquid no/n/a yes/semi-permanent—2-yr warranty (250 stored on instrument) 3 $\mu$ L yes/no yes/16 L 65 yes/40 $\mu$ L yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes	photometry, potentiometry (ISE), near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, chemiluminescence 5 (indirect) 65 124 100/100 65/11,850  168 hr/28 days/yes (2–10°C) yes yes no 180/132/5,280 liquid yes/294 (immuno) yes/2-yr (chemistry) warranty, semi-permanent 3 $\mu$ L yes/yes yes/16 L n/a — yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation  Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes/yes yes yes/yes  yes/yes yes/yes  yes no/yes 1 day/up to 90 days/up to 60 days/14 days none required	yes yes/yes/yes yes yes (chemistry)/yes (chemistry)  yes/yes yes (chemistry)/yes (chemistry)  yes (chemistry) no/yes 24 hr/up to 90 days/up to 60 days/14 days none required
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO <sub>2</sub> • Sodium, potassium, chloride, TCO <sub>2</sub> , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP  Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	38 sec, 90 specimens 38 sec, 90 specimens 8 min, 90 specimens  16 sec 24 hr/yes yes/yes yes	38 sec, 90 specimens 38 sec, 90 specimens 8 min, 90 specimens  36 sec 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface  Interfaces up and running in active user sites with  Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	onboard & optional add-on (Beckman Coulter DL2000)/yes (add'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no customer request	onboard & optional add-on (Beckman Coulter)/yes (add'l cost) Cerner, Misys yes (broadcast download & host query) yes yes yes customer request
Interface avail. (or will be) to automated specimen handling system	yes (Power Processor, total lab automation)	no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes  metro: same day, rural: same or next day/yes —/— daily: none; weekly: 5 min; monthly: 25 min no/no 5 days at vendor offices/yes —	yes/yes/yes  metro: same day, rural: same or next day/yes n/a/n/a daily: 15 min; weekly: 33.5 min; monthly: 25 min no/no 10 days at vendor offices/yes n/a
Distinguishing features	serum indices; centrifugable racks; clot detection; no-wait autoloader/linear racks; multiple wavelength blanking; smart modules, fiber optics; advanced workflow & data management; thermal ring and semipermanent glass cuvettes; pulsed xenon lamp; electronic stat notification; review by exception; reflex testing; add-on test; closed-tube sampling, near infrared detection (for high-sensitivity CRP), DL2000 Workflow and Results Manager	workstation consolidation without compromise through single point of sample entry for both chemistry and immunoassay testing; closed-tube sampling; one of fastest stats for chemistry samples; dual scheduling and parallel processing of chemistry and immunoassay samples for optimum throughput; menu equivalence to Synchron and Access product lines

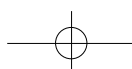
Tabulation does not represent an endorsement by the College of American Pathologists

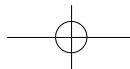




## Chemistry analyzers (for mid/high volume laboratories)

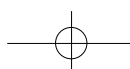
Part 9 of 18 <i>See related comments, page 14</i>	<b>HIGH</b>	<b>MID</b>	Carolina Liquid Chemistries Patricia A. Shugart pgshugart@carolinachemistries.com 510 W. Central Ave. Brea, CA 92823 800-471-7272 www.carolinachemistries.com
<b>Beckman Coulter Inc.</b> Dan Siegenthaler dmsiegenthaler@beckman.com 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822 800-526-3821 www.beckmancoulter.com			
<b>Name of instrument/First year sold in U.S.</b> <b>List price/Total No. sold in U.S. in 2005</b> <b>No. units in clinical use in U.S./Outside U.S.</b> <b>Country where designed/Manufactured/Where reagents mftd.</b> <b>Operational type/Reagent type</b>	UniCel DxC 800/2005 —/not available >150/>200 U.S./U.S./U.S. & Ireland continuous random access/open reagent system	A&T 504X/2006 \$190,000/— n/a/3 Japan/Japan/U.S. continuous random access/self-contained single-use cartridges-packages-slides rack, ring/floor standing 50 x 47.2 x 34.5/—	
<b>Sample handling system/Model type</b> <b>Dimensions in inches (H x W x D)/Instrument footprint</b>	racks, centrifugable/floor standing 62 x 70 x 41/19.9 sq ft		
<b>No. of tests for which analyzer has FDA-cleared applications</b> <b>Tests clinically released in last 12 months</b> <b>Tests cleared but not clinically released</b> <b>Tests not available in U.S. but submitted for 510(k) clearance</b> <b>Tests not available in U.S. but available in other countries</b> <b>Research-use-only assays</b> <b>Tests in development</b> <b>User-defined methods implemented for what analytes</b>	>100 n/a none none none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	— n/a n/a — n/a 80 different assays—contact company for listing 80 different assays—contact company for listing —	
<b>Methods supported/immunoassay methods</b> <b>No. of direct ion selective electrode channels</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/No. active simultaneously</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>Instrument has same capabilities when 3rd-party reagent used</b> <b>Walkaway capacity in minutes/Specimens/Tests-assays</b> <b>System is liquid or dry</b> <b>Uses disposable cuvettes/Max. No. stored</b> <b>Uses washable cuvettes/Replacement frequency</b> <b>Minimum sample volume aspirated precisely at one time</b> <b>Supplied with UPS (backup power)/Requires floor drain</b> <b>Requires dedicated water system/Water consumption per hour</b> <b>Noise generated in decibels</b> <b>Dedicated pediatric sample cup/Dead volume</b> <b>Primary tube sampling/Pierces caps on primary tubes</b> <b>Sample bar-code reading capability</b> <b>Reagent bar-code reading capability</b> <b>Bar code placement per CLSI standard Auto2A</b>	photometry, potentiometry (ISE), near-infrared bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay 5 70 100 100/70 70/approx. 3,500 (modular); 600 cartridge 168 hr/30 days/yes (2–8°C) yes yes no 83/132/5,280 liquid no yes/2-yr warranty, semi-permanent 3 µL optional/no yes/16 L 60 yes/40 µL (samples directly from bullet) yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes	photometry, potentiometry (ISE)/turbidimetry 3 (Na, K+, and Cl-) 48 48 10/10 48/400 720 hr/30 days/yes (6–10°C) yes yes yes 240/100/4,800 liquid — no/n/a 2 µL no/no no/45 L — —/— —/— yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes	
<b>Onboard test auto inventory (determines volume in container)</b> <b>Measures no. tests remaining/Short sample detection/Clot detection</b> <b>Automatic detection of adequate reagent for aspir. &amp; analysis</b> <b>Hemolysis/Turbidity detection-quantitation</b> <b>Dilution of patient samples onboard/Automatic rerun capability</b> <b>Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results</b> <b>Autocalibration or autocalibration alert</b> <b>Calibrants stored onboard/Multipoint calibration supported</b> <b>Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse</b> <b>Automatic shutdown/Startup programmable</b>	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes no/yes 1 day/up to 90 days/up to 60 days/14 days none required	yes yes/yes/yes yes —/yes yes/yes yes/yes yes yes/yes 24 hr/2 weeks/—/— yes/yes	
<b>Stat time to completion of all analytes, throughput per hr. for:</b> • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP <b>Typical time delay from ordering stat test to aspir. of sample</b> <b>How often QC required/Onboard SW capability to review QC</b> <b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b> <b>QC results transferred automatically to LIS</b>	2:23 (from standby), 91 specimens 2:22 (from standby), 91 specimens 12:32 (from standby), 76 specimens 16 sec 24 hr/yes yes/yes yes	10 min, 1,200 10 min, 1,200 10 min, 1,200 — shortest interval: 8 hr; longest: 24 hr/yes yes/yes yes	
<b>Data mgmt. capability/Instrument vendor supplies LIS interface</b> <b>Interfaces up and running in active user sites with</b> <b>Bidirectional interface capability</b> <b>Test results transmitted to LIS as soon as chem. time complete</b> <b>LIS interface operates simultaneously with running assays</b> <b>Uses LOINC to transmit orders &amp; results</b> <b>How labs get LOINC codes for reagent kits</b>	onboard & optional add-on (Beckman Coulter)/yes (add'l cost) Cerner, Misys, Meditech, Citation, Medlab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps yes (broadcast download & host query) yes yes yes customer request	onboard/yes (add'l cost; SW mfr: A&T) — yes (broadcast download & host query) yes yes yes Web site	
<b>Interface avail. (or will be) to automated specimen handling system</b>	yes, Beckman Coulter automation	yes, A&T	
<b>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component</b> <b>On-site time of svc. engineer/Onboard error codes for troubleshooting</b> <b>Mean time between failures/To repair failures</b> <b>Average time to complete maintenance by lab personnel</b> <b>Onboard maintenance records/Maint. training demo module</b> <b>Training provided with purchase/Advanced oper. training avail.</b> <b>Annual service contract cost (24 h/7 d)</b>	yes/yes/yes metro: same day, rural: same or next day/yes n/a/n/a daily: none; weekly: 10 min (tech time); monthly: 18 min (tech time) yes (includes audit trail of who replaced parts/yes 5 days at vendor offices/yes n/a	yes/yes/yes 24 hr/yes —/— daily: 10 min; weekly: 10 min; monthly: 10 min yes/yes 5 days on site, 4 days at vendor offices/yes \$19,000	
<b>Distinguishing features</b>	closed-tube sampling; serum indices/polychromatic correction; clot detection & correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; one of the fastest stat TAT; DL2000: stat notification, review by exception, reflex testing, add-on test notification	onboard automatic rerun using internal sample dilution cup; ready to connect with any laboratory automation system; small footprint	

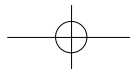




## Chemistry analyzers (for mid/high volume laboratories)

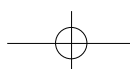
Part 10 of 18	<b>MID</b>	<b>MID</b>
<b>See related comments, page 14</b>	<b>Clinical Data</b> sismktg@clda.com 2 Thurber Blvd. Smithfield, RI 02917 800-345-2822 www.clda.com	<b>Clinical Data</b> sismktg@clda.com 2 Thurber Blvd. Smithfield, RI 02917 800-345-2822 www.clda.com
Name of instrument/First year sold in U.S. List price/Total No. sold in U.S. in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Vitalab Selectra XL/2004 \$98,750/— 0/— Netherlands/Netherlands/U.S. random access/multi-use bottles	Envoy 500/2005 \$96,750/— 40/— Italy/Italy/U.S. random access/self-contained multi-use cartridges, packages, slides
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	rotor/floor standing 45 x 46 x 30/12 sq ft	rotor/benchtop 24 x 22 x 39/—
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released	>31 — —	28 — —
Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	— — — —	n/a n/a n/a n/a
User-defined methods implemented for what analytes	hsCRP n/a	hsCRP n/a
Methods supported/immunoassay methods	photometry, potentiometry (ISE)/immunoturbidimetric	photometry, potentiometry (ISE)/—
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	4 40 40 5/40 70/700	4 40 40 40/40 40
Shortest/median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels	72 hr/7 days/yes (12°C below ambient) — yes yes 240/80/2,400 liquid no yes/every 10,000 reactions 1 µL yes/no no/0.8 L —	40 hr/10 days/yes (12–15°C) yes yes no 240/52/40 liquid no yes/never 1 µL yes/no no/— —
Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes/20 µL yes/no yes, as sample is being aspirated (2 of 5 interl., UPC, Codabar, codes 39 & 128) no yes	yes/50 µL yes/no yes, as sample is being aspirated yes —
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes/yes yes —/— yes/yes yes/no yes no/yes 4 hr/1–14 days/—/— yes/yes	yes yes/yes/yes yes no/no yes/yes yes/yes no no/yes 4 hr/7 days/n/a/n/a yes/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP	8 min, — 10 min, — 10 min, —	2 min 20 sec, 240 7 min 30 sec, 47 7 min, 28
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	6 min shortest interval: 4 hr; longest: once a day/yes no/yes yes	— daily/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface	optional add on/yes	no/yes (add'l cost)
Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	— yes yes yes — —	Antek, Labdaq, Fletcher-Flora, Labpak yes (broadcast download & host query) yes yes — —
Interface avail. (or will be) to automated specimen handling system	—	—
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/yes/yes within 24 hr/yes 6 mo/4 hr daily: 10 min; weekly: 20 min; monthly: 60 min no/yes 3 days on site/yes n/a	no/yes/yes 24 hr/yes n/a/n/a daily: 5 min; weekly: 15 min; monthly: 30 min no/no 5 days on site —
Distinguishing features	4 parameter dry ISE with CO <sub>2</sub> ; reusable reaction cuvette rotor; onboard wash system	4 parameter dry ISE with CO <sub>2</sub> ; 570 tests per hour benchtop; onboard touch screen LCD monitor

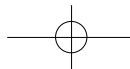




## Chemistry analyzers (for mid/high volume laboratories)

Part 11 of 18	<b>HIGH</b>	<b>HIGH</b>
<b>See related comments, page 14</b>	Dade Behring Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.dadebehring.com	Dade Behring Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.dadebehring.com
<b>Name of instrument/First year sold in U.S.</b>	Dimension Rxl. Max Integrated Chemistry System/2003	Dimension Vista 1500/2006
<b>List price/Total No. sold in U.S. in 2005</b>	—/—	—/—
<b>No. units in clinical use in U.S./Outside U.S.</b>	RxL: 2,500/—; RxL Max: >600/—	—/—
<b>Country where designed/Manufactured/Where reagents mftd.</b>	U.S./U.S./U.S.	U.S./U.S./U.S. and Germany
<b>Operational type/Reagent type</b>	batch, random access, continuous random access/self-contained multiuse cartridges-packages-slides	batch, random access, continuous random access/self-contained multi-use cartridges-packages-slides
<b>Sample handling system/Model type</b>	segmented sample wheel/floor standing	sample rack and aloquot plate system/floor standing
<b>Dimensions in inches (H x W x D)/Instrument footprint</b>	44 x 62.5 x 30.5/13.2 sq ft	55 x 84 x 43/26 sq ft
<b>No. of tests for which analyzer has FDA-cleared applications</b>	>90	—
<b>Tests clinically released in last 12 months</b>	cardiophase hsCRP	—
<b>Tests cleared but not clinically released</b>	CSA extended range	—
<b>Tests not available in U.S. but submitted for 510(k) clearance</b>	—	—
<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>	MPA, sirolimus, tacrolimus, ecstasy	120+
<b>User-defined methods implemented for what analytes</b>	propoxyphene, methaqualone, serum tricyclic antidepressant, serum barbiturate, serum benzodiazepine	0
<b>Methods supported/immunoassay methods</b>	photometry, potentiometry, Integrated Multisensor Technology (IMT)/heterogenous EIA using HM, EMIT latex particle turbidimetric, latex turbidimetric	photometry, potentiometry (ISE), advanced LOCI chemiluminescence technology, nephelometry, EMIT PETINIA PETIA ACMA LOCI, turbidimetric
<b>No. of direct ion selective electrode channels</b>	3 (indirect) ECO2 photometric	3 (indirect)
<b>No. of different measured assays onboard simultaneously</b>	44/88 with optional inventory management system	up to 100 methods simultaneously
<b>No. of different assays programmed, calibrated at once</b>	190	120+
<b>No. of user-definable (open) channels/No. active simultaneously</b>	10/10	—/up to 100 methods simultaneously
<b>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</b>	44-88/max. 360	100/20-1,200 tests, flex
<b>Shortest/median onboard reagent stability/Refrigerated onboard</b>	72 hr/30 days/yes (2-8°C)	—/30 days/yes
<b>Multiple reagent configurations supported</b>	yes	no
<b>Reagent container placed directly on system for use</b>	yes	yes
<b>Instrument has same capabilities when 3rd-party reagent used</b>	yes	no
<b>Walkaway capacity in minutes/Specimens/Tests-assays</b>	can be hours	>45 min/150/—
<b>System is liquid or dry</b>	liquid, reconstitutes onboard	liquid
<b>Uses disposable cuvettes/Max. No. stored</b>	yes/12,000	yes/>1,500 washed, disposable cuvettes and 1,000 LOCI vessels
<b>Uses washable cuvettes/Replacement frequency</b>	no/—	yes/automatic
<b>Minimum sample volume aspirated precisely at one time</b>	2 µL	2 µL
<b>Supplied with UPS (backup power)/Requires floor drain</b>	yes/no	yes/no
<b>Requires dedicated water system/Water consumption per hour</b>	yes/3.2 L	no/20 L
<b>Noise generated in decibels</b>	<70	<70
<b>Dedicated pediatric sample cup/Dead volume</b>	no/20 µL	yes/—
<b>Primary tube sampling/Pierces caps on primary tubes</b>	yes, 5, 7, 10 mL/no	yes/no
<b>Sample bar-code reading capability</b>	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
<b>Reagent bar-code reading capability</b>	yes	yes
<b>Bar code placement per CLSI standard Auto2A</b>	yes	yes
<b>Onboard test auto inventory (determines volume in container)</b>	yes	yes
<b>Measures no. tests remaining/Short sample detection/Clot detection</b>	yes/yes/no	yes/yes/yes
<b>Automatic detection of adequate reagent for aspir. &amp; analysis</b>	yes	no
<b>Hemolysis/Turbidity detection-quantitation</b>	yes/yes	yes/yes
<b>Dilution of patient samples onboard/Automatic rerun capability</b>	yes/yes	yes/yes
<b>Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results</b>	yes/yes	yes/no
<b>Autocalibration or autocalibration alert</b>	yes (with 7.4 software)	yes
<b>Calibrants stored onboard/Multipoint calibration supported</b>	yes/30-90 days	yes/yes
<b>Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse</b>	every 2 hr-autocalibrate/—/60-90 days/30 days	automatic every 4 hr/30-90 days/30 days/30 days
<b>Automatic shutdown/Startup programmable</b>	no/no (2 min tech time, 5 min instrument time)	no/no
<b>Stat time to completion of all analytes, throughput per hr. for:</b>		
• Sodium, potassium, chloride, TCO2	50 sec, 288 tests	2 min, 166
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	4.5 min, 500 tests	4-7 min, 166
• Album., bili. direct & total, AST, ALT, ALP	10-11 min, 500 tests	<15 min, 200
<b>Typical time delay from ordering stat test to aspir. of sample</b>	24 sec	<2 min
<b>How often QC required/Onboard SW capability to review QC</b>	24 hr/yes	shortest: 24 hr; longest: user defined/yes, via EasyLink
<b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b>	no/yes	yes/yes
<b>QC results transferred automatically to LIS</b>	yes	yes, via EasyLink
<b>Data mgmt. capability/Instrument vendor supplies LIS interface</b>	optional add-on (DBNet, Dade Behring)/yes (add'l cost)	onboard (Dade Behring)/—
<b>Interfaces up and running in active user sites with</b>	all major LIS vendors	—
<b>Bidirectional interface capability</b>	yes (broadcast download & host query)	yes (broadcast download & host query)
<b>Test results transmitted to LIS as soon as chem. time complete</b>	yes	yes
<b>LIS interface operates simultaneously with running assays</b>	yes	yes
<b>Uses LOINC to transmit orders &amp; results</b>	no	no
<b>How labs get LOINC codes for reagent kits</b>	—	n/a
<b>Interface avail. (or will be) to automated specimen handling system</b>	yes	yes, Dade Behring StreamLab, SpecTrak
<b>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component</b>	yes/yes/yes	yes/yes/yes
<b>On-site time of svc. engineer/Onboard error codes for troubleshooting</b>	2-8 hr/yes	2-8 hr/yes
<b>Mean time between failures/To repair failures</b>	—/—	—/—
<b>Average time to complete maintenance by lab personnel</b>	daily: 5 min; weekly: 10 min; monthly: 15 min	daily: none; weekly: none; monthly: 10-20 min
<b>Onboard maintenance records/Maint. training demo module</b>	no/no	in development/yes
<b>Training provided with purchase/Advanced oper. training avail.</b>	5 days on site, 4 days at vendor offices/yes	5 days on site, 5 days at vendor office/yes (online training available)
<b>Annual service contract cost (24 h/7 d)</b>	multiple types	varies—multiple types
<b>Distinguishing features</b>	integrates heterogenous immunoassays onboard with other chemistries; allows single platform for over 95 percent of most requested tests; eliminates sample splitting between general tests and immunoassays	ultra-integration using 4 detection systems with new LOCI and nephelometry; automatic QC and calibration with refrigerated onboard materials; proactive service system

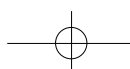


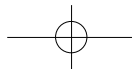


## Chemistry analyzers (for mid/high volume laboratories)

Part 12 of 18	<b>MID</b>	<b>HIGH</b>
<b>See related comments, page 14</b>	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympus.com	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympus.com
<b>Name of instrument/First year sold in U.S.</b>	AU400/1998; AU400e/2002	AU640/1999; AU640e/2002
<b>List price/Total No. sold in U.S. in 2005</b>	\$130,000/99	\$185,000/49
<b>No. units in clinical use in U.S./Outside U.S.</b>	>500/>2,000	>300/>1,000
<b>Country where designed/Manufactured/Where reagents mftd.</b>	Japan/Japan/U.S. & Ireland	Japan/Japan/U.S. & Ireland
<b>Operational type/Reagent type</b>	random access, discrete, continuous random access/open reagent system	random access, discrete, continuous random access/open reagent system
<b>Sample handling system/Model type</b>	rack & stat carousel/floor standing	rack & stat carousel/floor standing
<b>Dimensions in inches (H x W x D)/Instrument footprint</b>	47.6 x 57.1 x 29.9/62.7 sq ft	50 x 74 x 32/68 sq ft
<b>No. of tests for which analyzer has FDA-cleared applications</b>	125	125
<b>Tests clinically released in last 12 months</b>	—	—
<b>Tests cleared but not clinically released</b>	—	none
<b>Tests not available in U.S. but submitted for 510(k) clearance</b>	—	—
<b>Tests not available in U.S. but available in other countries</b>	—	—
<b>Research-use-only assays</b>	none	none
<b>Tests in development</b>	D-dimer	D-dimer
<b>User-defined methods implemented for what analytes</b>	fructosamine, ammonia, oxycodone	fructosamine, ammonia, oxycodone
<b>Methods supported/immunoassay methods</b>	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, calculated tests/homogeneous
<b>No. of direct ion selective electrode channels</b>	3	3
<b>No. of different measured assays onboard simultaneously</b>	up to 76	up to 51
<b>No. of different assays programmed, calibrated at once</b>	99	99
<b>No. of user-definable (open) channels/No. active simultaneously</b>	95/72	95/47
<b>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</b>	76/100–1,333	48 x 2/100–1,333
<b>Shortest/median onboard reagent stability/Refrigerated onboard</b>	120 hr/30 days/yes (4–12°C)	120 hr/30 days/yes (4–12°C)
<b>Multiple reagent configurations supported</b>	yes	yes
<b>Reagent container placed directly on system for use</b>	yes	yes
<b>Instrument has same capabilities when 3rd-party reagent used</b>	yes	yes
<b>Walkaway capacity in minutes/Specimens/Tests-assays</b>	varies/up to 102/varies	varies/up to 172/varies
<b>System is liquid or dry</b>	liquid	liquid
<b>Uses disposable cuvettes/Max. No. stored</b>	no/n/a	no/n/a
<b>Uses washable cuvettes/Replacement frequency</b>	yes/permanent	yes/permanent
<b>Minimum sample volume aspirated precisely at one time</b>	2 µL	2 µL
<b>Supplied with UPS (backup power)/Requires floor drain</b>	no (optional)/yes (no w/ optional water pump)	no (optional)/yes (no w/ optional water pump)
<b>Requires dedicated water system/Water consumption per hour</b>	yes/26 L per hr peak consumption	yes/40 L per hr peak consumption
<b>Noise generated in decibels</b>	65	65
<b>Dedicated pediatric sample cup/Dead volume</b>	no/n/a	no/n/a
<b>Primary tube sampling/Pierces caps on primary tubes</b>	yes/no	yes/no
<b>Sample bar-code reading capability</b>	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
<b>Reagent bar-code reading capability</b>	yes	yes
<b>Bar code placement per CLSI standard Auto2A</b>	yes	yes
<b>Onboard test auto inventory (determines volume in container)</b>	yes	yes
<b>Measures no. tests remaining/Short sample detection/Clot detection</b>	yes/yes/yes	yes/yes/yes
<b>Automatic detection of adequate reagent for aspir. &amp; analysis</b>	yes	yes
<b>Hemolysis/Turbidity detection-quantitation</b>	yes/yes	yes/yes
<b>Dilution of patient samples onboard/Automatic rerun capability</b>	yes/yes	yes/yes
<b>Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results</b>	yes/yes	yes/yes
<b>Autocalibration or autocalibration alert</b>	yes	yes
<b>Calibrants stored onboard/Multipoint calibration supported</b>	yes/yes	yes/yes
<b>Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse</b>	1 day/30 days/14 days/14–20 days	1 day/30 days/14 days/14–20 days
<b>Automatic shutdown/Startup programmable</b>	yes/yes	yes/yes
<b>Stat time to completion of all analytes, throughput per hr. for:</b>		
• Sodium, potassium, chloride, TCO2	<5 min, 200 specimens	<4 min, 200 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	<5 min, 80 specimens	<5 min, 160 specimens
• Album., bili. direct & total, AST, ALT, ALP	<9 min, 67 specimens	9 min, 133 specimens
<b>Typical time delay from ordering stat test to aspir. of sample</b>	<2 min	1 min
<b>How often QC required/Onboard SW capability to review QC</b>	per CLIA & laboratory's decision/yes	per CLIA & laboratory's decision/yes
<b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b>	yes/yes	yes/yes
<b>QC results transferred automatically to LIS</b>	yes	yes
<b>Data mgmt. capability/Instrument vendor supplies LIS interface</b>	onboard/no (optional)	onboard/no (optional)
<b>Interfaces up and running in active user sites with</b>	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC
<b>Bidirectional interface capability</b>	yes (broadcast download & host query)	yes (broadcast download & host query)
<b>Test results transmitted to LIS as soon as chem. time complete</b>	yes	yes
<b>LIS interface operates simultaneously with running assays</b>	yes	yes
<b>Uses LOINC to transmit orders &amp; results</b>	no	no
<b>How labs get LOINC codes for reagent kits</b>	—	—
<b>Interface avail. (or will be) to automated specimen handling system</b>	yes	yes
<b>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component</b>	yes/yes/yes	yes/yes/yes
<b>On-site time of svc. engineer/Onboard error codes for troubleshooting</b>	<24 hr/yes	<24 hr/yes
<b>Mean time between failures/To repair failures</b>	average 2 calls per yr/<24 hr	average 2 calls per yr/<24 hr
<b>Average time to complete maintenance by lab personnel</b>	daily: 3 min; weekly: 7 min; monthly: 45 min	daily: 3 min; weekly: 27 min; monthly: 45 min
<b>Onboard maintenance records/Maint. training demo module</b>	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
<b>Training provided with purchase/Advanced oper. training avail.</b>	3–5 days on site, 5 days at vendor offices/yes	3–5 days on site, 5 days at vendor offices/yes
<b>Annual service contract cost (24 h/7 d)</b>	inquire	inquire
<b>Distinguishing features</b>	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with family of chemistry immuno systems, the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems, the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation

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

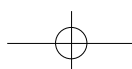




## Chemistry analyzers (for mid/high volume laboratories)

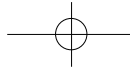
Part 13 of 18	<b>HIGH</b>	<b>HIGH</b>
<i>See related comments, page 14</i>	<b>Olympus America Inc.</b> 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympus.com	<b>Olympus America Inc.</b> 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympus.com
<b>Name of instrument/First year sold in U.S.</b> <b>List price/Total No. sold in U.S. in 2005</b> <b>No. units in clinical use in U.S./Outside U.S.</b> <b>Country where designed/Manufactured/Where reagents mftd.</b> <b>Operational type/Reagent type</b> <b>Sample handling system/Model type</b> <b>Dimensions in inches (H x W x D)/Instrument footprint</b>	AU2700/2000 \$320,000/13 >60/>450 Japan/Japan/U.S. & Ireland random access, discrete, continuous random access/open reagent system rack & stat carousel/floor standing 50 x 79 x 45/92 sq ft	AU5421 with dual ISE/2001 \$465,000/5 >100/300 Japan/Japan/U.S. & Ireland random access, discrete, continuous random access/open reagent system rack/floor standing 50 x 148 x 45/46.25 sq ft
<b>No. of tests for which analyzer has FDA-cleared applications</b> <b>Tests clinically released in last 12 months</b> <b>Tests cleared but not clinically released</b> <b>Tests not available in U.S. but submitted for 510(k) clearance</b> <b>Tests not available in U.S. but available in other countries</b> <b>Research-use-only assays</b> <b>Tests in development</b> <b>User-defined methods implemented for what analytes</b>	125 — none — — none D-dimer fructosamine, ammonia, oxycodone	125 — none — — none D-dimer fructosamine, ammonia, oxycodone
<b>Methods supported/immunoassay methods</b> <b>No. of direct ion selective electrode channels</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/No. active simultaneously</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>Instrument has same capabilities when 3rd-party reagent used</b> <b>Walkaway capacity in minutes/Specimens/Tests-assays</b> <b>System is liquid or dry</b> <b>Uses disposable cuvettes/Max. No. stored</b> <b>Uses washable cuvettes/Replacement frequency</b> <b>Minimum sample volume aspirated precisely at one time</b> <b>Supplied with UPS (backup power)/Requires floor drain</b> <b>Requires dedicated water system/Water consumption per hour</b> <b>Noise generated in decibels</b> <b>Dedicated pediatric sample cup/Dead volume</b> <b>Primary tube sampling/Pierces caps on primary tubes</b> <b>Sample bar-code reading capability</b> <b>Reagent bar-code reading capability</b> <b>Bar code placement per CLSI standard Auto2A</b>	photometry, potentiometry, calculated tests/homogeneous 3 up to 51 99 95/47 48 x 2/100–4,000 120 hr/30 days/yes (4–12°C) yes yes yes varies/up to 322/varies liquid no/n/a yes/permanent 1 µL no (optional)/yes yes/65 L per hr peak consumption <65 no/n/a yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes	photometry, potentiometry, calculated tests/homogeneous 3 99 99 95/95 48 x 4/100–4,000 120 hr/30 days/yes (4–12°C) yes yes yes varies/up to 300/varies liquid no/n/a yes/permanent 1 µL no (optional)/yes yes/120 L <65 no/n/a yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl.)/autodiscrimination yes yes
<b>Onboard test auto inventory (determines volume in container)</b> <b>Measures no. tests remaining/Short sample detection/Clot detection</b> <b>Automatic detection of adequate reagent for aspir. &amp; analysis</b> <b>Hemolysis/Turbidity detection-quantitation</b> <b>Dilution of patient samples onboard/Automatic rerun capability</b> <b>Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results</b> <b>Autocalibration or autocalibration alert</b> <b>Calibrants stored onboard/Multipoint calibration supported</b> <b>Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse</b> <b>Automatic shutdown/Startup programmable</b>	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes
<b>Stat time to completion of all analytes, throughput per hr. for:</b> • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP <b>Typical time delay from ordering stat test to aspir. of sample</b> <b>How often QC required/Onboard SW capability to review QC</b> <b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b> <b>QC results transferred automatically to LIS</b>	<4 min, 267 specimens <4 min, 267 specimens 9 min, 267 specimens 1 min per CLIA & laboratory's decision/yes yes/yes yes	—, max 600 —, max 600 —, max 533 — per CLIA & laboratory's decision/yes yes/yes yes
<b>Data mgmt. capability/Instrument vendor supplies LIS interface</b> <b>Interfaces up and running in active user sites with</b> <b>Bidirectional interface capability</b> <b>Test results transmitted to LIS as soon as chem. time complete</b> <b>LIS interface operates simultaneously with running assays</b> <b>Uses LOINC to transmit orders &amp; results</b> <b>How labs get LOINC codes for reagent kits</b>	onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC yes (broadcast download & host query) yes yes no —	onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC yes (broadcast download & host query) yes yes no —
<b>Interface avail. (or will be) to automated specimen handling system</b>	yes	yes
<b>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component</b> <b>On-site time of svc. engineer/Onboard error codes for troubleshooting</b> <b>Mean time between failures/To repair failures</b> <b>Average time to complete maintenance by lab personnel</b> <b>Onboard maintenance records/Maint. training demo module</b> <b>Training provided with purchase/Advanced oper. training avail.</b> <b>Annual service contract cost (24 h/7 d)</b>	yes/yes/yes <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 3–5 days on site, 5 days at vendor offices/yes inquire	yes/yes/yes <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes inquire
<b>Distinguishing features</b>	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation

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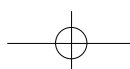


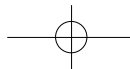




## Chemistry analyzers (for mid/high volume laboratories)

Part 15 of 18	HIGH	HIGH
<b>See related comments, page 14</b>	Ortho-Clinical Diagnostics Mia Ares-Borcky 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com	Ortho-Clinical Diagnostics Mia Ares-Borcky 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com
Name of instrument/First year sold in U.S. List price/Total No. sold in U.S. in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	VITROS 950, VITROS 950AT/1995 950: \$196,000; 950 AT: \$250,000 >1,500/— U.S./U.S./U.S. batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides	VITROS 250, VITROS 250AT/1993 250 \$105,000; 250 AT \$165,000 >2,000/— U.S./U.S./U.S. batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	sample trays/floor standing 55 x 68 x 38/26 sq ft	rack/floor standing 47 x 45.5 x 28/8.8 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	70 dHDL MicroSlide — — — — —	70 dHDL MicroSlide — — — — —
User-defined methods implemented for what analytes	—	none
Methods supported/immunoassay methods  No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	potentiometry, colorimetric, rate, immuno-rate/—  3 up to 75 up to 75 n/a/n/a up to 75/up to 60  48 hr/14 days/no yes yes n/a —/40/4,500 dry no/n/a no/n/a 6 µL available (not included)/no no/none — no special sample cup required/35 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	potentiometry, colorimetric, rate, immuno-rate/—  3 up to 60 up to 60 n/a/n/a up to 60/up to 60  48 hr/14 days/no yes yes n/a —/40/3,600 dry n/a/n/a n/a/n/a 6 µL available (not included)/no no/n/a — no special sample cup required/35 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes yes	yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes/yes yes not needed/not needed yes/no no/no  no no/yes reagent lot changes no/no	yes yes/yes/yes yes not needed/not needed yes/no yes/no  no no/yes reagent lot changes no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP	~6 min, 600 ~6 min, ~700 ~7 min, ~700	6 min, 240 7 min, 258 7 min 17 sec, 230
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	8 sec 24 hr/yes yes/yes yes	12 sec 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface  Interfaces up and running in active user sites with  Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	onboard/no (optional)  all common interfaces  yes (broadcast download) yes yes — —	onboard/no (optional)  all common interfaces  yes (broadcast download) yes yes — —
Interface avail. (or will be) to automated specimen handling system	yes (enGen)	yes (enGen)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/yes/yes  <4 hr/yes —/— daily: 2 min; weekly: 5 min; monthly: 15 min no/yes 3 days on site, 5 days at vendor offices/yes —	no/yes/yes  <4 hr/yes —/— daily: 2 min; weekly: 5 min; monthly: 15 min no/yes 3 days on site, 5 days at vendor offices/yes —
Distinguishing features	cost-effective MicroSlide Technology delivers low cost per reportable result and high reagent efficiency without the costs, maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required just once each day and calibration intervals up to six months with minimal interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily	cost-effective MicroSlide Technology delivers low cost per reportable result and high reagent efficiency without the costs, maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required just once each day and calibration intervals up to six months with minimal interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily

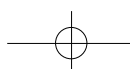


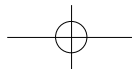


## Chemistry analyzers (for mid/high volume laboratories)



Part 16 of 18	<b>HIGH</b>	<b>MID</b>
<b>See related comments, page 14</b>	<b>Ortho-Clinical Diagnostics</b> Mia Ares-Borcky 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com	<b>Randox Laboratories Ltd</b> marketing@randox.com 4065 Oceanside Blvd., Ste. Q Oceanside, CA 92056 760-639-1506 www.randox.com
<b>Name of instrument/First year sold in U.S.</b> <b>List price/Total No. sold in U.S. in 2005</b> <b>No. units in clinical use in U.S./Outside U.S.</b> <b>Country where designed/Manufactured/Where reagents mftd.</b> <b>Operational type/Reagent type</b>	VITROS 5,1 FS Chemistry System/2004 \$305,000/— >350/>250 U.S./U.S./U.S. random access, discrete, continuous random access/ self-contained single-use cartridges-packages-slides; user-defined assay capability	RX imola/2006 —/— — Japan/Japan/United Kingdom random access/self-contained multi-use cartridges-packages-slides
<b>Sample handling system/Model type</b> <b>Dimensions in inches (H x W x D)/Instrument footprint</b>	universal sample tray/floor standing 52.5 x 92.2 x 33.4/21.4 sq ft	ring/benchtop 23 x 38 x 28/3.1 x 2.3
<b>No. of tests for which analyzer has FDA-cleared applications</b> <b>Tests clinically released in last 12 months</b> <b>Tests cleared but not clinically released</b> <b>Tests not available in U.S. but submitted for 510(k) clearance</b> <b>Tests not available in U.S. but available in other countries</b> <b>Research-use-only assays</b>	93 5 haptoglobin homocysteine none none	62 diff analytes/91 diff cat — — — — acetic acid, Apo E, Apo CIII, Apo CII, Apo AI, $\alpha$ -1-antitrypsin, $\alpha$ -1-acid glycoprotein, bile acids, butyryl cholinesterase, enzymatic chloride, glutamate dehydrogenase, glutathione reductase, haptoglobin, HBDH, leucine arylamidase, L-lactate, L-lactic acid, malic acid, total antioxidant status, $\beta$ -hydroxybutyrate, glutathione peroxidase, glycerol, NEFA, superoxide dismutase, zinc haptoglobin
<b>Tests in development</b> <b>User-defined methods implemented for what analytes</b>	opiates, PCP, cocaine, barbiturate, benzodiazapine, cannabinoid, methadone, amphetamine various	acetaminophen, drugs of abuse, salicylate, cyclosporine, alcohol, glycerol-3-phosphate, oxidase, phospholipids, maltose, T4, T-uptake
<b>Methods supported/immunoassay methods</b> <b>No. of direct ion selective electrode channels</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/No. active simultaneously</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>Instrument has same capabilities when 3rd-party reagent used</b> <b>Walkaway capacity in minutes/Specimens/Tests-assays</b> <b>System is liquid or dry</b> <b>Uses disposable cuvettes/Max. No. stored</b> <b>Uses washable cuvettes/Replacement frequency</b> <b>Minimum sample volume aspirated precisely at one time</b> <b>Supplied with UPS (backup power)/Requires floor drain</b> <b>Requires dedicated water system/Water consumption per hour</b> <b>Noise generated in decibels</b> <b>Dedicated pediatric sample cup/Dead volume</b> <b>Primary tube sampling/Pierces caps on primary tubes</b> <b>Sample bar-code reading capability</b>	photometry, potentiometry, immuno-rate, turbidimetric, colorimetric, spectrophotometric/— 3 (direct) up to 125 up to 125 20/10 up to 125/up to 100 48 hr/14 days/yes (temp: 10°C) yes yes yes varies/160/8,940 dry, liquid ready to use yes/348 no/disposable 2 $\mu$ L available (not included)/no no/n/a <60 no special sample cup required/35 $\mu$ L yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes	photometry, potentiometry (ISE)/immunoturbidimetric, latex enhanced immunoturbidimetric 3 40 60 10/10 37/71-1,053 8 hr/28 days/yes (8-12°C) yes yes yes 443/72/2,880 liquid no/— yes/5 yr 2 $\mu$ L no/yes yes/18 L — yes/20 $\mu$ L yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., UPC, Codabar, codes 39 & 128)/yes yes —
<b>Onboard test auto inventory (determines volume in container)</b> <b>Measures no. tests remaining/Short sample detection/Clot detection</b> <b>Automatic detection of adequate reagent for aspir. &amp; analysis</b> <b>Hemolysis/Turbidity detection-quantitation</b>	yes yes/yes/yes yes yes/yes	yes yes/yes/no yes yes/yes
<b>Dilution of patient samples onboard/Automatic rerun capability</b> <b>Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results</b> <b>Autocalibration or autocalibration alert</b> <b>Calibrants stored onboard/Multipoint calibration supported</b> <b>Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse</b> <b>Automatic shutdown/Startup programmable</b>	yes/yes system autodilutes no no/yes reagent lot changes no/no (instrument maintained in ready mode)	yes/yes yes/yes yes yes/yes daily/28 days/7 days/n/a yes/yes
<b>Stat time to completion of all analytes, throughput per hr. for:</b> • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP <b>Typical time delay from ordering stat test to aspir. of sample</b> <b>How often QC required/Onboard SW capability to review QC</b> <b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b> <b>QC results transferred automatically to LIS</b>	5.5 min, 400 5.75 min, 625 7.5 min, 360 ~10 sec once per 24 hr/yes yes/yes yes	2 min (not including TC02—non ISE), 240 11 min 55 sec, 560 12 min 15 sec, 400 30 sec shortest interval: daily; longest: customer's discretion yes/yes yes/yes
<b>Data mgmt. capability/Instrument vendor supplies LIS interface</b> <b>Interfaces up and running in active user sites with</b> <b>Bidirectional interface capability</b> <b>Test results transmitted to LIS as soon as chem. time complete</b> <b>LIS interface operates simultaneously with running assays</b> <b>Uses LOINC to transmit orders &amp; results</b> <b>How labs get LOINC codes for reagent kits</b>	onboard (optional add-on)/no all major LIS vendors yes (broadcast download & host query) yes yes yes no LOINC database	onboard/no no yes (host query) yes yes no —
<b>Interface avail. (or will be) to automated specimen handling system</b>	yes (enGen, plus any open point in space systems)	no
<b>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component</b> <b>On-site time of svc. engineer/Onboard error codes for troubleshooting</b> <b>Mean time between failures/To repair failures</b> <b>Average time to complete maintenance by lab personnel</b> <b>Onboard maintenance records/Maint. training demo module</b> <b>Training provided with purchase/Advanced oper. training avail.</b> <b>Annual service contract cost (24 h/7 d)</b>	yes/yes/yes <4 hr/yes —/— daily: 9 min; weekly: 5 min; monthly: 31 min in development/yes yes/yes varies	no/yes/yes within 24 hr —/— daily 5 min; weekly: 15 min; monthly: — no/no 3 days on site/yes —
<b>Distinguishing features</b>	cost-effective MicroSlide Technology delivers low cost per reportable result and high reagent efficiency without the costs, maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC required just once each day and calibration intervals up to lot change with min. interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides or disposable cuvette; eConnectivity interactive management system onboard	bench top analyzer offering more methods than most other analyzers in its class; multi-speed mixers allowing optimum mixing for each assay; comprehensive QC software providing unrivaled confidence in results

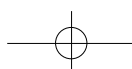
Tabulation does not represent an endorsement by the College of American Pathologists





## Chemistry analyzers (for mid/high volume laboratories)

<b>Part 17 of 18</b>  <b>See related comments, page 14</b>	 <b>Roche Diagnostics</b> Todd Atkinson, Product Manager 9115 Hague Rd., P.O. Box 50457 Indianapolis, IN 46250 800-428-5074 www. Roche.com	 <b>Roche Diagnostics</b> Lisa Hunter Ryden, Product Manager 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 ext. 14011 us.labsystems.roche.com
<b>Name of instrument/First year sold in U.S.</b> <b>List price/Total No. sold in 2005</b> <b>No. units in clinical use in U.S./Outside U.S.</b> <b>Country where designed/Manufactured/Where reagents mftd.</b> <b>Operational type/Reagent type</b>  <b>Sample handling system/Model type</b> <b>Dimensions in inches (H x W x D)/Instrument footprint</b>	<b>Cobas Integra 800/2001 (Integra introduced 1995)</b> \$265,000/— >500/>2,000 Switzerland/Switzerland/multiple countries random access, discrete, continuous random access/self-contained multi-use cartridges-packages-slides sample racks: RD 5-position rack/floor standing 47.3 x 74.8 x 35.4/—	<b>Integrated Modular Analytics/2002</b> varies/150 >100/>1,000 multiple countries/multiple countries/multiple countries continuous random access/self-contained, multi-use cartridges-packages-slides 5-position rack/floor-standing varies with configuration/varies with configuration
<b>No. of tests for which analyzer has FDA-cleared applications</b> <b>Tests clinically released in last 12 months</b> <b>Tests cleared but not clinically released</b> <b>Tests not available in U.S. but submitted for 510(k) clearance</b> <b>Tests not available in U.S. but available in other countries</b>  <b>Research-use-only assays</b> <b>Tests in development</b>  <b>User-defined methods implemented for what analytes</b>	137 — — none LDH (P→L), ALP (DGKC), AT3, CHE-D, GLDH, HBDH, lipoprotein(a), kappa/lambda light chains — MPA, sirolimus, tacrolimus	>140 LDL, CRP WR, UIBC n/a n/a kappa, lambda, apo A, apo B, Lp(a), osteocalcin, P1NP n/a ACTH, PAPP-A, vitamin D3, P1NP, anti-CMV IgG, anti-CMV IgM, anti-TSH receptor, homocysteine, mycophenolic acid, tacrolimus, protease inhibitors, hepatitis A, hepatitis B, HIV combi, rubella IgG & IgM, toxo IgG & IgM, IL-6, sCD40 ligand, CA 72-4 (gastric), cyfra 21-1/NSE (lung), NSE yes, varies
<b>Methods supported/immunoassay methods</b>  <b>No. of direct ion selective electrode channels</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/No. active simultaneously</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>Instrument has same capabilities when 3rd-party reagent used</b> <b>Walkaway capacity in minutes/Specimens/Tests-assays</b> <b>System is liquid or dry</b> <b>Uses disposable cuvettes/Max. No. stored</b> <b>Uses washable cuvettes/Replacement frequency</b> <b>Minimum sample volume aspirated precisely at one time</b> <b>Supplied with UPS (backup power)/Requires floor drain</b> <b>Requires dedicated water system/Water consumption per hour</b> <b>Noise generated in decibels</b> <b>Dedicated pediatric sample cup/Dead volume</b> <b>Primary tube sampling/Pierces caps on primary tubes</b> <b>Sample bar-code reading capability</b>  <b>Reagent bar-code reading capability</b> <b>Bar code placement per CLSI standard Auto2A</b>	photometry, potentiometry, fluorescence polarization/turbidimetric 4 72 72 0/n/a 72/50–800  336 hr/84 days/yes (8°C) yes yes no 450/180/4,000 liquid yes/3,600 no/n/a 2 µL yes/yes no (direct connection, type I NCCLS)/5–7 L 58.5 yes/approx. 50–70 µL yes/no yes (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination  yes yes	photometry, potentiometry (ion selective electrode)/electrochemiluminescence 3 72→140 72→140 varies 72→140/100–3,000  72 hr/90 days/yes (2–12°C) yes yes limited 6 hr/300/varies liquid yes, 1,000 tests yes/monthly 2 µL yes/yes yes/50 L <62 yes/50 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes
<b>Onboard test auto inventory (determines volume in container)</b> <b>Measures no. tests remaining/Short sample detection/Clot detection</b> <b>Automatic detection of adequate reagent for aspir. &amp; analysis</b> <b>Hemolysis/Turbidity detection-quantitation</b> <b>Dilution of patient samples onboard/Automatic rerun capability</b> <b>Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results</b> <b>Autocalibration or autocalibration alert</b> <b>Calibrants stored onboard/Multipoint calibration supported</b> <b>Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse</b> <b>Automatic shutdown/Startup programmable</b>	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes yes/yes 5 hr/once per lot/140 days/60 days yes/yes	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes no/yes 24 hr/varies from bottle change to lot change/bottle change/— yes/yes
<b>Stat time to completion of all analytes, throughput per hr. for:</b> <ul style="list-style-type: none"> <li>• Sodium, potassium, chloride, TCO2</li> <li>• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine</li> <li>• Album., bili. direct &amp; total, AST, ALT, ALP</li> </ul> <b>Typical time delay from ordering stat test to aspir. of sample</b> <b>How often QC required/Onboard SW capability to review QC</b> <b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b> <b>QC results transferred automatically to LIS</b>	8.6 min, 118 specimens 8.6 min, 99 specimens 9.8, 118 specimens 1 min typically once per 24 hr/yes yes/yes yes	3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10 min, 133–600 specimens 50 sec 24 hr/yes yes/yes yes
<b>Data mgmt. capability/Instrument vendor supplies LIS interface</b> <b>Interfaces up and running in active user sites with</b>  <b>Bidirectional interface capability</b> <b>Test results transmitted to LIS as soon as chem. time complete</b> <b>LIS interface operates simultaneously with running assays</b> <b>Uses LOINC to transmit orders &amp; results</b> <b>How labs get LOINC codes for reagent kits</b>	onboard/yes (add'l cost) Cerner, CHCS, Citation, CompuLab, DynaMedix, EDS, Fletcher Flora, McKesson (ALG, PathLabs, StarLabs), HMS, Intellilabs, Isys, LabDaq, Labforce, Labfusion, LabSoft, LCI, Meditech, Northern Soft, Orsys, Seacoast, Siemens, Soft Computer, Misys yes (broadcast download & host query) yes yes no —	onboard/no (add'l cost) all major LIS vendors  yes (broadcast download & host query) yes yes no database
<b>Interface avail. (or will be) to automated specimen handling system</b>	no	yes (Roche Pre-Analytical Modular)
<b>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component</b> <b>On-site time of svc. engineer/Onboard error codes for troubleshooting</b> <b>Mean time between failures/To repair failures</b> <b>Average time to complete maintenance by lab personnel</b> <b>Onboard maintenance records/Maint. training demo module</b>  <b>Training provided with purchase/Advanced oper. training avail.</b> <b>Annual service contract cost (24 h/7 d)</b>	yes/yes/yes  8 hr or next business day/yes —/— daily: <1 min; weekly: <5 min; monthly: none yes (includes audit trail of who replaced parts)/yes (onscreen help with diagrams & maintenance wizard) 1 day on site, 5 days at vendor offices/yes varies	yes/yes/yes  8 hr/yes 260 days/3.5 hr daily: 5 min hands-on; weekly: 30 min; monthly: 15 min yes (includes audit trail of who replaced parts)/yes  5 days at vendor offices/yes varies
<b>Distinguishing features</b>	comprehensive test menu including hemoglobin A1c; reagent cassette requires no operator prep. or special handling (can go straight from refrigerator to system with no warmup time); 97 percent of reagents are liquid, ready to use, system automatically reconstitutes if necessary, system forecasts daily reagent requirements based on history; operator maintenance automatically scheduled by system, based on actual use, not by calendar schedule; 800 has clot detection, bubble detection, and can accommodate universal five-position Roche rack for modular systems and Elecsys IA analyzers	high-throughput clinical chemistry and immunoassay system with single point of entry; single user interface; single host connection, providing productivity & efficiency gains; system offers flexibility to easily expand configuration on site; enhanced intelligent process management achieves optimized sample routing, seamless integration of stat samples into routine workflow, automatic rerun and repeat testing selectable by test and real-time reflex testing with Middleware Solutions



## Chemistry analyzers (for mid/high volume labs)

Part 18 of 18



Roche Diagnostics  
Lisa Hunter Ryden, Product Manager  
9115 Hague Rd.  
Indianapolis, IN 46250  
800-428-5074 ext. 14011  
us.labsystems.roche.com

See related comments, page 14

Name of instrument/First year sold in U.S. List price/Total No. sold in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Modular/1998 varies/150 >600/>4,000 multiple countries/multiple countries/multiple countries continuous random access/self-contained multiuse cartridges-packages-slides
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	5-position rack/floor standing varies per configuration/varies
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	>140 LDL, CRP WR, UIBC — — Lp(a), kappa, lambda, P/NP, TG none ACTH, PAPP-A, vitamin D3, P1NP, anti-CMV IgG, anti-CMV IgM, anti-TSH receptor, homocysteine, mycophenolic acid, tacrolimus, protease inhibitors, hepatitis A, hepatitis B, HIV combi, rubella IgG & IgM, toxo IgG & IgM, IL-6, sCD40 ligand, CA 72-4 (gastric), cyfra 21-1/NSE (lung), NSE
User-defined methods implemented for what analytes	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry/HbA1c
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously 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 Instrument has same capabilities when 3rd-party reagent used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	3 47->100 47->100 varies 47-100/100-3,000 72 hr/28 days/yes (2-12°C) yes yes limited varies/300/varies liquid no/n/a yes/monthly 2 µL yes/yes yes/varies (50 L/hr/mod) <62 yes/50 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation	yes yes/yes/yes yes yes/yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes/yes yes/yes yes yes/yes 24 hr/varies/bottle change/lot change yes/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP	3.5 min, 300-600 specimens 5.5 min, 160-600 specimens 10.5 min, 133-1,200 specimens
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	<1 min 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no
Interfaces up and running in active user sites with	all major LIS vendors
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes (broadcast download & host query) yes yes no database
Interface avail. (or will be) to automated specimen handling system	yes (Roche Pre-Analytical Modular)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes 8 hr/yes 260 days/3.5 hr daily: 5 min; weekly: 10 min; monthly: 15 min yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes varies
Distinguishing features	Roche Hitachi chemistry and automation proven reliability and more than 20 years of experience; capable of consolidating 95 percent of test menu on one high-throughput Integrated Modular System; system can be connected directly to preanalytical automation with 12 modules per configuration; flexible, expandable to lab's changing needs; up to four modules per system

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