Chemistry analyzers—all that's new and more

Anne Ford

As 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 immmunoassay 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.

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

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-

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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 principles, 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 attributable 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-

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 immunodiagnostics 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-

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petence than the federally mandated short test.

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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.

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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)

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 MicroTip 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, α_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 carryover."

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.

SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid/high volume laboratories)

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	MID	HIGH
	Abbott Diagnostics Mike Wright michael.wright@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 800-323-9100 www.abbott.com	Abbott Diagnostics Mike Wright michael.wright@abbott.com 100 Abbott Park Road Abbott Park, IL 60064 800-323-9100 www.abbott.com
Name of instrument/First year sold in U.S.	Abbott Architect c8000/2003	Abbott Aeroset/1998
List price/Total No. sold in 2005	$225,000/—	$345,000/—
No. units in clinical use in U.S./Outside U.S.	210/1,270	276/650
Country where designed/Manufactured/Where reagents mftd.	U.S., Japan/U.S., Japan/U.S.	Japan/Japan/U.S.
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/Model type	multi-dimensional retest sample handler, carousel/floor standing	rack, carousel/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	48 x 79 x 49/~26 sq ft	42.7 x 74.4 x 44.1/22.7 sq ft
No. of tests for which analyzer has FDA-cleared applications	83	82
Tests clinically released in last 12 months	amikacin, quinidine, UIBC, vancomycin, ammonia, ferritin, anti-streptolysin-O, α-1-antitrypsin, α-1-glycoprotein, Lp(a), myoglobin, IgE, CRP Vario, β-2-microglobulin, ultra HDL, D-LDL, ecstacy (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, α-1-antitrypsin, α-1-glycoprotein, Lp(a), myoglobin, IgE, CRP Vario, β-2-microglobulin, ultra HDL, D-LDL, ecstacy (SQ), amphet/meth (SQ), barbiturate (SQ), benzodiazepine (SQ), cannabinoid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase
Tests cleared but not clinically released	copper, P amylase, CK-MB, enzymatic creatinine	copper, P amylase, CK-MB, enzymatic creatinine
Tests not available in U.S. but submitted for 510(k) clearance	tobramycin, gentamicin, lithium	tobramycin, gentamicin, lithium
Tests not available in U.S. but available in other countries	copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin	copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin
Research-use-only assays	—	—
Tests in development	acetaminophen, salicylate, tricyclics, barbs-serum, benzo-serum, PCP (SQ), propoxyphene (SQ)	acetaminophen, salicylate, tricyclics, barbs-serum, benzo-serum, PCP (SQ), propoxyphene (SQ)
User-defined methods implemented for what analytes	lithium, gentamicin, acetaminophen, salicylate, tobramycin, primidone, tricyclics, LSD, D-dimer	lithium, gentamicin, acetaminophen, salicylate, tobramycin, primidone, tricyclics, LSD, D-dimer
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/—	photometry, potentiometry turbidimetric/—
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	68	59
No. of different assays programmed, calibrated at once	220	100
No. of user-definable (open) channels/No. active simultaneously	220/220	100/59
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	65/370	59/400
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/28 days/yes (2–8°C)	7 days/28 days/yes
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/215/69,000-68	60/231/50,000+
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/n/a
Uses washable cuvettes/Replacement frequency	yes/minimum 1-yr guarantee	yes/minimum 1-yr guarantee
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no
Requires dedicated water system/Water consumption per hour	yes/25 L	yes/45 L
Noise generated in decibels	—	—
Dedicated pediatric sample cup/Dead volume	yes/50 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	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
Reagent bar-code reading capability	yes, 2-D bar codes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	8 hr/30 days/14 days/7–14 days	8 hr/30 days/14 days/7–14 days
Automatic shutdown/Startup programmable	no/no	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2.5 min, 200 specimens, 800 tests	10 min, 200+ specimens
• Sodium, potassium, chloride, TCO2, 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
Typical time delay from ordering stat test to aspir. of sample	<20 sec	<15 sec
How often QC required/Onboard SW capability to review QC	shortest interval: 8 hr; longest: 24 hr/yes	shortest interval: 8 hr (ISE); longest: 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes (addt'l cost, SW mftr: Abbott)	no/yes (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Triple G, CIS, others	all major vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	no
How labs get LOINC codes for reagent kits	package insert	—
Interface avail. (or will be) to automated specimen handling system	yes	in development
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	no/no/no
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	>2 months/varies	>2 months/varies
Average time to complete maintenance by lab personnel	daily: <15 min; weekly: <45 min; monthly: 15 min	daily: 5 min; weekly: 10 min; monthly: 30 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	no/no
Training provided with purchase/Advanced oper. training avail.	5 days on site, 5 days at vendor offices/yes	5 days on site, 5 days at vendor offices/no
Annual service contract cost (24 h/7 d)	$18,500	$18,500
Distinguishing features	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 µL)

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

Survey editor: Raymond Aller, MD

Chemistry analyzers (for mid/high volume laboratories)

Part 2 of 18

See related comments, page 14

	MID	HIGH
	Abbott Diagnostics **Mike Wright** michael.wright@abbott.com **100 Abbott Park Rd.** **Abbott Park, IL 60064** **800-323-9100** www.abbott.com	**Abbott Diagnostics** **Mike Wright** michael.wright@abbott.com **100 Abbott Park Rd.** **Abbott Park, IL 60064** **800-323-9100** www.abbottdiagnostics.com
Name of instrument/First year sold in U.S.	**Abbott Architect ci8200/2003**	**Abbott Architect c16000/2007**
List price/Total No. sold in 2005	**$375,000/77**	**n/a/0**
No. units in clinical use in U.S./Outside U.S.	**111/—**	**0/2**
Country where designed/Manufactured/Where reagents mftd.	**U.S., Japan/U.S., Japan/U.S.**	**U.S., Japan/U.S., Japan/U.S.**
Operational type/Reagent type	**continuous random access/self-contained multi-use cartridges, open reagent system**	**continuous random access/open reagent system**
Sample handling system/Model type	**multi-dimensional retest sample handler/floor standing**	**multidimensional robotic sample handler and carousel/floor-standing**
Dimensions in inches (H x W x D)/Instrument footprint	**48 x 127 x 49/42 sq ft**	**48 x 79 x 49/26 sq ft**
No. of tests for which analyzer has FDA-cleared applications	**107**	**83**
Tests clinically released in last 12 months	**amikacin, quinidine, UIBC, vancomycin, ammonia, ferritin, anti-streptolysin-O, α-1-antitrypsin, α-1-glycoprotein, Lp(a), myoglobin, IgE, CRP Vario, β-2-microglobulin, ultra HDL, D-LDL, ecstacy (SQ), amphet/meth (SQ), barbiturate (SQ), benzodiazepine (SQ), cannabinoid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase**	**amikacin, quinidine, UIBC, vancomycin, ammonia, ferritin, anti-streptolysin-O, α-1-antitrypsin, α-1-glycoprotein, Lp(a), myoglobin, IgE, CRP Vario, β-2-microglobulin, ultra HDL, D-LDL, ecstacy (SQ), amphet/meth (SQ), barbiturate (SQ), benzodiazepine (SQ), cannabinoid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase**
Tests cleared but not clinically released	**copper, P amylase, CK-MB, enzymatic creatinine**	**copper, P amylase, CK-MB, enzymatic creatinine**
Tests not available in U.S. but submitted for 510(k) clearance	**tobramycin, gentamicin, lithium**	**tobramycin, gentamicin, lithium**
Tests not available in U.S. but available in other countries	**copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin**	**copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin**
Research-use-only assays	**—**	**—**
Tests in development	**acetaminophen, salicylate, tricyclics, barbs-serum, benzo-serum, PCP (SQ), propoxyphene (SQ)**	**acetaminophen, salicylate, tricyclics, barbs-serum, benzo-serum, PCP (SQ), propoxyphene (SQ)**
User-defined methods implemented for what analytes	**lithium, gentamicin, acetaminophen, salicylate, tobramycin, primidone, tricyclics, LSD, D-dimer**	**lithium, gentamicin, acetaminophen, salicylate, tobramycin, primidone, tricyclics, LSD, D-dimer**
Methods supported/immunoassay methods	**photometry, potentiometry, turbidimetric/chemiluminescence with flexible protocols**	**photometry, potentiometry (ISE), turbidimetric/n/a**
No. of direct ion selective electrode channels	**3**	**3**
No. of different measured assays onboard simultaneously	**93**	**68**
No. of different assays programmed, calibrated at once	**320**	**220**
No. of user-definable (open) channels/No. active simultaneously	**220/220**	**220/220**
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	**90/chem 370, immunoassay 100–500**	**65/370**
Shortest/median onboard reag. stability/Refrigerated onboard	**144 hr/30 days/yes (2–8°C)**	**144 hr/28 days/yes (2–8°C)**
Multiple reag. configurations supported	**yes**	**yes**
Reag. container placed directly on system for use	**yes**	**yes**
Instrument has same capabilities when 3rd-party reag. used	**yes**	**yes**
Walkaway capacity in minutes/Specimens/Tests-assays	**varies >300/365/81,000-93,000**	**varies/215/69,000 +**
System is liquid or dry	**liquid**	**liquid**
Uses disposable cuvettes/Max. No. stored	**yes, immunoassay/1,200**	**no/330**
Uses washable cuvettes/Replacement frequency	**yes, chemistry/minimum 1-yr guarantee**	**yes/minimum 1-yr guarantee**
Minimum sample volume aspirated precisely at one time	**2 µL**	**2 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes/no**	**yes/yes**
Requires dedicated water system/Water consumption per hour	**yes/30.5 L**	**yes/56 µL**
Noise generated in decibels	**—**	**—**
Dedicated pediatric sample cup/Dead volume	**yes/50 µL**	**yes/50 µL**
Primary tube sampling/Pierces caps on primary tubes	**yes/no**	**yes/no**
Sample bar-code reading capability	**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**
Reagent bar-code reading capability	**yes**	**yes**
Bar code placement per CLSI standard Auto2A	**yes**	**yes**
Onboard test auto inventory (determines volume in container)	**yes**	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/yes/yes**	**yes/yes/yes**
Automatic detection of adequate reag. for aspir. & analysis	**yes**	**yes**
Hemolysis/Turbidity detection-quantitation	**yes/yes**	**yes/yes**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/yes**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes/yes (for chemistry)**	**yes/yes**
Autocalibration or autocalibration alert	**no**	**no**
Calibrants stored onboard/Multipoint calibration supported	**yes, for chemistry only/yes**	**yes/yes**
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	**8 hr/30 days/14 days/7–14 days**	**8 hr/30 days/14 days/7–13 days**
Automatic shutdown/Startup programmable	**no/no**	**no/no**
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	**2.5 min, 200 specimens, 800 tests**	**2.5 min, 200 samples**
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	**9.6 min, 160 specimens, 1,120 tests**	**9.6 min, 200 samples**
• Album., bili. direct & total, AST, ALT, ALP	**9.6 min, 133 specimens, 800 tests**	**9.6 min, 300 samples**
Typical time delay from ordering stat test to aspir. of sample	**<20 sec**	**3 sec**
How often QC required/Onboard SW capability to review QC	**shortest interval: 8 hr; longest: 24 hr/yes**	**shortest interval: 8 hr; longest: 24 hr**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
QC results transferred automatically to LIS	**yes**	**yes**
Data mgmt. capability/Instrument vendor supplies LIS interface	**yes (addt'l cost, SW mftr: Abbott)**	**optional add-on (addt'l—price varies; SW mftr: Abbott)**
Interfaces up and running in active user sites with	**Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Triple G, CIS, others**	**Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Citation, CHCS, Antec, Orchard, others**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes (broadcast download & host query)**
Test results transmitted to LIS as soon as chem. time complete	**yes**	**yes**
LIS interface operates simultaneously with running assays	**yes**	**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	**no**	**yes**
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	**yes/yes/yes**	**yes/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**<24 hr/yes**	**<24 hr/yes**
Mean time between failures/To repair failures	**>2 months/varies**	**—/—**
Average time to complete maintenance by lab personnel	**daily: 23 min; weekly: <45 min; monthly: 15 min**	**daily: 15 min; weekly: <45 min; monthly: 15 min**
Onboard maintenance records/Maint. training demo module	**yes/yes**	**yes (includes audit trail of who rplaced parts)/yes**
Training provided with purchase/Advanced oper. training avail.	**5 days on site, 5 days at vendor offices/yes**	**5 days on site, 5 days at vendor office/yes**
Annual service contract cost (24 h/7 d)	**$28,500**	**n/a**
Distinguishing features	**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 µL); 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)

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HIGH

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

Name of instrument/First year sold in U.S.	Abbott Architect ci16200/2007
List price/Total No. sold in 2005	n/a/0
No. units in clinical use in U.S./Outside U.S.	0/0
Country where designed/Manufactured/Where reagents mftd.	U.S., Japan/U.S., Japan/U.S.
Operational type/Reagent type	continuous random access/open reagent system
Sample handling system/Model type	multi-dimensional robotic sample handler and carousel/floor-standing
Dimensions in inches (H x W x D)/Instrument footprint	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, α-1-antistrypsin, α-1-glycoprotein, Lp(a), myoglobin, IgE, CRP Vario, β-2-microglobulin, ultra HDL, D-LDL, ecstasy (SQ), amphat/meth (SQ), barbs (SQ), benzo (SQ), cannabinoid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase
Tests cleared but not clinically released	anti-Tg, AFP, ferritin, insulin, copper
Tests not available in U.S. but submitted for 510(k) clearance	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 reag. containers onboard at once/Tests per container set	93/370 chemistry; 100–500 immunoassay
Shortest/median onboard reag. stability/Refrigerated onboard	144 hr/30 days/yes (2–8°C)
Multiple reag. configurations supported	yes
Reag. container placed directly on system for use	yes
Instrument has same capabilities when 3rd-party reag. 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 µL
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 µL
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 reag. 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, TCO2	2.5 min, 200 samples
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	9.6 min, 200 samples
• Album., bili. direct & total, AST, ALT, ALP	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 (addt'l price varies; SW mftr: Abbott)
Interfaces up and running in active user sites with	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, 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

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

SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid/high volume laboratories)

Part 4 of 18

See related comments, page 14

	MID	MID
	Awareness Technology Inc. **Chris Schneider** info@awaretech.com **P.O. Box 1679** **Palm City, FL 34991** **772-283-6540** www.awaretech.com	**Bayer Healthcare, Diagnostics Division** **Eric LaFleche** eric.lafleche.b@bayer.com **511 Benedict Ave.** **Tarrytown, NY 10591** **914-333-6130** labnews.com
Name of instrument/First year sold in U.S.	**ChemWell/1999**	**ADVIA 1200/2005**
List price/Total No. sold in U.S. in 2005	**$25,000/—**	**$189,000/—**
No. units in clinical use in U.S./Outside U.S.	**10/800**	**n/a/n/a**
Country where designed/Manufactured/Where reagents mftd.	**U.S./U.S./open system**	**Japan/Japan/Ireland**
Operational type/Reagent type	**continuous random access/open ragent system**	**random access/open reagent system**
Sample handling system/Model type	**rack of 96 samples/benchtop**	**carousel/floor standing**
Dimensions in inches (H x W x D)/Instrument footprint	**19 x 36 x 22 in/7 sq ft**	**33.5 x 48 x 44 in/1.04 square meters**
No. of tests for which analyzer has FDA-cleared applications	**22**	**79**
Tests clinically released in last 12 months	**none**	**TIBC, ammonia, HbA1C, microalbumin, ASO, ApoA, ApoB, wrCRP, haptoglobin, IgA, IgG, IgM, carbamazepine, gentamicin, lithium, phenobarb, tobramycin, vancomycin, acetaminophen, ethanol, salicylate, DAUs, lactate**
Tests cleared but not clinically released	**none**	**none**
Tests not available in U.S. but submitted for 510(k) clearance	**18 EIA kits manuf. by BioCheck have been submitted**	**none**
Tests not available in U.S. but available in other countries	**open system**	**none**
Research-use-only assays	**open system**	**none**
Tests in development	**none**	**—**
User-defined methods implemented for what analytes	**all colorimetric biochemistry & EIA that read between 340–700 nm**	**open system architecture, CK-MB, myoglobin, fructosamine, β-2 microglobulin, D-dimer, caffeine, TCA, Lp(a)**
Methods supported/immunoassay methods	**photometry/microwell assays**	**photometry, potentiometry, turbidimetric/—**
No. of direct ion selective electrode channels	**0**	**3**
No. of different measured assays onboard simultaneously	**27**	**40 colorimetric, 3 ISE**
No. of different assays programmed, calibrated at once	**unlimited**	**100**
No. of user-definable (open) channels/No. active simultaneously	**unlimited/27**	**62/62**
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	**27/reagent dependent**	**43/700**
Shortest/median onboard reag. stability/Refrigerated onboard	**reagent dependent/yes (15°C below ambient) optional**	**7 days/45 days/yes**
Multiple reag. configurations supported	**yes**	**yes**
Reag. container placed directly on system for use	**reagent dependent**	**yes**
Instrument has same capabilities when 3rd-party reag. used	**yes**	**yes**
Walkaway capacity in minutes/Specimens/Tests-assays	**not limited/96/not limited**	**20,000 photometrics**
System is liquid or dry	**liquid**	**liquid**
Uses disposable cuvettes/Max. No. stored	**yes (optional)/96**	**no/231**
Uses washable cuvettes/Replacement frequency	**yes (optional)/weekly**	**yes/4 mos**
Minimum sample volume aspirated precisely at one time	**2 µL**	**1 µL**
Supplied with UPS (backup power)/Requires floor drain	**no/no**	**yes/yes**
Requires dedicated water system/Water consumption per hour	**no/<1 L**	**yes/20 L**
Noise generated in decibels	**60**	**<60 decibels**
Dedicated pediatric sample cup/Dead volume	**no**	**yes/50 µL**
Primary tube sampling/Pierces caps on primary tubes	**no/no**	**yes/no**
Sample bar-code reading capability	**yes, by handheld scanner as tubes are loaded onto instrument (2 or 5 interl., UPC, Codabar, codes 39 & 128)/autodiscrimination depends on handheld scanner models**	**yes**
Reagent bar-code reading capability	**no**	**yes**
Bar code placement per CLSI standard Auto2A	**no**	**yes**
Onboard test auto inventory (determines volume in container)	**yes**	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/yes/no**	**yes/yes/yes**
Automatic detection of adequate reag. for aspir. & analysis	**yes**	**yes**
Hemolysis/Turbidity detection-quantitation	**no/no**	**yes/yes**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/yes**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes/no**	**yes/yes**
Autocalibration or autocalibration alert	**yes**	**yes**
Calibrants stored onboard/Multipoint calibration supported	**yes/yes**	**yes/yes**
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	**user defined for all**	**daily/30 days/30 days/14 days**
Automatic shutdown/Startup programmable	**yes/yes**	**yes/yes**
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	**n/a**	**2.5 min**
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	**n/a**	**10 min**
• Album., bili. direct & total, AST, ALT, ALP	**5.5 min, 28 specimens**	**10 min**
Typical time delay from ordering stat test to aspir. of sample	**15 sec**	**10 sec**
How often QC required/Onboard SW capability to review QC	**reagent dependent/yes**	**per laboratory protocol/yes**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
QC results transferred automatically to LIS	**yes**	**yes**
Data mgmt. capability/Instrument vendor supplies LIS interface	**onboard/yes (included in price)**	**yes/n/a**
Interfaces up and running in active user sites with	**not known**	**Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens, others**
Bidirectional interface capability	**yes (broadcast download)**	**yes (broadcast download & host query)**
Test results transmitted to LIS as soon as chem. time complete	**yes**	**yes**
LIS interface operates simultaneously with running assays	**yes**	**yes**
Uses LOINC to transmit orders & results	**no**	**yes**
How labs get LOINC codes for reagent kits	**supplied by reagent manufacturer**	**yes**
Interface avail. (or will be) to automated specimen handling system	**no**	**n/a**
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	**yes/yes/sometimes**	**yes/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**48 hr/yes**	**varies by location, generally <4 hr/yes**
Mean time between failures/To repair failures	**depends on user and varies/depends on problem and varies**	**—/—**
Average time to complete maintenance by lab personnel	**daily: <5 min; weekly: about 15 min; monthly: about 30 min or less**	**—**
Onboard maintenance records/Maint. training demo module	**no/no**	**no/yes**
Training provided with purchase/Advanced oper. training avail.	**2 days on site, 3 days at vendor offices/yes**	**yes/no**
Annual service contract cost (24 h/7 d)	**$4,000**	**n/a**
Distinguishing features	**price; one instrument for EIA & biochemistry; completely open and user programmable; special discounts for biochemistry only; calculates indices; very flexible formatting of reports**	**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 & ADVIA 1650) and uses same reagents; short sample detection; liquid level sensing, refrigerated compartment for calibrators/QC; integration to Centralink**

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Chemistry analyzers (for mid/high volume laboratories)

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	HIGH	HIGH
	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** labnews.com
Name of instrument/First year sold in U.S.	**ADVIA 1650/1999**	**ADVIA 2400/2003**
List price/Total No. sold in U.S. in 2005	**$279,000/—**	**$305,000/—**
No. units in clinical use in U.S./Outside U.S.	**n/a/n/a**	**n/a/n/a**
Country where designed/Manufactured/Where reagents mftd.	**Japan/Japan/Ireland**	**Japan/Japan/Ireland**
Operational type/Reagent type	**random access/open reagent system**	**random access/open reagent system**
Sample handling system/Model type	**carousel rack handler option, automation option/floor standing**	**carousel, rack handler option, automation optionl/floor standing**
Dimensions in inches (H x W x D)/Instrument footprint	**45 x 59 x 34/14 sq ft**	**1,157 x 1,711 x 934 mm/—**
No. of tests for which analyzer has FDA-cleared applications	**80**	**79**
Tests clinically released in last 12 months	**lithium, vancomycin**	**lithium, vancomycin**
Tests cleared but not clinically released	**none**	**none**
Tests not available in U.S. but submitted for 510(k) clearance	**none**	**none**
Tests not available in U.S. but available in other countries	**none**	**none**
Research-use-only assays	**none**	**none**
Tests in development	**—**	**—**
User-defined methods implemented for what analytes	**open system architecture, CK-MB, myoglobin, fructosamine, caffeine, TCA, Lp(a), β-2-microglobulin, D-dimer**	**open system architecture, CK-MB, myoglobin, fructosamine, caffeine, TCA, Lp(a), β-2-microglobulin, D-dimer**
Methods supported/immunoassay methods	**photometry, potentiometry, turbidimetrics/—**	**photometry, potentiometry turbidimetric/—**
No. of direct ion selective electrode channels	**3**	**3**
No. of different measured assays onboard simultaneously	**46 colorimetric, 3 ISE**	**46 colormetric, 3 ISE**
No. of different assays programmed, calibrated at once	**100**	**100**
No. of user-definable (open) channels/No. active simultaneously	**62/62**	**62/62**
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	**49/850**	**49/850**
Shortest/median onboard reag. stability/Refrigerated onboard	**7 days/45 days/yes**	**7 days/45 days/yes**
Multiple reag. configurations supported	**yes**	**yes**
Reag. container placed directly on system for use	**yes**	**yes**
Instrument has same capabilities when 3rd-party reag. used	**yes**	**yes**
Walkaway capacity in minutes/Specimens/Tests-assays	**32,000 photometrics**	**32,000 photometric**
System is liquid or dry	**liquid**	**liquid**
Uses disposable cuvettes/Max. No. stored	**no/221**	**no/340**
Uses washable cuvettes/Replacement frequency	**yes/4 months**	**yes/every 4 months**
Minimum sample volume aspirated precisely at one time	**2 µL of diluted specimen**	**2 µL of diluted specimen**
Supplied with UPS (backup power)/Requires floor drain	**yes/yes**	**yes/yes (or sink)**
Requires dedicated water system/Water consumption per hour	**yes/25 L**	**yes/40 L**
Noise generated in decibels	**<45 decibels**	**<50 decibels**
Dedicated pediatric sample cup/Dead volume	**yes/50 µL**	**yes/~50 µL**
Primary tube sampling/Pierces caps on primary tubes	**yes/no**	**yes/no**
Sample bar-code reading capability	**yes**	**yes**
Reagent bar-code reading capability	**yes**	**yes**
Bar code placement per CLSI standard Auto2A	**yes**	**yes**
Onboard test auto inventory (determines volume in container)	**yes**	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/yes/yes**	**yes/yes/yes**
Automatic detection of adequate reag. for aspir. & analysis	**yes**	**yes**
Hemolysis/Turbidity detection-quantitation	**yes/yes**	**yes/yes**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/yes**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes/yes**	**yes/yes**
Autocalibration or autocalibration alert	**yes**	**yes**
Calibrants stored onboard/Multipoint calibration supported	**yes/yes**	**yes/yes**
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	**daily/30 days/30 days/14 days**	**daily/30 days/30 days/14 days**
Automatic shutdown/Startup programmable	**yes/yes**	**yes/yes**
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	**2.5 min**	**2.5 min**
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	**10 min**	**10 min**
• Album., bili. direct & total, AST, ALT, ALP	**10 min**	**10 min**
Typical time delay from ordering stat test to aspir. of sample	**10 sec**	**10 sec**
How often QC required/Onboard SW capability to review QC	**per laboratory protocol/yes**	**per laboratory protocol/yes**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
QC results transferred automatically to LIS	**yes**	**yes**
Data mgmt. capability/Instrument vendor supplies LIS interface	**yes/n/a**	**yes/n/a**
Interfaces up and running in active user sites with	**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**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes (broadcast download & host query)**
Test results transmitted to LIS as soon as chem. time complete	**yes**	**yes**
LIS interface operates simultaneously with running assays	**yes**	**yes**
Uses LOINC to transmit orders & results	**yes**	**yes**
How labs get LOINC codes for reagent kits	**e-mail, software**	**via software**
Interface avail. (or will be) to automated specimen handling system	**yes (all systems)**	**yes (with ADVIA WorkCell as of October 2003)**
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	**yes/yes/yes**	**yes/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**varies by location, generally <4 hr/yes**	**varies by location, generally <4 hr/yes**
Mean time between failures/To repair failures	**—/—**	**—/—**
Average time to complete maintenance by lab personnel	**automated daily maintenance**	**automated daily maintenance**
Onboard maintenance records/Maint. training demo module	**no/yes**	**no/yes**
Training provided with purchase/Advanced oper. training avail.	**yes/yes**	**yes/yes**
Annual service contract cost (24 h/7 d)	**n/a**	**n/a**
Distinguishing features	**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**

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Chemistry analyzers (for mid/high volume laboratories)

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	MID	MID
	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.	Synchron CX9 Pro/2001	UniCel DxC 600/2004
List price/Total No. sold in U.S. in 2005	$220,600/not available	$340,000/not available
No. units in clinical use in U.S./Outside U.S.	>1,000/>600	>250/>100
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. & Ireland	U.S./U.S./U.S. & Ireland
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/Model type	sectors, centrifugable/floor standing	racks, centrifugable/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	69 x 74 x 30 in/15.4 sq ft	62 x 62 x 41 in/17.7 sq ft
No. of tests for which analyzer has FDA-cleared applications	>100	>100
Tests clinically released in last 12 months	none	none
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays	none	none
Tests in development	sirolimus, tacrolimus, tricyclics, semiquantitative drugs of abuse	sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse
User-defined methods implemented for what analytes	UIBC, cyclosporine, homocysteine	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	5 (indirect)	5
No. of different measured assays onboard simultaneously	33	65
No. of different assays programmed, calibrated at once	59	100
No. of user-definable (open) channels/No. active simultaneously	102/33	100/65
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	33/25–2,500	65/about 3,500 modular; about 600 cartridge
Shortest/median onboard reag. stability/Refrigerated onboard	168 hr/30 days/yes (2–8°C)	168 hr/30 days/yes (2–8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	no
Walkaway capacity in minutes/Specimens/Tests-assays	100/63/2,079	83/132/5,280
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/n/a	n/a
Uses washable cuvettes/Replacement frequency	yes/permanent–2-yr warranty (80 stored on instrument)	yes/2-yr warranty, semi-permanent
Minimum sample volume aspirated precisely at one time	3 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	optional/no
Requires dedicated water system/Water consumption per hour	yes/7 L	yes/16 L
Noise generated in decibels	70	60
Dedicated pediatric sample cup/Dead volume	yes/40 µL	yes/40 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/yes
Sample bar-code reading capability	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
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hr/up to 90 days/up to 60 days/14 days	1 day/up to 90 days/up to 60 days/14 days
Automatic shutdown/Startup programmable	none required	none required
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	52 sec, 75 specimens	6:15 from standby, 96 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	52 sec, 75 specimens	6:15 from standby, 96 specimens
• Album., bili. direct & total, AST, ALT, ALP	10 min, 32 specimens	13:07 from standby, 57 specimens
Typical time delay from ordering stat test to aspir. of sample	45 sec	16 sec
How often QC required/Onboard SW capability to review QC	24 hr/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard & optional add-on (SW mftr: Beckman Coulter)/yes (addt'l cost)	onboard & optional add-on (SW mftr: Beckman Coulter)/yes (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	customer request	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	yes/no/no	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day, rural: same or next day/yes	metro: same day, rural: same or next day/yes
Mean time between failures/To repair failures	—/—	n/a/n/a
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 15 min; monthly: 25 min	daily: none; weekly: 7 min (tech time); monthly: 11 min (tech time)
Onboard maintenance records/Maint. training demo module	no/no	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	—
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

See related comments, page 14

	MID	HIGH
	Beckman Coulter Inc. **Katie Blount** kjblount@beckman.com **P.O. Box 8000** **Brea, CA 92822-8000** **800-526-3821** www.beckmancoulter.com	**Beckman Coulter Inc.** **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.	**Unicel DxC 600i/2006**	**Synchron LX20/1997**
List price/Total No. sold in U.S. in 2005	**—/0**	**$278,000/not available**
No. units in clinical use in U.S./Outside U.S.	**6/2**	**>800/>300**
Country where designed/Manufactured/Where reagents mftd.	**U.S./U.S./U.S., Ireland**	**U.S./U.S./U.S. & Ireland**
Operational type/Reagent type	**continuous random access/open reagent system**	**continuous random access/open reagent system**
Sample handling system/Model type	**racks, closed-tube/floor-standing**	**racks, centrifugable/floor standing**
Dimensions in inches (H x W x D)/Instrument footprint	**62 x 126.5 x 48/42.16**	**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	**>150**	**>100**
Tests clinically released in last 12 months	**intrinsic factor Ab**	**n/a**
Tests cleared but not clinically released	**0**	**none**
Tests not available in U.S. but submitted for 510(k) clearance	**DHEA-S, TPO Ab, iPTH**	**none**
Tests not available in U.S. but available in other countries	**IL-6, TPO Ab, EPO, iPTH**	**none**
Research-use-only assays	**IL-6**	**none**
Tests in development	**EPO, ANA Screen, ds DNA Ab, β-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**	**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	**5**	**5 (indirect)**
No. of different measured assays onboard simultaneously	**89**	**41**
No. of different assays programmed, calibrated at once	**>150**	**100**
No. of user-definable (open) channels/No. active simultaneously	**100/65**	**100/41**
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	**89/about 300 cartridge (chem), 50 per pack (immuno)**	**41/10,650**
Shortest/median onboard reag. stability/Refrigerated onboard	**168 hr/28 days/yes (2–10°C)**	**168 hr/30 days/yes (2–8°C)**
Multiple reag. configurations supported	**yes**	**yes**
Reag. container placed directly on system for use	**yes**	**yes**
Instrument has same capabilities when 3rd-party reag. used	**no**	**no**
Walkaway capacity in minutes/Specimens/Tests-assays	**180/96/5,280**	**83/132/5,280**
System is liquid or dry	**liquid**	**liquid**
Uses disposable cuvettes/Max. No. stored	**yes/294 (immuno)**	**no/n/a**
Uses washable cuvettes/Replacement frequency	**yes/2-yr warranty (chem)**	**yes/semi-permanent—2-yr warranty (250 stored on instrument)**
Minimum sample volume aspirated precisely at one time	**5 µL**	**3 µL**
Supplied with UPS (backup power)/Requires floor drain	**optional/yes**	**yes/no**
Requires dedicated water system/Water consumption per hour	**yes/16 L**	**yes/16 L**
Noise generated in decibels	**—**	**65**
Dedicated pediatric sample cup/Dead volume	**yes/n/a**	**yes/40 µL (samples directly from pediatric bullet)**
Primary tube sampling/Pierces caps on primary tubes	**yes/yes**	**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**	**yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination**
Reagent bar-code reading capability	**yes**	**yes**
Bar code placement per CLSI standard Auto2A	**yes**	**yes**
Onboard test auto inventory (determines volume in container)	**yes**	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/yes/yes**	**yes/yes/yes**
Automatic detection of adequate reag. for aspir. & analysis	**yes**	**yes**
Hemolysis/Turbidity detection-quantitation	**yes/yes**	**yes/yes**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/yes**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes/no**	**yes/yes**
Autocalibration or autocalibration alert	**no**	**yes**
Calibrants stored onboard/Multipoint calibration supported	**no/yes**	**no/yes**
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	**1 day/90 days/up to 60 days/14 days**	**24 hr/up to 90 days/up to 60 days/14 days**
Automatic shutdown/Startup programmable	**none required**	**none required**
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	**8:15 from standby, 96 specimens**	**38 sec, 90 specimens**
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	**8:15 from standby, 96 specimens**	**38 sec, 90 specimens**
• Album., bili. direct & total, AST, ALT, ALP	**15:07 from standby, 57 specimens**	**8 min, 90 specimens**
Typical time delay from ordering stat test to aspir. of sample	**2:16**	**16 sec**
How often QC required/Onboard SW capability to review QC	**24 hr/—**	**24 hr/yes**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
QC results transferred automatically to LIS	**yes/yes**	**yes**
Data mgmt. capability/Instrument vendor supplies LIS interface	**onboard & optional add-on (sw mftr: Beckman Coulter)**	**onboard & optional add-on (Beckman Coulter DL2000)/yes (addt'l cost)**
Interfaces up and running in active user sites with	**Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps**	**Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes (broadcast download & host query)**
Test results transmitted to LIS as soon as chem. time complete	**yes**	**yes**
LIS interface operates simultaneously with running assays	**yes**	**yes**
Uses LOINC to transmit orders & results	**yes**	**no**
How labs get LOINC codes for reagent kits	**customer request**	**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	**yes/yes/yes**	**yes/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**metro: same day; rural: same day or next**	**metro: same day, rural: same or next day/yes**
Mean time between failures/To repair failures	**n/a/n/a**	**—/—**
Average time to complete maintenance by lab personnel	**daily: <15 min, weekly: 36 min; monthly: 11 min**	**daily: none; weekly: 5 min; monthly: 25 min**
Onboard maintenance records/Maint. training demo module	**yes (includes audit trail of who replaced parts)/no**	**no/no**
Training provided with purchase/Advanced oper. training avail.	**10 days at vendor offices/yes**	**5 days at vendor offices/yes**
Annual service contract cost (24 h/7 d)	**n/a**	**—**
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

See related comments, page 14

	HIGH	HIGH
	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** kjblount@beckman.com **200 South Kraemer Blvd.** **P.O. Box 8000** **Brea, CA 92822** **800-526-3821** www.beckmancoulter.com
Name of instrument/First year sold in U.S.	**Synchron LX20 Pro/2001**	**Synchron LXi725/2002**
List price/Total No. sold in U.S. in 2005	**$343,000/—**	**—/not available**
No. units in clinical use in U.S./Outside U.S.	**>800/>300**	**>400/>250**
Country where designed/Manufactured/Where reagents mftd.	**U.S./U.S./U.S. & Ireland**	**U.S./U.S./U.S.**
Operational type/Reagent type	**continuous random access/open reagent system**	**continuous random access/open reagent system**
Sample handling system/Model type	**racks, centrifugable/floor standing**	**racks, centrifugable/floor standing**
Dimensions in inches (H x W x D)/Instrument footprint	**60 x 70 x 41/19.9 sq ft**	**60 x 134.5 x 48/44.8 sq ft**
No. of tests for which analyzer has FDA-cleared applications	**>100**	**>135**
Tests clinically released in last 12 months	**n/a**	**n/a**
Tests cleared but not clinically released	**none**	**none**
Tests not available in U.S. but submitted for 510(k) clearance	**none**	**none**
Tests not available in U.S. but available in other countries	**none**	**none**
Research-use-only assays	**none**	**none**
Tests in development	**sirolimus, tacrolimus, tricyclics, semiquantitative drugs of abuse**	**intact PTH, EPO, IL-6, dsDNA, TNF-α, soluble transferrin receptor, β-2-gylcoprotein 1 Ab**
User-defined methods implemented for what analytes	**UIBC, cyclosporine, homocysteine**	**UIBC, homocysteine, cyclosporine**
Methods supported/immunoassay methods	**photometry, potentiometry, near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay**	**photometry, potentiometry (ISE), near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, chemiluminescence**
No. of direct ion selective electrode channels	**5 (indirect)**	**5 (indirect)**
No. of different measured assays onboard simultaneously	**41**	**65**
No. of different assays programmed, calibrated at once	**100**	**124**
No. of user-definable (open) channels/No. active simultaneously	**100/41**	**100/100**
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	**41/10,650**	**65/11,850**
Shortest/median onboard reag. stability/Refrigerated onboard	**168 hr/30 days/yes (2–8°C)**	**168 hr/28 days/yes (2–10°C)**
Multiple reag. configurations supported	**yes**	**yes**
Reag. container placed directly on system for use	**yes**	**yes**
Instrument has same capabilities when 3rd-party reag. used	**no**	**no**
Walkaway capacity in minutes/Specimens/Tests-assays	**83/132/5,280**	**180/132/5,280**
System is liquid or dry	**liquid**	**liquid**
Uses disposable cuvettes/Max. No. stored	**no/n/a**	**yes/294 (immuno)**
Uses washable cuvettes/Replacement frequency	**yes/semi-permanent—2-yr warranty (250 stored on instrument)**	**yes/2-yr (chemistry) warranty, semi-permanent**
Minimum sample volume aspirated precisely at one time	**3 µL**	**3 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes/no**	**yes/yes**
Requires dedicated water system/Water consumption per hour	**yes/16 L**	**yes/16 L**
Noise generated in decibels	**65**	**n/a**
Dedicated pediatric sample cup/Dead volume	**yes/40 µL**	**—**
Primary tube sampling/Pierces caps on primary tubes	**yes/yes**	**yes/yes**
Sample bar-code reading capability	**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**
Reagent bar-code reading capability	**yes**	**yes**
Bar code placement per CLSI standard Auto2A	**yes**	**yes**
Onboard test auto inventory (determines volume in container)	**yes**	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/yes/yes**	**yes/yes/yes**
Automatic detection of adequate reag. for aspir. & analysis	**yes**	**yes**
Hemolysis/Turbidity detection-quantitation	**yes/yes**	**yes (chemistry)/yes (chemistry)**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/yes**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes/yes**	**yes (chemistry)/yes (chemistry)**
Autocalibration or autocalibration alert	**yes**	**yes (chemistry)**
Calibrants stored onboard/Multipoint calibration supported	**no/yes**	**no/yes**
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	**1 day/up to 90 days/up to 60 days/14 days**	**24 hr/up to 90 days/up to 60 days/14 days**
Automatic shutdown/Startup programmable	**none required**	**none required**
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	**38 sec, 90 specimens**	**38 sec, 90 specimens**
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	**38 sec, 90 specimens**	**38 sec, 90 specimens**
• Album., bili. direct & total, AST, ALT, ALP	**8 min, 90 specimens**	**8 min, 90 specimens**
Typical time delay from ordering stat test to aspir. of sample	**16 sec**	**36 sec**
How often QC required/Onboard SW capability to review QC	**24 hr/yes**	**24 hr/yes**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
QC results transferred automatically to LIS	**yes**	**yes**
Data mgmt. capability/Instrument vendor supplies LIS interface	**onboard & optional add-on (Beckman Coulter DL2000)/yes (addt'l cost)**	**onboard & optional add-on (Beckman Coulter)/yes (addt'l cost)**
Interfaces up and running in active user sites with	**Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs**	**Cerner, Misys**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes (broadcast download & host query)**
Test results transmitted to LIS as soon as chem. time complete	**yes**	**yes**
LIS interface operates simultaneously with running assays	**yes**	**yes**
Uses LOINC to transmit orders & results	**no**	**yes**
How labs get LOINC codes for reagent kits	**customer request**	**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	**yes/yes/yes**	**yes/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**metro: same day, rural: same or next day/yes**	**metro: same day, rural: same or next day/yes**
Mean time between failures/To repair failures	**—/—**	**n/a/n/a**
Average time to complete maintenance by lab personnel	**daily: none; weekly: 5 min; monthly: 25 min**	**daily: 15 min; weekly: 33.5 min; monthly: 25 min**
Onboard maintenance records/Maint. training demo module	**no/no**	**no/no**
Training provided with purchase/Advanced oper. training avail.	**5 days at vendor offices/yes**	**10 days at vendor offices/yes**
Annual service contract cost (24 h/7 d)	**—**	**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

SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid/high volume laboratories)

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See related comments, page 14

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

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

Chemistry analyzers (for mid/high volume laboratories)

Part 10 of 18

See related comments, page 14

	MID	MID
	Clinical Data slsmktg@clda.com **2 Thurber Blvd.** **Smithfield, RI 02917** **800-345-2822** www.clda.com	**Clinical Data** slsmktg@clda.com **2 Thurber Blvd.** **Smithfield, RI 02917** **800-345-2822** www.clda.com
Name of instrument/First year sold in U.S.	**Vitalab Selectra XL/2004**	**Envoy 500/2005**
List price/Total No. sold in U.S. in 2005	**$98,750/—**	**$96,750/—**
No. units in clinical use in U.S./Outside U.S.	**0/—**	**40/—**
Country where designed/Manufactured/Where reagents mftd.	**Netherlands/Netherlands/U.S.**	**Italy/Italy/U.S.**
Operational type/Reagent type	**random access/multi-use bottles**	**random access/self-contained multi-use cartridges, packages, slides**
Sample handling system/Model type	**rotor/floor standing**	**rotor/benchtop**
Dimensions in inches (H x W x D)/Instrument footprint	**45 x 46 x 30/12 sq ft**	**24 x 22 x 39/—**
No. of tests for which analyzer has FDA-cleared applications	**>31**	**28**
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	**—**	**n/a**
Tests not available in U.S. but available in other countries	**—**	**n/a**
Research-use-only assays	**—**	**n/a**
Tests in development	**—**	**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	**4**	**4**
No. of different measured assays onboard simultaneously	**40**	**40**
No. of different assays programmed, calibrated at once	**40**	**40**
No. of user-definable (open) channels/No. active simultaneously	**5/40**	**40/40**
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	**70/700**	**40**
Shortest/median onboard reag. stability/Refrigerated onboard	**72 hr/7 days/yes (12°C below ambient)**	**40 hr/10 days/yes (12–15°C)**
Multiple reag. configurations supported	**—**	**yes**
Reag. container placed directly on system for use	**yes**	**yes**
Instrument has same capabilities when 3rd-party reag. used	**yes**	**no**
Walkaway capacity in minutes/Specimens/Tests-assays	**240/80/2,400**	**240/52/40**
System is liquid or dry	**liquid**	**liquid**
Uses disposable cuvettes/Max. No. stored	**no**	**no**
Uses washable cuvettes/Replacement frequency	**yes/every 10,000 reactions**	**yes/never**
Minimum sample volume aspirated precisely at one time	**1 µL**	**1 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes/no**	**yes/no**
Requires dedicated water system/Water consumption per hour	**no/0.8 L**	**no/—**
Noise generated in decibels	**—**	**—**
Dedicated pediatric sample cup/Dead volume	**yes/20 µL**	**yes/50 µL**
Primary tube sampling/Pierces caps on primary tubes	**yes/no**	**yes/no**
Sample bar-code reading capability	**yes, as sample is being aspirated (2 of 5 interl., UPC, Codabar, codes 39 & 128)**	**yes, as sample is being aspirated**
Reagent bar-code reading capability	**no**	**yes**
Bar code placement per CLSI standard Auto2A	**yes**	**—**
Onboard test auto inventory (determines volume in container)	**yes**	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/yes/yes**	**yes/yes/yes**
Automatic detection of adequate reag. for aspir. & analysis	**yes**	**yes**
Hemolysis/Turbidity detection-quantitation	**—/—**	**no/no**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/yes**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes/no**	**yes/yes**
Autocalibration or autocalibration alert	**yes**	**no**
Calibrants stored onboard/Multipoint calibration supported	**no/yes**	**no/yes**
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	**4 hr/1–14 days/—/—**	**4 hr/7 days/n/a/n/a**
Automatic shutdown/Startup programmable	**yes/yes**	**yes/yes**
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	**8 min, —**	**2 min 20 sec, 240**
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	**10 min, —**	**7 min 30 sec, 47**
• Album., bili. direct & total, AST, ALT, ALP	**10 min, —**	**7 min, 28**
Typical time delay from ordering stat test to aspir. of sample	**6 min**	**—**
How often QC required/Onboard SW capability to review QC	**shortest interval: 4 hr; longest: once a day/yes**	**daily/yes**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**no/yes**	**yes/yes**
QC results transferred automatically to LIS	**yes**	**yes**
Data mgmt. capability/Instrument vendor supplies LIS interface	**optional add on/yes**	**no/yes (addt'l cost)**
Interfaces up and running in active user sites with	**—**	**Antek, Labdaq, Fletcher-Flora, Labpak**
Bidirectional interface capability	**yes**	**yes (broadcast download & host query)**
Test results transmitted to LIS as soon as chem. time complete	**yes**	**yes**
LIS interface operates simultaneously with running assays	**yes**	**yes**
Uses LOINC to transmit orders & results	**—**	**—**
How labs get LOINC codes for reagent kits	**—**	**—**
Interface avail. (or will be) to automated specimen handling system	**—**	**—**
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	**no/yes/yes**	**no/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**within 24 hr/yes**	**24 hr/yes**
Mean time between failures/To repair failures	**6 mo/4 hr**	**n/a/n/a**
Average time to complete maintenance by lab personnel	**daily: 10 min; weekly: 20 min; monthly: 60 min**	**daily: 5 min; weekly: 15 min; monthly: 30 min**
Onboard maintenance records/Maint. training demo module	**no/yes**	**no/no**
Training provided with purchase/Advanced oper. training avail.	**3 days on site/yes**	**5 days on site**
Annual service contract cost (24 h/7 d)	**n/a**	**—**
Distinguishing features	**4 parameter dry ISE with CO_2; reusable reaction cuvette rotor; onboard wash system**	**4 parameter dry ISE with CO_2; 570 tests per hour benchtop; onboard touch screen LCD monitor**

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

Chemistry analyzers (for mid/high volume laboratories)

Part 11 of 18

See related comments, page 14

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

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

Chemistry analyzers (for mid/high volume laboratories)

Part 12 of 18

See related comments, page 14

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

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See related comments, page 14

	HIGH	HIGH
	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
Name of instrument/First year sold in U.S.	AU2700/2000	AU5421 with dual ISE/2001
List price/Total No. sold in U.S. in 2005	$320,000/13	$465,000/5
No. units in clinical use in U.S./Outside U.S.	>60/>450	>100/300
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S. & Ireland	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	random access, discrete, continuous random access/open reagent system	random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	rack & stat carousel/floor standing	rack/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	50 x 79 x 45/92 sq ft	50 x 148 x 45/46.25 sq ft
No. of tests for which analyzer has FDA-cleared applications	125	125
Tests clinically released in last 12 months	—	—
Tests cleared but not clinically released	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	—	—
Research-use-only assays	none	none
Tests in development	D-dimer	D-dimer
User-defined methods implemented for what analytes	fructosamine, ammonia, oxycodone	fructosamine, ammonia, oxycodone
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 51	99
No. of different assays programmed, calibrated at once	99	99
No. of user-definable (open) channels/No. active simultaneously	95/47	95/95
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	48 x 2/100–4,000	48 x 4/100–4,000
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4–12°C)	120 hr/30 days/yes (4–12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/up to 322/varies	varies/up to 300/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/n/a	no/n/a
Uses washable cuvettes/Replacement frequency	yes/permanent	yes/permanent
Minimum sample volume aspirated precisely at one time	1 µL	1 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes	no (optional)/yes
Requires dedicated water system/Water consumption per hour	yes/65 L per hr peak consumption	yes/120 L
Noise generated in decibels	<65	<65
Dedicated pediatric sample cup/Dead volume	no/n/a	no/n/a
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	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.)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/30 days/14 days/14–20 days	1 day/30 days/14 days/14–20 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	<4 min, 267 specimens	—, max 600
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	<4 min, 267 specimens	—, max 600
• Album., bili. direct & total, AST, ALT, ALP	9 min, 267 specimens	—, max 533
Typical time delay from ordering stat test to aspir. of sample	1 min	—
How often QC required/Onboard SW capability to review QC	per CLIA & laboratory's decision/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	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
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	TBD/TBD	TBD/TBD
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 30 min; monthly: 45 min	daily: 5 min; weekly: 30 min; monthly: 45 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	3–5 days on site, 5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	inquire
Distinguishing features	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

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

Chemistry analyzers (for mid/high volume laboratories)

Part 14 of 18

See related comments, page 14

	HIGH	MID
	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympus.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.	AU5431 with dual ISE/2001	VITROS 350/2005
List price/Total No. sold in U.S. in 2005	$575,000/22	$110,000/—
No. units in clinical use in U.S./Outside U.S.	>100/300	—/—
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S. & Ireland	U.S./U.S./U.S.
Operational type/Reagent type	random access, discrete, continuous random access/open reagent system	batch, random access, discrete, continuous random access/self-contained single-use cartridges, packages, slides
Sample handling system/Model type	rack/floor standing	rack/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	50 x 200 x 45/62.5 sq ft	47 x 45.5 x 28/8.8 sq ft
No. of tests for which analyzer has FDA-cleared applications	125	70
Tests clinically released in last 12 months	—	none
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for 510(k) clearance	—	none
Tests not available in U.S. but available in other countries	—	none
Research-use-only assays	none	none
Tests in development	D-dimer	none
User-defined methods implemented for what analytes	fructosamine, ammonia, oxycodone	—
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	potentiometry, colorimetric, rate, immuno-rate/—
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 147	up to 60
No. of different assays programmed, calibrated at once	99	up to 60
No. of user-definable (open) channels/No. active simultaneously	95/95	n/a/n/a
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	48 x 6/100–4,000	up to 60/18, 50, 60
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4–12°C)	48 hr/14 days/no
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	n/a
Walkaway capacity in minutes/Specimens/Tests-assays	varies/up to 300/varies	varies/40/200
System is liquid or dry	liquid	dry
Uses disposable cuvettes/Max. No. stored	no/n/a	n/a
Uses washable cuvettes/Replacement frequency	yes/permanent	n/a
Minimum sample volume aspirated precisely at one time	1 µL	6 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes	available (not included)/no
Requires dedicated water system/Water consumption per hour	yes/180 L	no/n/a
Noise generated in decibels	—	61
Dedicated pediatric sample cup/Dead volume	no/n/a	no special sample cup required/35 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	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
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	not needed/not needed
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/no
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/no
Autocalibration or autocalibration alert	yes	no
Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/30 days/14 days/14–20 days	reagent lot changes
Automatic shutdown/Startup programmable	yes/yes	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	—, max 600	6 min, 240
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	—, max 600	6 min 24 sec, 287
• Album., bili. direct & total, AST, ALT, ALP	—, max 800	6 min 40 sec, 261
Typical time delay from ordering stat test to aspir. of sample	—	12 sec
How often QC required/Onboard SW capability to review QC	per CLIA & laboratory's decision/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC	in development
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	no
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<4 hr
Mean time between failures/To repair failures	TBD/TBD	TBD/TBD
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 30 min; monthly: 45 min	daily: 2 min; weekly: 5 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	no/yes
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	3 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	varies
Distinguishing features	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	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

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

Chemistry analyzers (for mid/high volume laboratories)

Part 15 of 18

See related comments, page 14

	HIGH	HIGH
	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.	VITROS 950, VITROS 950AT/1995	VITROS 250, VITROS 250AT/1993
List price/Total No. sold in U.S. in 2005	950: $196,000; 950 AT: $250,000	250 $105,000; 250 AT $165,000
No. units in clinical use in U.S./Outside U.S.	>1,500/—	>2,000/—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	U.S./U.S./U.S.
Operational type/Reagent type	batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides	batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides
Sample handling system/Model type	sample trays/floor standing	rack/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	55 x 68 x 38/26 sq ft	47 x 45.5 x 28/8.8 sq ft
No. of tests for which analyzer has FDA-cleared applications	70	70
Tests clinically released in last 12 months	dHDL MicroSlide	dHDL MicroSlide
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	—	none
Methods supported/immunoassay methods	potentiometry, colorimetric, rate, immuno-rate/—	potentiometry, colorimetric, rate, immuno-rate/—
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 75	up to 60
No. of different assays programmed, calibrated at once	up to 75	up to 60
No. of user-definable (open) channels/No. active simultaneously	n/a/n/a	n/a/n/a
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	up to 75/up to 60	up to 60/up to 60
Shortest/median onboard reag. stability/Refrigerated onboard	48 hr/14 days/no	48 hr/14 days/no
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	n/a	n/a
Walkaway capacity in minutes/Specimens/Tests-assays	—/40/4,500	—/40/3,600
System is liquid or dry	dry	dry
Uses disposable cuvettes/Max. No. stored	no/n/a	n/a/n/a
Uses washable cuvettes/Replacement frequency	no/n/a	n/a/n/a
Minimum sample volume aspirated precisely at one time	6 µL	6 µL
Supplied with UPS (backup power)/Requires floor drain	available (not included)/no	available (not included)/no
Requires dedicated water system/Water consumption per hour	no/none	no/n/a
Noise generated in decibels	—	—
Dedicated pediatric sample cup/Dead volume	no special sample cup required/35 µL	no special sample cup required/35 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	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
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	not needed/not needed	not needed/not needed
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	no/no	yes/no
Autocalibration or autocalibration alert	no	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	reagent lot changes	reagent lot changes
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	~6 min, 600	6 min, 240
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	~6 min, ~700	7 min, 258
• Album., bili. direct & total, AST, ALT, ALP	~7 min, ~700	7 min 17 sec, 230
Typical time delay from ordering stat test to aspir. of sample	8 sec	12 sec
How often QC required/Onboard SW capability to review QC	24 hr/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces	all common interfaces
Bidirectional interface capability	yes (broadcast download)	yes (broadcast download)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	—
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes (enGen)	yes (enGen)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<4 hr/yes	<4 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 2 min; weekly: 5 min; monthly: 15 min	daily: 2 min; weekly: 5 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	no/yes	no/yes
Training provided with purchase/Advanced oper. training avail.	3 days on site, 5 days at vendor offices/yes	3 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	—
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

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Chemistry analyzers (for mid/high volume laboratories)

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See related comments, page 14

	HIGH	MID
	Ortho-Clinical Diagnostics Mia Ares-Borcky 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com	Randox Laboratories Ltd marketing@randox.com 4065 Oceanside Blvd., Ste. Q Oceanside, CA 92056 760-639-1506 www.randox.com
Name of instrument/First year sold in U.S.	VITROS 5,1 FS Chemistry System/2004	RX imola/2006
List price/Total No. sold in U.S. in 2005	$305,000/—	—/—
No. units in clinical use in U.S./Outside U.S.	>350/>250	—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	Japan/Japan/United Kingdom
Operational type/Reagent type	random access, discrete, continuous random access/ self-contained single-use cartridges-packages-slides; user-defined assay capability	random access/self-contained multi-use cartridges-packages-slides
Sample handling system/Model type	universal sample tray/floor standing	ring/benchtop
Dimensions in inches (H x W x D)/Instrument footprint	52.5 x 92.2 x 33.4/21.4 sq ft	23 x 38 x 28/3.1 x 2.3
No. of tests for which analyzer has FDA-cleared applications	93	62 diff analytes/91 diff cat
Tests clinically released in last 12 months	5	—
Tests cleared but not clinically released	haptoglobin	—
Tests not available in U.S. but submitted for 510(k) clearance	homocysteine	—
Tests not available in U.S. but available in other countries	none	—
Research-use-only assays	none	acetic acid, Apo E, Apo CIII, Apo CII, Apo AII, α-1-antitrypsin, α-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, β-hydroxybutyrate, glutathione peroxidase, glycerol, NEFA, superoxide dismutase, zinc
Tests in development	opiates, PCP, cocaine, barbiturate, benzodiazapine, cannabinoid, methadone, amphetamine	haptoglobin
User-defined methods implemented for what analytes	various	acetaminophen, drugs of abuse, salicylate, cyclosporine, alcohol, glycerol-3-phosphate, oxidase, phospholipids, maltose, T4, T-uptake
Methods supported/immunoassay methods	photometry, potentiometry, immuno-rate, turbidimetric, colorimetric, spectrophotometeric/—	photometry, potentiometry (ISE)/immunoturbidimetric, latex enhanced immunoturbidimetric
No. of direct ion selective electrode channels	3 (direct)	3
No. of different measured assays onboard simultaneously	up to 125	40
No. of different assays programmed, calibrated at once	up to 125	60
No. of user-definable (open) channels/No. active simultaneously	20/10	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	up to 125/up to 100	37/71–1,053
Shortest/median onboard reag. stability/Refrigerated onboard	48 hr/14 days/yes (temp: 10°C)	8 hr/28 days/yes (8–12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/160/8,940	443/72/2,880
System is liquid or dry	dry, liquid ready to use	liquid
Uses disposable cuvettes/Max. No. stored	yes/348	no/—
Uses washable cuvettes/Replacement frequency	no/disposable	yes/5 yr
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	available (not included)/no	no/yes
Requires dedicated water system/Water consumption per hour	no/n/a	yes/18 L
Noise generated in decibels	<60	—
Dedicated pediatric sample cup/Dead volume	no special sample cup required/35 µL	yes/20 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	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, UPC, Codabar, codes 39 &128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	—
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/no
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	system autodilutes	yes/yes
Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	reagent lot changes	daily/28 days/7 days/n/a
Automatic shutdown/Startup programmable	no/no (instrument maintained in ready mode)	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	5.5 min, 400	2 min (not including TC02—non ISE), 240
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.75 min, 625	11 min 55 sec, 560
• Album., bili. direct & total, AST, ALT, ALP	7.5 min, 360	12 min 15 sec, 400
Typical time delay from ordering stat test to aspir. of sample	~10 sec	30 sec
How often QC required/Onboard SW capability to review QC	once per 24 hr/yes	shortest interval: daily; longest: customer's discretion
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes/yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard (optional add-on)/no	onboard/no
Interfaces up and running in active user sites with	all major LIS vendors	no
Bidirectional interface capability	yes (broadcast download & host query)	yes (host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	LOINC database	—
Interface avail. (or will be) to automated specimen handling system	yes (enGen, plus any open point in space systems)	no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<4 hr/yes	within 24 hr
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 9 min; weekly: 5 min; monthly: 31 min	daily 5 min; weekly: 15 min; monthly: —
Onboard maintenance records/Maint. training demo module	in development/yes	no/no
Training provided with purchase/Advanced oper. training avail.	yes/yes	3 days on site/yes
Annual service contract cost (24 h/7 d)	varies	—
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 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

SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid/high volume laboratories)

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See related comments, page 14

	MID	MID
	Roche Diagnostics Todd Atkinson, Product Manager 9115 Hague Rd., P.O. Box 50457 Indianapolis, IN 46250 800-428-5074 www.roche.com	Roche Diagnostics Lisa Hunter Ryden, Product Manager 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 ext. 14011 us.labsystems.roche.com
Name of instrument/First year sold in U.S.	Cobas Integra 800/2001 (Integra introduced 1995)	Integrated Modular Analytics/2002
List price/Total No. sold in 2005	$265,000/—	varies/150
No. units in clinical use in U.S./Outside U.S.	>500/>2,000	>100/>1,000
Country where designed/Manufactured/Where reagents mftd.	Switzerland/Switzerland/multiple countries	multiple countries/multiple countries/multiple countries
Operational type/Reagent type	random access, discrete, continuous random access/self-contained multi-use cartridges-packages-slides	continuous random access/self-contained, multi-use cartridges-packages-slides
Sample handling system/Model type	sample racks: RD 5-position rack/floor standing	5-position rack/floor-standing
Dimensions in inches (H x W x D)/Instrument footprint	47.3 x 74.8 x 35.4/—	varies with configuration/varies with configuration
No. of tests for which analyzer has FDA-cleared applications	137	>140
Tests clinically released in last 12 months	—	LDL, CRP WR, UIBC
Tests cleared but not clinically released	—	n/a
Tests not available in U.S. but submitted for 510(k) clearance	none	n/a
Tests not available in U.S. but available in other countries	LDH (P→L), ALP (DGKC), AT3, CHE-D, GLDH, HBDH, lipoprotein(a), kappa/lambda light chains	kappa, lambda, apo A, apo B, Lp(a), osteocalcin, P1NP
Research-use-only assays	—	n/a
Tests in development	MPA, sirolimus, tacrolimus	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	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry, fluorescence polarization/turbidimetric	photometry, potentiometry (ion selective electrode)/electrochemiluminescence
No. of direct ion selective electrode channels	4	3
No. of different measured assays onboard simultaneously	72	72–>140
No. of different assays programmed, calibrated at once	72	72–>140
No. of user-definable (open) channels/No. active simultaneously	0/n/a	varies
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	72/50–800	72–>140/100–3,000
Shortest/median onboard reag. stability/Refrigerated onboard	336 hr/84 days/yes (8°C)	72 hr/90 days/yes (2–12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	no	limited
Walkaway capacity in minutes/Specimens/Tests-assays	450/180/4,000	6 hr/300/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	yes/3,600	yes, 1,000 tests
Uses washable cuvettes/Replacement frequency	no/n/a	yes/monthly
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	no (direct connection, type I NCCLS)/5–7 L	yes/50 L
Noise generated in decibels	58.5	<62
Dedicated pediatric sample cup/Dead volume	yes/approx. 50–70 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes (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
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	5 hr/once per lot/140 days/60 days	24 hr/varies from bottle change to lot change/bottle change/—
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	8.6 min, 118 specimens	3.5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	8.6 min, 99 specimens	5.5 min, 160–600 specimens
• Album., bili. direct & total, AST, ALT, ALP	9.8, 118 specimens	10 min, 133–600 specimens
Typical time delay from ordering stat test to aspir. of sample	1 min	50 sec
How often QC required/Onboard SW capability to review QC	typically once per 24 hr/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/yes (addt'l cost)	onboard/no (addt'l cost)
Interfaces up and running in active user sites with	Cerner, CHCS, Citation, Compton, 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	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	database
Interface avail. (or will be) to automated specimen handling system	no	yes (Roche Pre-Analytical Modular)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	8 hr or next business day/yes	8 hr/yes
Mean time between failures/To repair failures	—/—	260 days/3.5 hr
Average time to complete maintenance by lab personnel	daily: <1 min; weekly: <5 min; monthly: none	daily: 5 min hands-on; weekly: 30 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes (onscreen help with diagrams & maintenance wizard)	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	1 day on site, 5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	varies	varies
Distinguishing features	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

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SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid/high volume labs)

Part 18 of 18

HIGH

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See related comments, page 14

Name of instrument/First year sold in U.S.	Modular/1998
List price/Total No. sold in 2005	varies/150
No. units in clinical use in U.S./Outside U.S.	>600/>4,000
Country where designed/Manufactured/Where reagents mftd.	multiple countries/multiple countries/multiple countries
Operational type/Reagent type	continuous random access/self-contained multiuse cartridges-packages-slides
Sample handling system/Model type	5-position rack/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	varies per configuration/varies
No. of tests for which analyzer has FDA-cleared applications	>140
Tests clinically released in last 12 months	LDL, CRP WR, UIBC
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	Lp(a), kappa, lambda, P/NP, TG
Research-use-only assays	none
Tests in development	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	3
No. of different measured assays onboard simultaneously	47–>100
No. of different assays programmed, calibrated at once	47–>100
No. of user-definable (open) channels/No. active simultaneously	varies
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	47–100/100–3,000
Shortest/median onboard reag. stability/Refrigerated onboard	72 hr/28 days/yes (2–12°C)
Multiple reag. configurations supported	yes
Reag. container placed directly on system for use	yes
Instrument has same capabilities when 3rd-party reag. used	limited
Walkaway capacity in minutes/Specimens/Tests-assays	varies/300/varies
System is liquid or dry	liquid
Uses disposable cuvettes/Max. No. stored	no/n/a
Uses washable cuvettes/Replacement frequency	yes/monthly
Minimum sample volume aspirated precisely at one time	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes
Requires dedicated water system/Water consumption per hour	yes/varies (50 L/hr/mod)
Noise generated in decibels	<62
Dedicated pediatric sample cup/Dead volume	yes/50 µL
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)/autodiscrimination
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 reag. 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
Autocalibration or autocalibration alert	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hr/varies/bottle change/lot change
Automatic shutdown/Startup programmable	yes/yes
Stat time to completion of all analytes, throughput per hr. for:	
• Sodium, potassium, chloride, TCO2	3.5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 min, 160–600 specimens
• Album., bili. direct & total, AST, ALT, ALP	10.5 min, 133–1,200 specimens
Typical time delay from ordering stat test to aspir. of sample	<1 min
How often QC required/Onboard SW capability to review QC	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	onboard/no
Interfaces up and running in active user sites with	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes
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On-site time of svc. engineer/Onboard error codes for troubleshooting	8 hr/yes
Mean time between failures/To repair failures	260 days/3.5 hr
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 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 at vendor offices/yes
Annual service contract cost (24 h/7 d)	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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