Chemistry analyzers—all that's new and more

Anne Ford

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

Many of the vendors in this month's instrumentation survey, which encompasses chemistry and chemistry-immunoassay analyzers for midto 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 se-

ries. The latter offers 88 clinical chemistry and immunoassay reagent channels, runs up to 1,170 tests per hour, fea-

tures a stat interruption mode, and requires 33 square feet of floor space. All Cobas 6000 instruments will offer Cobas Link, which Van Overwalle calls "one of the most comprehensive connectivity solutions in the market" and which will offer "screen sharing, remote diagnostics, and reporting," among other features. To come in 2008, he adds, is the Cobas 8000 analyzer series, aimed at the high-volume market.

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

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

ical." 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 midvolume 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 prin-



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

Survey of chemistry analyzers

(for mid- and high-volume labs),

pages 19-55

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 there for esupposedly have lower professional skills. Yet the passing rate at the second attempt is virtually identical to the passing rate of all participants at the first attempt. It would be virtually impossible to conclude that the huge decrease in the failure rate from 100 percent to 10 percent is attrib-

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

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

Another product intended for introduction at the AACC meeting is Olympus America's Olympus Partner Advantage personal computer workstation, or OPA. Michael Argentieri, vice president of sales and marketing in the company's diagnostic systems group, says the OPA "combines several key processes, programs, and services under one portal through a single workstation" and "enables our customers to

have direct access to our technical library, training and educational materials, third-party QC peer review for their Olympus analyzers, technical updates, reagent updates, and service communications and other notices." Olympus America developed the OPA after discovering through a customer satisfaction survey that its clientele wanted to be able to access the company's programs and services, as well as those of third parties, through a single gateway. Olympus will also display the AU-Connector system, which allows Olympus clinical

petence than the federally mandated short test.

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

Molecular testing

In this age of genomics, microbiologists who have been in the profession for many years have to heed and act on the message of the bestselling 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.

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 thirdparty and archive racks," A rgentieri 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*continued on page 18*



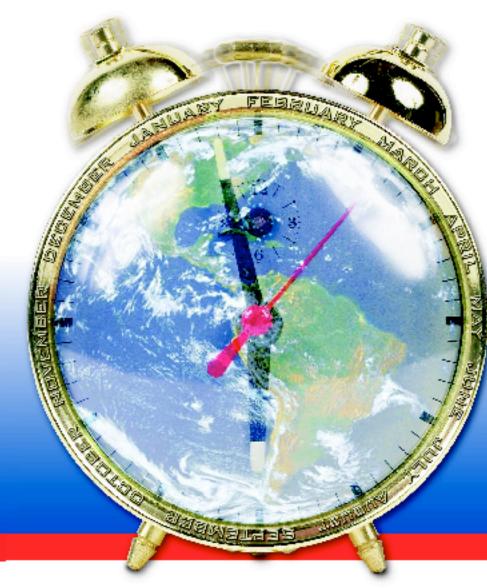
"It's like having three mosquitoes in the back yard and blanketing the entire county with DDT."

—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)

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Chemistry analyzers

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dependent of sample and test mix." In the meantime, the company continues to offer the Vitros 5,1 FS chemistry system. Introduced in 2004, the Vitros 5,1 FS system was the first instrument to o ffer the Vitros Micro Tip technology, which allows users to process assays with disposable tips and cuvettes, and the first Vitros system with open-channel capability. In the next few months, Ortho-Clinical Diagnostics intends to add eight d rugs 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: "Stand ardization 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 A rchitect 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 highvolume 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.





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Anne Ford is a writer in Chicago.



Chemistry analyzers (for mid/high volume laboratories)

Part 1 of 18	Abbott Diagnostics Mike Wright michael.wright@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064	Abbott Diagnostics Mike Wright michael.wright@abbott.com 100 Abbott Park Road Abbott Park, IL 60064
See related comments, page 14	800-323-9100 www.abbott.com	800-323-9100 www.abbott.com
Name of instrument/First year sold in U.S. List price/Total No. sold in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	Abbott Architect c8000/2003 \$225,000/— 210/1,270 U.S., Japan/U.S., Japan/U.S. continuous random access/open reagent system multi-dimensional retest sample handler, carousel/floor standing 48 x 79 x 49/~26 sq ft	Abbott Aeroset/1998 \$345,000/— 276/650 Japan/Japan/U.S. continuous random access/open reagent system rack, carousel/floor standing 42.7 x 74.4 x 44.1/22.7 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	83 amikacin, quinidine, UIBC, vancomycin, ammonia, ferritin, anti- streptolysin-0, 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), cannabi- noid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase copper, P amylase, CK-MB, enzymatic creatinine tobramycin, gentamicin, lithium copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin	82 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), cerulo- plasmin, cholinesterase copper, P amylase, CK-MB, enzymatic creatinine tobramycin, gentamicin, lithium copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin
Research-use-only assays Tests in development User-defined methods implemented for what analytes		acetaminophen, salicylate, tricyclics, barbs-serum, benzo-serum, PCP (SQ), propoxyphene (SQ) lithium, gentamicin, acetaminophen, salicylate, tobramycin,
Mathada aumantad//mmunaaaaau mathada	primidone, tricyclics, LSD, D-dimer	primidone, tricyclics, LSD, D-dimer
Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	photometry, potentiometry, turbidimetric/— 3 68 220 220/220 65/370	photometry, potentiometry turbidimetric/— 3 59 100 100/59 59/400
Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry	7 days/28 days/yes (2–8°C) yes yes varies/215/69,000-68 liquid	7 days/28 days/yes yes yes 60/231/50,000+ liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels	no/— yes/minimum 1-yr guarantee 2 µL yes/no yes/25 L	no/n/a yes/minimum 1-yr guarantee 2 μL no/no yes/45 L —
Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes/50 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes, 2-D bar codes yes	yes/50 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation	yes yes/yes/yes yes yes/yes	yes yes/yes yes yes/yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes/yes yes/yes no yes/yes 8 hr/30 days/14 days/7–14 days no/no	yes/yes yes/yes yes/yes 8 hr/30 days/14 days/7–14 days yes/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP	2.5 min, 200 specimens, 800 tests 9.6 min, 160 specimens, 1,120 tests 9.6 min, 133 specimens, 800 tests	10 min, 200+ specimens 10 min, 200+ specimens 10 min, 200+ specimens
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	<20 sec shortest interval: 8 hr; longest: 24 hr/yes yes/yes yes	<15 sec shortest interval: 8 hr (ISE); longest: 24 hr/yes yes/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 Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Triple G, CIS, others yes (broadcast download & host query) yes yes	all major vendors yes (broadcast download & host query) yes yes no
How labs get LOINC codes for reagent kits	package insert	_
Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/	yes yes/yes/yes	in development
Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail.	<24 hr/yes >2 months/varies daily: <15 min; weekly: <45 min; monthly: 15 min yes (includes audit trail of who replaced parts)/yes 5 days on site, 5 days at vendor offices/yes	<24 hr/yes >2 months/varies daily: 5 min; weekly: 10 min; monthly: 30 min no/no 5 days on site, 5 days at vendor offices/no
Annual service contract cost (24 h/7 d) Distinguishing features	\$18,500 unique multi-dimensional retest sample handler provides excep- tional 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	\$18,500 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)

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Survey editor: Raymond Aller, MD

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Chemistry analyzers (for mid/high volume laboratories)

Part 2 of 18	Abbott Diagnostics Mike Wright michael.wright@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 800-323-9100	Abbott Diagnostics Mike Wright michael.wright@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 200 232 0100
See related comments, page 14	www.abbott.com	800-323-9100 www.abbottdiagnostics.com
Name of instrument/Eirst year sold in U.S.	Abbott Architect ci8200/2002	Abbatt Architect c16000/2007
Name of instrument/First year sold in U.S. List price/Total No. sold in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Abbott Architect ci8200/2003 \$375,000/77 111/— U.S., Japan/U.S., Japan/U.S. continuous random access/self-contained multi-use cartridges, open	Abbott Architect c16000/2007 n/a/0 0/2 U.S., Japan/U.S., Japan/U.S. continuous random access/open reagent system
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	reagent system multi-dimensional retest sample handler/floor standing 48 x 127 x 49/42 sq ft	multidimensional robotic sample handler and carousel/floor-standing 48 x 79 x 49/26 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	107 amikacin, quinidine, UIBC, vancomycin, ammonia, ferritin, anti- streptolysin-0, 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), cannabi- noid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase copper, P amylase, CK-MB, enzymatic creatinine tobramycin, gentamicin, lithium copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin	83 amikacin, quinidine, UIBC, vancomycin, ammonia, ferritin, anti- streptolysin-0, 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), cannabi- noid (SQ), cocaine (SQ), ethanol (SQ), methadone (SQ), opiates (SQ), ceruloplasmin, cholinesterase copper, P amylase, CK-MB, enzymatic creatinine tobramycin, gentamicin, lithium copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, gentamicin
Research-use-only assays Tests in development User-defined methods implemented for what analytes	— acetaminophen, salicylate, tricyclics, barbs-serum, benzo-serum, PCP (SQ), propoxyphene (SQ) lithium, gentamicin, acetaminophen, salicylate, tobramycin, primidone, tricyclics, LSD, D-dimer	— acetaminophen, salicylate, tricyclics, barbs-serum, benzo-serum, PCP (SQ), propoxyphene (SQ) lithium, gentamicin, acetaminophen, salicylate, tobramycin, primidone, tricyclics, LSD, D-dimer
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/chemiluminescence with	photometry, potentiometry (ISE), turbidimetric/n/a
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results	flexible protocols 3 93 320 220/220 90/chem 370, immunoassay 100–500 144 hr/30 days/yes (2–8°C) yes yes yes yes yes yes varies >300/365/81,000-93,000 liquid yes, immunoassay/1,200 yes, chemistry/minimum 1-yr guarantee 2 µL yes/no yes, chemistry/minimum 1-yr guarantee 2 µL yes/no yes/30.5 L 	3 68 220 220/220 65/370 144 hr/28 days/yes (2-8°C) yes yes yes yes yes yes yes/so particle (2 of 5 interl., Codabar, codes 39 & 128)/yes yes yes yes yes yes yes yes
Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	no yes, for chemistry only/yes 8 hr/30 days/14 days/7–14 days no/no	no yes/yes 8 hr/30 days/14 days/7–13 days no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard and time OC/Support multiple OC let Non- are analyted	2.5 min, 200 specimens, 800 tests 9.6 min, 160 specimens, 1,120 tests 9.6 min, 133 specimens, 800 tests <20 sec shortest interval: 8 hr; longest: 24 hr/yes	2.5 min, 200 samples 9.6 min, 200 samples 9.6 min, 300 samples 3 sec shortest interval: 8 hr; longest: 24 hr
Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface	yes/yes yes yes (addťl cost, SW mftr: Abbott)	yes/yes yes optional add-on (addt'l—price varies; SW mftr: Abbott)
Bata mynt, capability instrument ventor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem, time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes (add r cost, sw mitr: Addott) Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Triple G, CIS, others yes (broadcast download & host query) yes yes 	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Citation, CHCS, Antec, Orchard, others yes (broadcast download & host query) yes yes package insert
Interface avail. (or will be) to automated specimen handling system	no	yes
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes <24 hr/yes >2 months/varies daily: 23 min; weekly: <45 min; monthly: 15 min yes/yes 5 days on site, 5 days at vendor offices/yes \$28,500	yes/yes/yes <pre><24 hr/yes —/— daily: 15 min; weekly: <45 min; monthly: 15 min yes (includes audit trail of who rplaced parts)/yes 5 days on site, 5 days at vendor office/yes n/a</pre>
Distinguishing features Tabulation does not represent an endorsement by the College of American Patholo	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

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Chemistry analyzers (for mid/high volume labs)

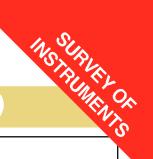
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July 2006

	Part 3 of 18	Abbott Diagnostics
XI	HIGH	Mike Wright michael.wright@abbott.com
	indu	100 Abbott Park Rd. Abbott Park, IL 60064
	See related comments, page 14	800-323-9100 www.abbottdiagnostics.com
A DESCRIPTION OF THE OWNER OWNER OF THE OWNER OWNER OF THE OWNER	Name of instrument/First year sold in U.S.	Abbott Architect ci16200/2007
	List price/Total No. sold in 2005 No. units in clinical use in U.S./Outside U.S.	n/a/0 0/0
	Country where designed/Manufactured/Where reagents mftd.	U.S., Japan/U.S., Japan/U.S.
	Operational type/Reagent type Sample handling system/Model type	continuous random access/open reagent system 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
he Pathologists' Meeting"	Tests cleared but not clinically released	
	Tests not available in U.S. but submitted for 510(k) clearance	anti-Tg, AFP, ferritin, insulin, copper anti-TPO, SHBG, P. amylase, CK-MB, enzymatic creatinine, tobramycin, gentamicin,
SEPTEMBER 10-13	Tests not available in U.S. but available in other countries	lithium AFP, anti-HBc, anti-HBc IqM, anti-HBe, anti-HBs, anti-HCV, anti-Tq, anti-TPO, B12,
ANCHESTER GRAND HYATT		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,
Learn from expert 👘		digitoxin, gentamicin
faculty and take	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
back practical,	Hoer defined methods implemented for what each ter	rubella IgG, AFP, others
seful tools to help	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)
/ou manage your	No. of direct ion selective electrode channels	3
practice.	No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	93 320
	No. of user-definable (open) channels/No. active simultaneously	220/220
egister for CAP '06 and	No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	93/370 chemistry; 100–500 immunoassay
gn up for the Practice	Shortest/median onboard reag. stability/Refrigerated onboard	144 hr/30 days/yes (2–8°C)
kingement institute	Multiple reag. configurations supported Reag. container placed directly on system for use	yes yes
DUISES.	Instrument has same capabilities when 3rd-party reag. used Walkaway capacity in minutes/Specimens/Tests-assays	yes varies/365/81,000–93,000
	System is liquid or dry	liquid
PM100: The Pathologist	Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	yes/1,200 (IA) yes/minimum 1-yr guarantee
as Manager of	Minimum sample volume aspirated precisely at one time	2μL
Anatomic	Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour	yes/yes yes/59 L
Pathology	Noise generated in decibels Dedicated pediatric sample cup/Dead volume	 yes/50 μL
PM101: Laboratory and	Primary tube sampling/Pierces caps on primary tubes	yes/no
Practice Finance	Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, codabar, codes 39 & 128)/yes
PM102: Service and	Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes .
		yes
Quality	Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection	yes yes/yes/yes
PM103: Patient Safety and	Automatic detection of adequate reag. for aspir. & analysis	yes
the Pathologist	Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes/yes yes/yes
PM104: The Many Roles of	Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results	yes/yes (for chemistry)
-	Autocalibration or autocalibration alert	no
the Pathologist—	Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	yes/yes 8 hr/30 days/14 days/ 7–13 days
How to Meet the	Automatic shutdown/Startup programmable	no/no
Expectations	Stat time to completion of all analytes, throughput per hr. for:	
	Sodium, potassium, chloride, TC02	2.5 min, 200 samples
Register today at	 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP 	9.6 min, 200 samples 9.6 min, 300 samples
	Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC	3 sec shortest interval: 8 hr; longest: 24 hr/yes
www.cap2006.org.or	Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes
call 800-323-4040	QC results transferred automatically to LIS	yes
option 1 #.	Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	optional add-on (addt'l price varies; SW mftr: Abbott) Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Citation.
opinon i n.		CHCS, Antec, Orchard, others
	Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete	yes (broadcast download & host query) yes
CALL COLOR MAN	LIS interface operates simultaneously with running assays	yes
CARLEN MARKE	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	Vac
AND A CARLEN AND A		yes
	Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	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 5 days on site, 5 days at vendor offices/yes
		D LIANS ON SUP ID DAYS AT VENDOR OTTICES/VES
	Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	n/a
	Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	n/a
	Training provided with purchase/Advanced oper. training avail.	n/a uniquely multi-dimensional sample handler; <0.1 ppm carryover claim (SmartWash); large request and sample capacity; IA/CC testing integrated without compromise of sta
	Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	n/a uniquely multi-dimensional sample handler; <0.1 ppm carryover claim (SmartWash);

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Chemistry analyzers (for mid/high volume laboratories)

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Modem servicing available/Can diagnose own malfunctions/ yes/yes/sometimes yes/yes/yes Determine malfunctioning component yes/yes/sometimes yes/yes/yes	
Determine malfunctioning component	
Alean 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: a bout 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; dilutions, repeats, reflex testing; open-system for calculates indices; very flexible formatting of reports part of family of chemistry systems (ADVIA 2400 8	tem for 3rd party assay
calculates indices; very flexible formatting of reports part of family of chemistry systems (ADVIA 2400 8 uses same reagents; short sample detection; liqui	
refrigerated compartment for calibrators/QC; integ	
Centralink	

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

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28 / CAP TODAY

Chemistry analyzers (for mid/high volume laboratories)

	N	
Part 5 of 18	Bayer HealthCare, Diagnostics Division	Bayer HealthCare, Diagnostics Division
	Eric LaFleche eric.lafleche.b@bayer.com	Eric LaFleche eric.lafleche.b@bayer.com
	Eric LaFleche eric.lafleche.b@bayer.com 511 Benedict Ave.	511 Benedict Ave.
		Tarrytown, NY 10591
	914-333-6162	914-333-6162
See related comments, page 14	labnews.com	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,	open system architecture, CK-MB, myoglobin, fructosamine,
	caffeine, TCA, Lp(a), β-2-microglobulin, D-dimer	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	49/850	49/850
reag. containers onboard at once/Tests per container set		
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
		No.2
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
Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis		•
Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation	yes/yes yes yes/yes	yes/yes
Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes/yes yes yes/yes yes/yes	yes/yes yes
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Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results	yes/yes yes yes/yes yes/yes	yes/yes yes yes/yes yes/yes
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Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported	yes/yes yes yes/yes yes/yes yes/yes yes	yes/yes yes yes/yes yes/yes yes/yes yes
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Tabulation does not represent an endorsement by the College of American Pathologists

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Chemistry analyzers (for mid/high volume laboratories)

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

JEVEY OF TS

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Chemistry analyzers (for mid/high volume laboratories)

Part 7 of 18	Beckman Coulter Inc. Katie Blount kjblount@beckman.com P.O. Box 8000 Brea, CA 92822-8000 800-526-3821	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821
See related comments, page 14	www.beckmancoulter.com	www.beckmancoulter.com
Name of instrument/First year sold in U.S. List price/Total No. sold in U.S. in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Unicel DxC 600i/2006 —/0 6/2 U.S./U.S., Ireland continuous random access/open reagent system	Synchron LX20/1997 \$278,000/not available >800/>300 U.S./U.S./U.S. & Ireland continuous random access/open reagent system
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	racks, closed-tube/floor-standing 62 x 126.5 x 48/42.16	racks, centrifugable/floor standing LX20 60 x 70 x 41/19.9 sq ft; LX4201 60 x 140 x 41/39.8 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months	>150 intrinsic factor Ab	>100 n/a
Tests cleared but not clinically released	0	none
Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	DHEA-S, TPO Ab, iPTH IL-6, TPO Ab, EPO, iPTH	none
Research-use-only assays Tests in development	IL-6 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	none sirolimus, tacrolimus, tricyclics, semiquantitative drugs of abuse homocysteine
User-defined methods implemented for what analytes	UIBC, cyclosporine, homocysteine	UIBC, cyclosporine, homocysteine
Methods supported/immunoassay methods	photometry, potentiometry (ISE), turbidimetric, enzyme immunoassay/chemiluminescence	photometry, potentiometry, near infrared/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates	5 89 >150 100/65 89/about 300 cartridge (chem), 50 per pack (immuno)	5 (indirect) 41 100 100/41 41/10,650
reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used	168 hr/28 days/yes (2–10°C) yes yes no	168 hr/30 days/yes (2–8°C) yes no no
Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	180/96/5,280 liquid yes/294 (immuno) yes/2-yr warranty (chem)	83/132/5,280 liquid no/n/a yes/semi-permanent—2-yr warranty (250 stored on instrument)
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels	5 µL optional/yes yes/16 L	3 µL yes/no yes/16 L 65
Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	yes/n/a yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, Codabar, codes 39 & 128)/yes	yes/40 µL (samples directly from pediatric bullet) yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes yes	yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes yes yes/yes yes/yes yes/no no no/yes 1 day/90 days/up to 60 days/14 days none required	yes yes/yes yes yes/yes yes/yes yes/yes yes yes 24 hr/up to 90 days/up to 60 days/14 days none required
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP	8:15 from standby, 96 specimens 8:15 from standby, 96 specimens 15:07 from standby, 57 specimens	38 sec, 90 specimens 38 sec, 90 specimens 8 min, 90 specimens
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	2:16 24 hr/— yes/yes yes/yes	16 sec 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface	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 Bidirectional interface capability	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps yes (broadcast download & host query)	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes yes yes	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 On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes metro: same day; rural: same day or next n/a/n/a daily: <15 min, weekly: 36 min; monthly: 11 min yes (includes audit trail of who replaced parts)/no 10 days at vendor offices/yes n/a	yes/yes/yes metro: same day, rural: same or next day/yes —/— daily: none; weekly: 5 min; monthly: 25 min no/no 5 days at vendor offices/yes —
Distinguishing features Tabulation does not represent an endorsement by the College of American Pathologists	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 chem- istry 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

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Chemistry analyzers (for mid/high volume laboratories)

Part 8 of 18	HIGH	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821	Beckman Coulter Inc. Kathleen Blount kjblount@beckman.com 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822
See related comme	ents, page 14	www.beckmancoulter.com	800-526-3821 www.beckmancoulter.com
Name of instrument/F List price/Total No. so No. units in clinical us Country where design	old in U.S. in 2005	Synchron LX20 Pro/2001 \$343,000/— >800/>300 U.S./U.S. & Ireland	Synchron LXi725/2002 —/not available >400/>250 U.S./U.S./U.S.
Operational type/Reag Sample handling syst	gent type	continuous random access/open reagent system racks, centrifugable/floor standing 60 x 70 x 41/19.9 sq ft	continuous random access/open reagent system racks, centrifugable/floor standing 60 x 134.5 x 48/44.8 sq ft
No. of tests for which Tests clinically releas Tests cleared but not		>100 n/a none	>135 n/a none
Tests not available in	U.S. but submitted for 510(k) clearance U.S. but available in other countries says	none none none sirolimus, tacrolimus, tricyclics, semiquantitative drugs of abuse	none none none intact PTH, EPO, IL-6, dsDNA, TNF- α , soluble transferrin receptor,
	s implemented for what analytes	UIBC, cyclosporine, homocysteine	β -2-gylcoprotein 1 Ab UIBC, homocysteine, cyclosporine
No. of direct ion selec	nmunoassay methods	photometry, potentiometry, near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay 5 (indirect)	photometry, potentiometry (ISE), near infrared-bidentate turbidi- metric, direct turbidimetric, particle enhanced turbidimetric/en- zyme immunoassay, chemiluminescence 5 (indirect)
No. of different assays No. of user-definable (No. of different analyt	red assays onboard simultaneously programmed, calibrated at once open) channels/No. active simultaneously tes for which system accommodates	41 100 100/41 41/10,650	65 124 100/100 65/11,850
Shortest/median onbo Multiple reag. configu Reag. container place	d directly on system for use	168 hr/30 days/yes (2–8°C) yes yes	168 hr/28 days/yes (2–10°C) yes yes
Walkaway capacity in System is liquid or dr Uses disposable cuve	ttes/Max. No. stored	no 83/132/5,280 liquid no/n/a	no 180/132/5,280 liquid yes/294 (immuno)
Minimum sample volu Supplied with UPS (ba	tes/Replacement frequency ume aspirated precisely at one time ackup power)/Requires floor drain rater system/Water consumption per hour ecibels	yes/semi-permanent—2-yr warranty (250 stored on instrument) 3 μL yes/no yes/16 L 65	yes/2-yr (chemistry) warranty, semi-permanent 3 µL yes/yes yes/16 L n/a
		yes/40 µL yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes	
Bar code placement p	per ČLSI standard Auto2A	yes	yes
Measures no. tests re	entory (determines volume in container) maining/Short sample detection/Clot detection of adequate reag. for aspir. & analysis letection-quantitation	yes yes/yes yes yes/yes	yes yes/yes yes yes (chemistry)/yes (chemistry)
		yes/yes yes/yes yes	yes/yes yes (chemistry)/yes (chemistry) yes (chemistry)
Calibrants stored onb Typical calib. frequen	oard/Multipoint calibration supported cy for ISE/Metabolites/Ther. drugs/Drugs of abuse Startup programmable	no/yes 1 day/up to 90 days/up to 60 days/14 days none required	no/yes 24 hr/up to 90 days/up to 60 days/14 days none required
 Sodium, potassium Sodium, potassium 	on of all analytes, throughput per hr. for: n, chloride, TCO2 n, chloride, TCO2, glucose, urea, creatinine t & total, AST, ALT, ALP	38 sec, 90 specimens 38 sec, 90 specimens 8 min, 90 specimens	38 sec, 90 specimens 38 sec, 90 specimens 8 min, 90 specimens
How often QC require	m ordering stat test to aspir. of sample d/Onboard SW capability to review QC /Support multiple QC lot Nos. per analyte d automatically to LIS	16 sec 24 hr/yes yes/yes yes	36 sec 24 hr/yes yes/yes yes
Data mgmt. capability	y/Instrument vendor supplies LIS interface	onboard & optional add-on (Beckman Coulter DL2000)/	onboard & optional add-on (Beckman Coulter)/
Bidirectional interface	ning in active user sites with e capability ed to LIS as soon as chem. time complete	yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query)	yes (addt'l cost) Cerner, Misys yes (broadcast download & host query)
	s simultaneously with running assays it orders & results	yes yes no customer request	yes yes customer request
Interface avail. (or wi	ll be) to automated specimen handling system	yes (Power Processor, total lab automation)	no
Determine malfunct On-site time of svc. e	ngineer/Onboard error codes for troubleshooting	yes/yes/yes metro: same day, rural: same or next day/yes	yes/yes metro: same day, rural: same or next day/yes
Average time to comp Onboard maintenance	ailures/To repair failures olete maintenance by lab personnel e records/Maint. training demo module h purchase/Advanced oper. training avail. act cost (24 h/7 d)	—/— daily: none; weekly: 5 min; monthly: 25 min no/no 5 days at vendor offices/yes —	n/a/n/a daily: 15 min; weekly: 33.5 min; monthly: 25 min no/no 10 days at vendor offices/yes n/a
Distinguishing feature	25	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 im- munoassay samples for optimum throughput; menu equivalence to Synchron and Access product lines
	cont an ondercoment by the College of American Dathelegiste		

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Chemistry analyzers (for mid/high volume laboratories)

Part 9 of 18 See related comments, page 14 Name of instrument/First year sold in U.S. List price/Total No. sold in U.S. in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint No. of tests for which analyzer has FDA-cleared applications Tests cleared but not clinically released 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 Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	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 UniCel DxC 800/2005 /not available >150/>200 U.S./U.S./U.S. & Ireland continuous random access/open reagent system racks, centrifugable/floor standing 62 x 70 x 41/19.9 sq ft >100 n/a none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	Carolina Liquid Chemistries Patricia A. Shugart pgshugart@carolinachemistries.com 510 W. Central Ave. Brea, CA 92823 800-471-7272 www.carolinachemistries.com A&T 504X/2006 \$190,000/— n/a/3 Japan/Japan/U.S. continuous random access/self-contained single-use cartridges-packages-slides rack, ring/floor standing 50 x 47.2 x 34.5/— n/a n/a n/a
Name of instrument/First year sold in U.S. List price/Total No. sold in U.S. in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development User-defined methods implemented for what analytes Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	800-526-3821 www.beckmancoulter.com UniCel DxC 800/2005 —/not available >150/>200 U.S./U.S./U.S. & Ireland continuous random access/open reagent system racks, centrifugable/floor standing 62 x 70 x 41/19.9 sq ft >100 n/a none none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	A&T 504X/2006 \$190,000/
List price/Total No. sold in U.S. in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Deparational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released Fests not available in U.S. but submitted for 510(k) clearance Fests not available in U.S. but available in other countries Research-use-only assays Tests in development Jser-defined methods implemented for what analytes Methods supported/immunoassay methods	 —/not available >150/>200 U.S./U.S./U.S. & Ireland continuous random access/open reagent system racks, centrifugable/floor standing 62 x 70 x 41/19.9 sq ft >100 n/a none none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine 	\$190,000/— n/a/3 Japan/Japan/U.S. continuous random access/self-contained single-use cartridges-packages-slides rack, ring/floor standing 50 x 47.2 x 34.5/—
No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Deperational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint No. of tests for which analyzer has FDA-cleared applications Fests clinically released in last 12 months Fests cleared but not clinically released Fests not available in U.S. but submitted for 510(k) clearance Fests not available in U.S. but available in other countries Research-use-only assays Fests in development Jser-defined methods implemented for what analytes Wethods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	 >150/>200 U.S./U.S./U.S. & Ireland continuous random access/open reagent system racks, centrifugable/floor standing 62 x 70 x 41/19.9 sq ft >100 n/a none none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine 	n/a/3 Japan/Japan/U.S. continuous random access/self-contained single-use cartridges-packages-slides rack, ring/floor standing 50 x 47.2 x 34.5/—
Country where designed/Manufactured/Where reagents mftd. Deperational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development Jser-defined methods implemented for what analytes Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	U.S./U.S./U.S. & Ireland continuous random access/open reagent system racks, centrifugable/floor standing 62 x 70 x 41/19.9 sq ft >100 n/a none none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	Japan/Japan/U.S. continuous random access/self-contained single-use cartridges-packages-slides rack, ring/floor standing 50 x 47.2 x 34.5/
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development Jser-defined methods implemented for what analytes Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	racks, centrifugable/floor standing 62 x 70 x 41/19.9 sq ft >100 n/a none none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	cartridges-packages-slides rack, ring/floor standing 50 x 47.2 x 34.5/ n/a n/a
Dimensions in inches (H x W x D)/Instrument footprint No. of tests for which analyzer has FDA-cleared applications Fests clinically released in last 12 months Fests cleared but not clinically released Fests not available in U.S. but submitted for 510(k) clearance Fests not available in U.S. but available in other countries Research-use-only assays Fests in development Jser-defined methods implemented for what analytes Wethods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	62 x 70 x 41/19.9 sq ft >100 n/a none none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	rack, ring/floor standing 50 x 47.2 x 34.5/— n/a n/a —
No. of tests for which analyzer has FDA-cleared applications Fests clinically released in last 12 months Fests cleared but not clinically released Fests not available in U.S. but submitted for 510(k) clearance Fests not available in U.S. but available in other countries Research-use-only assays Fests in development Jser-defined methods implemented for what analytes Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	>100 n/a none none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	 n/a
Tests clinically released in last 12 months Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development Jser-defined methods implemented for what analytes Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	n/a none none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	n/a n/a —
Fests cleared but not clinically released Fests not available in U.S. but submitted for 510(k) clearance Fests not available in U.S. but available in other countries Research-use-only assays Fests in development Jser-defined methods implemented for what analytes Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	none none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	n/a —
Fests not available in U.S. but submitted for 510(k) clearance Fests not available in U.S. but available in other countries Research-use-only assays Fests in development Jser-defined methods implemented for what analytes Wethods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	none none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	_
Fests not available in U.S. but available in other countries Research-use-only assays Fests in development Jser-defined methods implemented for what analytes Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	none none sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	n/a
Tests in development User-defined methods implemented for what analytes Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine	
User-defined methods implemented for what analytes Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	UIBC, cyclosporine, homocysteine	80 different assays—contact company for listing 80 different assays—contact company for listing
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once		
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	photometry, potentiometry (ISE), near-infrared bidentate turbidimetric,	photometry, potentiometry (ISE)/turbidimetry
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay	
No. of different assays programmed, calibrated at once	5	3 (Na, K+, and Cl-)
	70 100	48 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 Reag. container placed directly on system for use	yes yes	yes yes
nstrument has same capabilities when 3rd-party reag. used	no	yes
Valkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry	83/132/5,280 liquid	240/100/4,800 liquid
Jses disposable cuvettes/Max. No. stored Jses washable cuvettes/Replacement frequency	NO voc/2_vr.warrantvcomi_normanont	
Vinimum sample volume aspirated precisely at one time	yes/2-yr warranty, semi-permanent 3 μL	no/n/a 2 μL
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour	optional/no yes/16 L	no/no no/45 L
loise generated in decibels	60	
Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes	yes/40 μL (samples directly from bullet) ves/ves	—/— —/—
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5	yes, on sample transport, shortly before sample is aspirated (2
Reagent bar-code reading capability	interl., Codabar, codes 39 & 128)/autodiscrimination yes	of 5 interl., Codabar, codes 39 & 128)/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 Automatic detection of adequate reag. for aspir. & analysis	yes/yes/yes ves	yes/yes/yes ves
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 Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	no/yes 1 day/up to 90 days/up to 60 days/14 days	yes/yes 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 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine 	2:23 (from standby), 91 specimens 2:22 (from standby), 91 specimens	10 min, 1,200 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
Dnboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	yes/yes	yes/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)
		Substant job (adda i 003), ON milli Addij
nterfaces 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)
Fest results transmitted to LIS as soon as chem. time complete .IS interface operates simultaneously with running assays	yes yes	yes yes
Jses LOINC to transmit orders & results	yes	yes
low labs get LOINC codes for reagent kits	customer request	Web site
nterface avail. (or will be) to automated specimen handling system	yes, Beckman Coulter automation	yes, A&T
Nodem servicing available/Can diagnose own malfunctions/	yes/yes/	yes/yes
Determine malfunctioning component Dn-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day, rural: same or next day/yes	24 hr/yes
Nean time between failures/To repair failures Average time to complete maintenance by lab personnel	n/a/n/a 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
Fraining provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	5 days at vendor offices/yes n/a	5 days on site, 4 days at vendor offices/yes \$19,000
· ·	closed-tube sampling; serum indices/polychromatic correction; clot detection & correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring with	onboard automatic rerun using internal sample dilution cup; ready to connect with any laboratory automation system; small footprint
Distinguishing features	autoloader, calibration data provided on disk, render ning with	·
· ·	semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; one of the fastest stat TAT; DL2000: stat	
	semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive	
· ·	semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; one of the fastest stat TAT; DL2000: stat notification, review by excep tion, reflex testing, add-on test	

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Chemistry analyzers (for mid/high volume laboratories)

See related comments, page 14 Summa Name of instrument/First year sold in U.S. Vital List price/Total No. sold in U.S. in 2005 \$98,75 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mtd. Wetware Operational type/Reagent type rotor/file Status Status Sample handling system/Model type rotor/file Totor/file Dimensions in inches (H x W x D)/Instrument footprint 45 x 44 No. of tests for which analyzer has FDA-cleared applications 731 Tests cleared but not clinically released 74 Tests not available in U.S. but submitted for 510(k) clearance 7 Tests in development 7 User-defined methods implemented for what analytes n/a Methods supported/immunoassay methods photor No. of different measured assays onboard simultaneously 40 No. of different measured assays onboard simultaneously 40 No. of different analytes for which system accommodates 70/700 Reag. contalines placed directly on system for use yes Instrument has same capabilities when 3rd-party reag, used yes <tr< th=""><th>rlands/Netherlands/U.S. m access/multi-use bottles floor standing 6 x 30/12 sq ft metry, potentiometry (ISE)/immunoturbidimetric metry, potentiometry (ISE)/immunoturbidimetric 0 7 days/yes (12°C below ambient) 0/2,400 //ery 10,000 reactions</th><th>Clinical Data slsmktg@clda.com 2 Thurber Blvd. Smithfield, RI 02917 800-345-2822 www.clda.com Envoy 500/2005 \$96,750/ 40/ Italy/Italy/U.S. random access/self-contained multi-use cartridges, packages, slides rotor/benchtop 24 x 22 x 39/ 28 n/a n/a n/a n/a n/a n/a n/a n/a</th></tr<>	rlands/Netherlands/U.S. m access/multi-use bottles floor standing 6 x 30/12 sq ft metry, potentiometry (ISE)/immunoturbidimetric metry, potentiometry (ISE)/immunoturbidimetric 0 7 days/yes (12°C below ambient) 0/2,400 //ery 10,000 reactions	Clinical Data slsmktg@clda.com 2 Thurber Blvd. Smithfield, RI 02917 800-345-2822 www.clda.com Envoy 500/2005 \$96,750/ 40/ Italy/Italy/U.S. random access/self-contained multi-use cartridges, packages, slides rotor/benchtop 24 x 22 x 39/ 28 n/a n/a n/a n/a n/a n/a n/a n/a
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No. of different measured assays onboard simultaneously 40 No. of different measured assays programmed, calibrated at once 40 No. of different analytes for which system accommodates 70/700 reag. containers onboard at once/Tests per container set 72 hr/ Shortest/median onboard reag. stability/Refrigerated onboard 72 hr/ Multiple reag. configurations supported — 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 240/80 System is liquid or dry liquid Uses disposable cuvettes/Replacement frequency yes/ev Minimum sample volume aspirated precisely at one time 1 µL Supplied with UPS (backup power)/Requires floor drain yes/20 Primary tube sampling/Pierces caps on primary tubes yes/az Sample bar-code reading capability no 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 -//-/- Dilution of patient samples onboard/Automatic rerun out-of-linear- range high/low results	7 days/yes (12°C below ambient) 0/2,400 very 10,000 reactions δ δ L Ο μL ο s sample is being aspirated (2 of 5 interl., UPC, Codabar,	40 40 40/40 40 40 40 40 40 40 40 40 40
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Automatic shutdown/Startup programmable yes/ye Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 8 min,	-14 days/—/—	4 hr/7 days/n/a/n/a
• Sodium, potassium, chloride, TCO2 8 min,	-	yes/yes
• Sodium, potassium, chloride, TCO2 8 min,		
	.—	2 min 20 sec, 240
Sodium, potassium, chloride, TCO2, glucose, urea, creatinine 10 mir	n, —	7 min 30 sec, 47
Album., bili. direct & total, AST, ALT, ALP 10 mir	n, —	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 shorte	est interval: 4 hr; longest: once a day/yes	daily/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte no/yes	S	yes/yes
QC results transferred automatically to LIS yes		yes
Data mgmt. capability/Instrument vendor supplies LIS interface option	al add on/yes	no/yes (addt'l cost)
Interfaces up and running in active year sites with		Antok Labdag Elotabar Elora Labrak
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 Uses LOINC to transmit orders & results		yes —
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/ no/yes	s/yes	no/yes/yes
Determine malfunctioning component 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	•	24 nr/yes 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
	s on site/yes	5 days on site
Annual service contract cost (24 h/7 d) n/a		
		4 parameter dry ISE with CO ₂ ; 570 tests per hour benchtop;
onboa	meter dry ISE with CO ₂ ; reusable reaction cuvette rotor;	
	meter dry ISE with $\rm CO_2$; reusable reaction cuvette rotor; rd wash system	onboard touch screen LCD monitor

URVEYOFUS

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Chemistry analyzers (for mid/high volume laboratories)

Part 11 of 18	Dade Behring Inc.	Dade Behring Inc.
	1717 Deerfield Rd.	1717 Deerfield Rd.
HIGH	Deerfield, IL 60015	Deerfield, IL 60015
	800-242-3233	800-242-3233
See related comments, page 14	www.dadebehring.com	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-	batch, random access, continuous random access/self-
	contained multiuse cartridges-packages-slides	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 and susible in U.O. but submitted for 540(1) stranges		
Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	none	Ξ
	lione	
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,	0
	serum barbiturate, serum benzodiazepine	
Methods supported/immunoassay methods	photometry, potentiometry, Integrated Multisensor Technology	photometry, potentiometry (ISE), advanced LOCI chemilumines-
	(IMT)/heterogenous EIA using HM, EMIT latex particle turbidi-	cence technology, nephelometry, EMIT PETINIA PETIA ACMIA LOCI,
	metric, latex turbidimetric	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 No. of user-definable (open) channels/No. active simultaneously	190 10/10	120+ —/up to 100 methods simultaneously
No. of different analytes for which system accommodates	44–88/max. 360	100/20-1,200 tests, flex
reag. containers onboard at once/Tests per container set		
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 Walkaway capacity in minutes/Specimens/Tests-assays	yes	no >45 min/150/—
System is liquid or dry	can be hours liquid, reconstitutes onboard	iquid
Uses disposable cuvettes/Max. No. stored	yes/12,000	ves/>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 Dedicated pediatric sample cup/Dead volume	<70 no/20 µL	<70 ves/—
Primary tube sampling/Pierces caps on primary tubes	yes, 5, 7, 10 mL/no	yes/me
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2	yes, on sample transport, shortly before sample is aspirated (2
	of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	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/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-	yes/yes	yes/no
range high/low results Autocalibration or autocalibration alert	yes (with 7.4 software)	yes
Calibrants stored onboard/Multipoint calibration supported	yes/30–90 days	ves/ves
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 englytee, throughout new by ferr		
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 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 QC results transferred automatically to LIS	no/yes ves	yes/yes yes, via EasyLink
	yes	Joo, Ha Laguint
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	-
Ridirectional interface canability	ves (broadcast download & bost query)	ves (broadcast download & bost query)

Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes (broadcast download & host query) yes yes no	yes (broadcast download & host query) yes no 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 On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail.	yes/yes/yes 2–8 hr/yes —/— daily: 5 min; weekly: 10 min; monthly: 15 min no/no 5 days on site, 4 days at vendor offices/yes	yes/yes/yes 2–8 hr/yes —/— daily: none; weekly: none; monthly: 10–20 min in development/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

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Chemistry analyzers (for mid/high volume laboratories)

1			
1	Part 12 of 18	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034
	See related comments, page 14	484-896-5000 www.olympus.com	484-896-5000 www.olympus.com
	Name of instrument/First year sold in U.S. List price/Total No. sold in U.S. in 2005	AU400/1998; AU400e/2002 \$130,000/99	AU640/1999; AU640e/2002 \$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	random access, discrete, continuous random access/open
		reagent system	reagent system
	Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	rack & stat carousel/floor standing 47.6 x 57.1 x 29.9/62.7 sq ft	rack & stat carousel/floor standing 50 x 74 x 32/68 sq ft
ľ	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 submitted for 510(k) clearance	_	_
		_	_
	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 No. of direct ion selective electrode channels	photometry, potentiometry, calculated tests/homogeneous 3	photometry, potentiometry, calculated tests/homogeneous 3
	No. of different measured assays onboard simultaneously	up to 76	up to 51
	No. of different assays programmed, calibrated at once	99 05 (72)	99 05/47
	No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates	95/72 76/100–1,333	95/47 48 x 2/100–1,333
	reag. containers onboard at once/Tests per container set	10/100-1,000	+0 X 2/100 1,000
	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 Walkaway capacity in minutes/Specimens/Tests-assays	yes varies/up to 102/varies	yes 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 Noise generated in decibels	yes/26 L per hr peak consumption 65	yes/40 L per hr peak consumption 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	yes, on sample transport, shortly before sample is aspirated (2
	Descured have and an edition and title	of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
	Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes yes	yes yes
		300	300
	Onboard test auto inventory (determines volume in container)	yes was have have	yes weekweekwee
	Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis	yes/yes yes	yes/yes yes
	Hemolysis/Turbidity detection-guantitation	yes/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-	yes/yes	yes/yes
	range high/low results		
	Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported	yes ves/ves	yes ves/ves
	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
ſ	Stat time to completion of all analytes, throughput per hr. for:		
	Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, clucoso, uroa, creatining,	<5 min, 200 specimens <5 min, 80 specimens	<4 min, 200 specimens <5 min, 160 specimens
	 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP 	<9 min, 67 specimens	S min, 160 specimens 9 min, 133 specimens
	Tunical time delay from ordering shet test to serve of serverts	-0 min	1 min
	Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC	<2 min per CLIA & laboratory's decision/yes	1 min 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
	Determined and hith discharge in the state of		
	Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/no (optional) all common interfaces including Cerner, Antrim, CCA,	onboard/no (optional) all common interfaces including Cerner, Antrim, CCA,
	menaues up and running in delive user siles will	Chemware, Dawning Technol., ADAC, Dynamic Healthcare,	Chemware, Dawning Technol., ADAC, Dynamic Healthcare,
		Antek Siemens McKesson (Data Innov.) CPSI Meditech Misvs	Antek Siemens McKesson (Data Innov.) CPSI Meditech Misvs

Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC yes (broadcast download & host query) yes yes no 	Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC yes (broadcast download & host query) yes yes no
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes <24 hr/yes average 2 calls per yr/<24 hr daily: 3 min; weekly: 7 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 3–5 days on site, 5 days at vendor offices/yes inquire	yes/yes/yes <24 hr/yes average 2 calls per yr/<24 hr daily: 3 min; weekly: 27 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 3–5 days on site, 5 days at vendor offices/yes inquire
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

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Chemistry analyzers (for mid/high volume laboratories)

Part 13 of 18	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034
See related comments, page 14	484-896-5000 www.olympus.com	484-896-5000 www.olympus.com
Name of instrument/First year sold in U.S. List price/Total No. sold in U.S. in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	AU2700/2000 \$320,000/13 >60/>450 Japan/Japan/U.S. & Ireland random access, discrete, continuous random access/open	AU5421 with dual ISE/2001 \$465,000/5 >100/300 Japan/Japan/U.S. & Ireland random access, discrete, continuous random access/open
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	reagent system rack & stat carousel/floor standing 50 x 79 x 45/92 sq ft	reagent system rack/floor standing 50 x 148 x 45/46.25 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months	125	125
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 Tests in development	none D-dimer	none D-dimer
User-defined methods implemented for what analytes	fructosamine, ammonia, oxycodone	fructosamine, ammonia, oxycodone
Methods supported/immunoassay methods No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	photometry, potentiometry, calculated tests/homogeneous 3 up to 51 99 95/47 48 x 2/100-4,000 120 hr/30 days/yes (4-12°C) yes yes yes yes yes varies/up to 322/varies liquid no/n/a yes/permanent 1 µL no (optional)/yes yes/65 L per hr peak consumption <65 no/n/a yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes yes yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes	photometry, potentiometry, calculated tests/homogeneous 3 99 95/95 48 x 4/100-4,000 120 hr/30 days/yes (4-12°C) yes yes yes yes varies/up to 300/varies liquid no/n/a yes/permanent 1 µL no (optional)/yes yes/120 L <65 no/n/a yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl.)/autodiscrimination yes yes yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes
 Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS 	<4 min, 267 specimens <4 min, 267 specimens 9 min, 267 specimens 1 min per CLIA & laboratory's decision/yes yes/yes yes	—, max 600 —, max 600 —, max 533 — per CLIA & laboratory's decision/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC yes (broadcast download & host query) yes yes no	onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC yes (broadcast download & host query) yes yes no
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/ <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 3–5 days on site, 5 days at vendor offices/yes inquire	yes/yes/ <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes inquire
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

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Chemistry analyzers (for mid/high volume laboratories)

Dest 44 - 640		
Part 14 of 18	Olympus America Inc. 3500 Corporate Parkway	Ortho-Clinical Diagnostics Mia Ares-Borcky
HIGH>	Center Valley, PA 18034	1001 U.S. Highway 202
	484-896-5000	Raritan, NJ 08869
See related comments, page 14	www.olympus.com	800-828-6316 www.orthoclinical.com
	· 3 · Free	
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. Operational type/Reagent type	Japan/Japan/U.S. & Ireland random access, discrete, continuous random access/open	U.S./U.S. batch, random access, discrete, continuous random
operational type/neagent type	reagent system	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 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
Research-use-only assays	none	none
Tests in development	D-dimer	none
Here defined with de Samlemented for other excludes	for the second	
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 05/05	up to 60
No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates	95/95 48 x 6/100–4,000	n/a/n/a up to 60/18, 50, 60
reag. containers onboard at once/Tests per container set		
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 Uses disposable cuvettes/Max. No. stored	liquid no/n/a	dry n/a
Uses washable cuvettes/Replacement frequency	ves/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	<i>—</i> ,,	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 Sample bar-code reading capability	yes/no yes, on sample transport, shortly before sample is aspirated (2	yes/no yes, on sample transport, shortly before sample is aspirated (2
	of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	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 ves/ves	yes waa kuoo kuoo
Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis	yes/yes/yes yes	yes/yes ves
Hemolysis/Turbidity detection-quantitation	yes/yes	not needed/not needed
	yes/yes	yes/no
Dilution of patient samples onboard/Automatic rerun capability	,,	
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-	yes/yes	yes/no
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results	yes/yes	
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert	yes/yes yes	no
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported	yes/yes yes yes/yes	no no/yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert	yes/yes yes	no
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days	no no/yes reagent lot changes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for:	yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes	no no/yes reagent lot changes no/no
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02	yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes —, max 600	no no/yes reagent lot changes no/no 6 min, 240
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine	yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes , max 600 , max 600	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02	yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes —, max 600	no no/yes reagent lot changes no/no 6 min, 240
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC	yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes , max 600 , max 600	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287 6 min 40 sec, 261
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes -, max 600 -, max 600 -, max 800 -, max 800	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287 6 min 40 sec, 261 12 sec 24 hr/yes yes/yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC	yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes -, max 600 -, max 600 -, max 800 -, max 800 -, max 800 -, max 800	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287 6 min 40 sec, 261 12 sec 24 hr/yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes -, max 600 -, max 600 -, max 800 -, max 800	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287 6 min 40 sec, 261 12 sec 24 hr/yes yes/yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface	yes/yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes -, max 600 -, max 600 -, max 800 -, max 800 -, max 800 -, omboard/no (optional)	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287 6 min 40 sec, 261 12 sec 24 hr/yes yes/yes yes onboard/no (optional)
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Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability	yes/yes yes/yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes -, max 600 -, max 600 -, max 800 -, max 8	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287 6 min 40 sec, 261 12 sec 24 hr/yes yes/yes yes onboard/no (optional) in development yes (broadcast download)
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Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes/yes yes/yes yes/yes -, max 600 -, max 600 -, max 800 -, max 800 -, max 800 -, max 800 -, max 800 -, and a laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC yes (broadcast download & host query) yes no	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287 6 min 40 sec, 261 12 sec 24 hr/yes yes/yes yes onboard/no (optional) in development yes (broadcast download) yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays	yes/yes yes/yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes -, max 600 -, max 600 -, max 800 - per CLIA & laboratory's decision/yes yes/yes yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC yes (broadcast download & host query) yes yes	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287 6 min 40 sec, 261 12 sec 24 hr/yes yes/yes yes onboard/no (optional) in development yes (broadcast download) yes yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes/yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes -, max 600 -, max 600 -, max 800 -, max 800 	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287 6 min 40 sec, 261 12 sec 24 hr/yes yes/yes yes onboard/no (optional) in development yes (broadcast download) yes yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system	yes/yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes -, max 600 -, max 600 -, max 800 -, max 900 -, ma	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287 6 min 40 sec, 261 12 sec 24 hr/yes yes/yes yes onboard/no (optional) in development yes (broadcast download) yes yes no
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfun	yes/yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes -, max 600 -, max 600 -, max 800 -, max 800 	no no/yes reagent lot changes no/no 6 min, 240 6 min 24 sec, 287 6 min 40 sec, 261 12 sec 24 hr/yes yes/yes yes onboard/no (optional) in development yes (broadcast download) yes yes no
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Tabulation does not represent an endorsement by the College of American Pathologists

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Chemistry analyzers (for mid/high volume laboratories)

Part 15 of 18	Ortho-Clinical Diagnostics Mia Ares-Borcky	Ortho-Clinical Diagnostics Mia Ares-Borcky
HIGH	1001 U.S. Highway 202	1001 U.S. Highway 202
	Raritan, NJ 08869	Raritan, NJ 08869
Convoluted commenter rese 14	800-828-6316	800-828-6316
See related comments, page 14	www.orthoclinical.com	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. Operational type/Reagent type	U.S./U.S./U.S. batch, random access, discrete, continuous random	U.S./U.S.
operational type/neagent type	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 75	up to 60
No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously	up to 75 n/a/n/a	up to 60 n/a/n/a
No. of different analytes for which system accommodates	up to 75/up to 60	up to 60/up to 60
reag. containers onboard at once/Tests per container set		
Shortest/median onboard reag. stability/Refrigerated onboard	48 hr/14 days/no	48 hr/14 days/no
Multiple reag. configurations supported Reag. container placed directly on system for use	yes yes	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 no (n /o	dry n/c/n/c
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	no/n/a no/n/a	n/a/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	
Primary tube sampling/Pierces caps on primary tubes	ves/no	Ves/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2	yes, on sample transport, shortly before sample is aspirated (2
	of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
		N00
Bar code placement per CLSI standard Auto2A	yes	yes
Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container)	yes yes	yes yes
Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection	yes yes/yes/yes	yes yes/yes/yes
Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis	yes yes/yes/yes yes	yes yes/yes/yes yes
Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation	yes yes/yes/yes yes not needed/not needed	yes yes/yes/yes yes not needed/not needed
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Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported	yes yes/yes/yes yes/yes/yes not needed/not needed yes/no no/no no no	yes yes/yes/yes yes not needed/not needed yes/no yes/no no no no/yes
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Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes/yes yes not needed/not needed yes/no no/no no no no/yes reagent lot changes	yes yes/yes/yes yes not needed/not needed yes/no yes/no no no/yes reagent lot changes
Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for:	yes yes/yes/yes yes not needed/not needed yes/no no/no no no/yes reagent lot changes no/no	yes yes/yes/yes yes not needed/not needed yes/no yes/no no no/yes reagent lot changes no/no
Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02	yes yes yes/yes/yes yes not needed/not needed yes/no no/no no no/yes reagent lot changes no/no ~6 min, 600	yes yes/yes/yes yes not needed/not needed yes/no yes/no no yes/no no/yes reagent lot changes no/no 6 min, 240
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Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP	yes yes yes/yes/yes yes not needed/not needed yes/no no/no no/no no no/ses reagent lot changes no/no ~6 min, 600 ~6 min, ~700 ~7 min, ~700	yes yes/yes/yes yes not needed/not needed yes/no yes/no no no/yes reagent lot changes no/no 6 min, 240 7 min, 258 7 min 17 sec, 230
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Chemistry analyzers (for mid/high volume laboratories)

Part 16 of 18	Orthe Clinical Disgnastics	Randox Laboratories Ltd
	Ortho-Clinical Diagnostics Mia Ares-Borcky	marketing@randox.com
HIGH>	1001 U.S. Highway 202	4065 Oceanside Blvd., Ste. Q
	Raritan, NJ 08869	Oceanside, CA 92056
See related comments, page 14	800-828-6316 www.orthoclinical.com	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.	Japan/Japan/United Kingdom random access/self-contained multi-use cartridges-packages-slides
Operational type/Reagent type	random access, discrete, continuous random access/ self-contained single-use cartridges-packages-slides;	random access/sen-contained multi-use cardinges-packages-sildes
	user-defined assay capability	
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 Tests not available in U.S. but available in other countries	homocysteine	-
Research-use-only assays	none	acetic acid, Apo E, Apo CIII, Apo CII, Apo AII, $lpha$ -1-antitrypsin, $lpha$ -1-
		acid glycoprotein, bile acids, butyryl cholinesterase, enzymatic chlo-
		ride, glutamate dehydrogenase, glutathione reductase, haptoglobin,
		HBDH, leucine arylamidase, L-lactate, L-lactic acid, malic acid, total antioxidant status, β -hydroxybutyrate, glutathione peroxidase, glyc-
		erol, NEFA, superoxide dismutase, zinc
Tests in development	opiates, PCP, cocaine, barbiturate, benzodiazapine, cannabinoid,	haptoglobin
llear defined methods implemented for what such the	methadone, amphetamine	anotaminanhan druga of abuse asligulate surlessative states
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, colori-	photometry, potentiometry (ISE)/immunoturbidimetric, latex
No. of direct ion selective electrode channels	metric, spectrophotometeric/— 3 (direct)	enhanced immunoturbidimetric 3
No. of different measured assays onboard simultaneously	up to 125	3 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 Walkaway capacity in minutes/Specimens/Tests-assays	yes varies/160/8,940	yes 443/72/2,880
System is liquid or dry	dry, liquid ready to use	1445/7272,880 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 Supplied with UPS (backup power)/Requires floor drain	2 μL available (not included)/no	2 µL no/yes
Requires dedicated water system/Water consumption per hour	no/n/a	yes/18 L
Noise generated in decibels	<60	<u> </u>
Dedicated pediatric sample cup/Dead volume	no special sample cup required/35 µL	yes/20 µL
Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	yes/no yes, on sample transport, shortly before sample is aspirated	yes/no yes, on sample transport, shortly before sample is aspirated
	(2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	(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/no
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation	yes yes/yes	yes yes/yes
	Jon Jon	<i>Job, Job</i>
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 Album., bili. direct & total, AST, ALT, ALP 	5.75 min, 625 7.5 min, 360	11 min 55 sec, 560 12 min 15 sec, 400
• Album, bill, direct & total, AS1, AL1, ALP Typical time delay from ordering stat test to aspir. of sample	~10 sec	12 min 15 sec, 400 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
	yes (broadcast download & host query)	yes (host query)
Bidirectional interface capability	Ves	
	yes yes	yes yes
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes no	yes no
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays	yes	yes
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes no	yes no
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system	yes no LOINC database yes (enGen, plus any open point in space systems)	yes no no
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/	yes no LOINC database	yes no
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes no LOINC database yes (enGen, plus any open point in space systems) yes/yes/yes	yes no
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures	yes no LOINC database yes (enGen, plus any open point in space systems)	yes no no
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel	yes no LOINC database yes (enGen, plus any open point in space systems) yes/yes/yes <4 hr/yes -/ daily: 9 min; weekly: 5 min; monthly: 31 min	yes no
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module	yes no LOINC database yes (enGen, plus any open point in space systems) yes/yes/yes <4 hr/yes -/ daily: 9 min; weekly: 5 min; monthly: 31 min in development/yes	yes no no no no/yes/yes within 24 hr -/ daily 5 min; weekly: 15 min; monthly: no/no
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Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes no LOINC database yes (enGen, plus any open point in space systems) yes/yes <4 hr/yes -/ daily: 9 min; weekly: 5 min; monthly: 31 min in development/yes yes/yes varies cost-effective MicroSlide Technology delivers low cost per reportable result and high reagent efficiency without the costs, maintenance,	yes no
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes no LOINC database yes (enGen, plus any open point in space systems) yes/yes/yes <4 hr/yes -/ daily: 9 min; weekly: 5 min; monthly: 31 min in development/yes yes/yes varies cost-effective MicroSlide Technology delivers low cost per reportable	yes no no no/yes/yes within 24 hr -/ daily 5 min; weekly: 15 min; monthly: no/no 3 days on site/yes bench top analyzer offering more methods than most other
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Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes no LOINC database yes (enGen, plus any open point in space systems) yes/yes/yes <4 hr/yes -/ daily: 9 min; weekly: 5 min; monthly: 31 min in development/yes yes/yes varies 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	yes no

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Chemistry analyzers (for mid/high volume laboratories)

Part 17 of 18	Roche Diagnostics Todd Atkinson, Product Manager 9115 Hague Rd., P.O. Box 50457 Indianapolis, IN 46250	Roche Diagnostics Lisa Hunter Ryden, Product Manager 9115 Hague Rd. Indianapolis, IN 46250
See related comments, page 14	800-428-5074 www.roche.com	800-428-5074 ext. 14011 us.labsystems.roche.com
Name of instrument/First year sold in U.S. List price/Total No. sold in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Cobas Integra 800/2001 (Integra introduced 1995) \$265,000/— >500/>2,000 Switzerland/Switzerland/multiple countries random access, discrete, continuous random access/self-	Integrated Modular Analytics/2002 varies/150 >100/>1,000 multiple countries/multiple countries/multiple countries continuous random access/self-contained, multi-use cartridges-
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	contained multi-use cartridges-packages-slides sample racks: RD 5-position rack/floor standing 47.3 x 74.8 x 35.4/—	packages-slides 5-position rack/floor-standing varies with configuration/varies with configuration
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months	137	>140 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	— none LDH (P—L), ALP (DGKC), AT3, CHE-D, GLDH, HBDH, lipoprotein(a),	n/a n/a kappa, lambda, apo A, apo B, Lp(a), osteocalcin, P1NP
Research-use-only assays Tests in development	kappa/lambda light chains — MPA, sirolimus, tacrolimus	n/a ACTH, PAPP-A, vitamin D3, P1NP, anti-CMV IgG, anti-CMV IgM, anti-TSH receptor, homocysteine, mycophenolic acid, tacrolimus, protease inhibitors, hepatitis A, hepatitis B, HIV combi, rubella IgG & IgM, toxo Igf
User-defined methods implemented for what analytes	yes, varies	& IgM, IL-6, sCD40 ligand, CA 72-4 (gastric), cyfra 21-1/NSE (lung), NSE yes, varies
Methods supported/immunoassay methods No. of direct ion selective electrode channels	photometry, potentiometry, fluorescence polarization/ turbidimetric 4	photometry, potentiometry (ion selective electrode)/electrochemilu- minescence 3
No. of different measured assays onboard simultaneously	72	72->140
No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously	72 0/n/a	72->140 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 Reag. container placed directly on system for use	yes yes	yes yes
Instrument has same capabilities when 3rd-party reag. used	no	limited
Nalkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry	450/180/4,000 liquid	6 hr/300/varies liquid
Jses disposable cuvettes/Max. No. stored	yes/3,600	yes, 1,000 tests
Jses washable cuvettes/Replacement frequency Ainimum sample volume aspirated precisely at one time	no/n/a 2 μL	yes/monthly 2 μL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour loise generated in decibels	no (direct connection, type I NCCLS)/5–7 L 58.5	yes/50 L <62
Dedicated pediatric sample cup/Dead volume	yes/approx. 50–70 μL	yes/50 μL
Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	yes/no yes (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes yes	yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis	yes yes/yes yes	yes yes/yes yes
Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-	yes/yes yes/yes yes/yes	yes/yes yes/yes yes/yes
range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported	yes yes/yes	yes no/ves
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	5 hr/once per lot/140 days/60 days yes/yes	24 hr/varies from bottle change to lot change/bottle change/— 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 Typical time delay from ordering stat test to aspir. of sample 	9.8, 118 specimens 1 min	10 min, 133–600 specimens 50 sec
How often QC required/Onboard SW capability to review QC	typically once per 24 hr/yes	24 hr/yes
Dnboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	yes/yes yes	yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/yes (addt'l cost) Cerner, CHCS, Citation, Compton, CompuLab, DynaMedix, EDS, Fletcher Flora, McKesson (ALG, PathLabs, StarLabs), HMS, Intellilabs,	onboard/no (addt'l cost) all major LIS vendors
Bidirectional interface capability	lsys, LabDaq, Labforce, Labfusion, LabSoft, LCI, Meditech, Northern Soft, Orsys, Seacoast, Siemens, Soft Computer, Misys yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays	yes yes	yes yes
Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	no 	no database
nterface avail. (or will be) to automated specimen handling system	no	yes (Roche Pre-Analytical Modular)
Modem servicing available/Can diagnose own malfunctions/	yes/yes	yes/yes/yes
Determine malfunctioning component 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 Average time to complete maintenance by lab personnel	—/— daily: <1 min; weekly: <5 min; monthly: none	260 days/3.5 hr 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. Annual service contract cost (24 h/7 d)	1 day on site, 5 days at vendor offices/yes varies	5 days at vendor offices/yes varies
Distinguishing features	comprehensive test menu including hemoglobin A1c; reagent cas- sette requires no operator prep. or special handling (can go straight	high-throughput clinical chemistry and immunoassay system with single point of entry; single user interface; single host connection,

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Chemistry analyzers (for mid/high volume labs)

	Sector Se
Part 18 of 18	Roche Diagnostics Lisa Hunter Ryden, Product Manager 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 ext. 14011
See related comments, page 14	us.labsystems.roche.com
Name of instrument/First year sold in U.S. List price/Total No. sold in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Modular/1998 varies/150 >600/>4,000 multiple countries/multiple countries/multiple countries continuous random access/self-contained multiuse cartridges-packages-slides
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	5-position rack/floor standing varies per configuration/varies
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	>140 LDL, CRP WR, UIBC — Lp(a), kappa, lambda, P/NP, TG none ACTH, PAPP-A, vitamin D3, P1NP, anti-CMV IgG, anti-CMV IgM, anti-TSH receptor, homocysteine, mycophenolic acid, tacrolimus, protease inhibitors, hepatitis A, hepati- tis 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 No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability Bar code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation	photometry, potentiometry/HbA1c 3 47->100 47->100 varies 47-100/100-3,000 72 hr/28 days/yes (2-12°C) yes yes limited varies/300/varies liquid no/n/a yes/monthly 2 μL yes/yes yes/varies (50 L/hr/mod) <62 yes/50 μL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	yes/yes yes yes yes/yes 24 hr/varies/bottle change/lot change yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	onboard/no all major LIS vendors





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Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes (broadcast download & host query) yes yes no database	
Interface avail. (or will be) to automated specimen handling system	yes (Roche Pre-Analytical Modular)	
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes 8 hr/yes 260 days/3.5 hr daily: 5 min; weekly: 10 min; monthly: 15 min yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes varies	
Distinguishing features	Roche Hitachi chemistry and automation proven reliability and more than 20 years of experience; capable of consolidating 95 percent of test menu on one high-throughput Integrated Modular System; system can be connected directly to preanalytical automation with 12 modules per configuration; flexible, expandable to lab's changing needs; up to four modules per system	

