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*



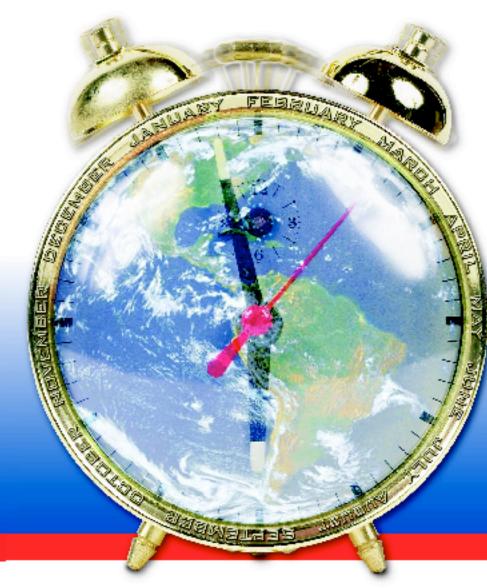
"It's like having three mosquitoes in the back yard and blanketing the entire county with DDT."

—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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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 |
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| 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)

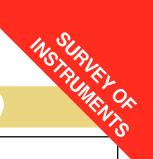
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July 2006

| | 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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| Sample bar-code reading capability sets by handheld scanner as tubes are loaded onto instrument (2 or 5 intert, 10°C, Coddars, codes 33 & 120/autodiscrimination depends on handheld scanner models on handheld scanner models on bandheld scanner models on processing scale and scal | |
| Bitter, UPC, Codabar, codes 39 & 128/autodiscrimination depends on handheld scanner models Reagent bar-code reading capability no yes Bar code placement per CLSI standard Auto2A no yes Bar code placement per CLSI standard Auto2A no yes Mobord test auto inventory (determines volume in container) yes yes Measures no. tests remaining/Short sample detection/Cloid detection yes/yes/yes yes/yes Mutonatic detection-quantitation no/no yes/yes Nutonatic detection-quantitation no/no yes/yes Sample volume can be reduced/increased to rerun out-of-linear yes/yes yes/yes range high/Now results yes yes yes Jutoration obaer/Multiping calibration allert yes yes yes Sample volume can be reduced/increased to rerun out-of-linear yes/yes yes/yes yes/yes Sample volume can be reduced/increased to rerun out-of-linear yes yes yes Sample volume can be reduced/increased to rerun out-of-linear yes/yes yes/yes yes/yes Subition of all analytes, throughput per hr. for: - - - - - <t< td=""><td></td></t<> | |
| Reagent bar-code reading capability no yes Bar code placement per CLSI standard Auto2A no yes Obcord test attic inventory (determines volume in container) yes yes/yes/no Masuras no. tests remaining/Short sample detection/Cld detection yes/yes/no yes/yes/yes Matomatic detection of adequate reag. for aspir. & analysis yes yes/yes Matomatic detection of adequate reag. for aspir. & analysis yes yes/yes Sample volume can be reduced/fit detection-quantitation no/no yes/yes Sample volume can be reduced/fit detection-quantitation yes/yes yes/yes Calibrants stored onboard/Automatic rerun capability yes/yes yes/yes Varcalization or autocalibration supported yes/yes yes/yes Vipcial calib. frequency for ISE/Metabolits/Ther. ror: rs/a 2.5 min Stat time to completion of all analytes, throughput per hr. for: rs/a 2.5 min * Sodium, potassium, chloride, TOO2 n/a 2.5 min Yop of there data work on analytes, throughput per hr. for: rs/a 2.5 min * Sodium, potassium, chloride, TOO2 rs/a 10 min Yop of there data work on analytes, throughput per hr. for: rs/a 2.5 min * Sodium, potassium, chloride, toda S, A, LT, ALP Spin, 28 specimens 10 min <td></td> | |
| Dubard test auto inventory (determines volume in container) yes Measures no. tests remaining/Short sample detection/Clot detection yes/yes/no Wes/yes no. tests remaining/Short sample detection/Clot detection yes/yes/no yes/yes/so yes/yes Hemotysis/Turbidity detection - quantitation yes/yes Sample volume can be reduced/Increased to rerun out-of-linear yes/no yes/yes yes/yes Autoralito detection - autocalibration supported yes/yes yes/yes yes/yes Calibrants stored on baard/Multipoint calibration supported yes/yes yes/yes yes/yes Stat time to completion of all analytes, throughput per hr. for: - Sodium, potassium, chloride, TOG2 n/a Stat time to completion of all analytes, throughput per hr. for: - Sodium, potassium, chloride, TOG2 n/a Ypical calib. fuerts total, Total | |
| Measures no. tests remaining/Short sample detection/Cloid detectionyes/yes/noyes/yesAutomatic detection - adquate reag. for aspir. & analysisyesyesHemolysis/Turbidity detection - quantitationno/noyes/yesSample volume can be reduced/Increased to rerun out-of-linear-range high/low resultsyes/yesyes/yesYaccalibration or autocalibration alertyes/yesyes/yesAutocalibration or autocalibration alertyes/yesyes/yesZalibratis stored onboard/Multipoint calibration supportedyes/yesyes/yesZalibratis stored onboard/Multipoint calibration supportedyes/yesyes/yesStat time to completion or all analytes, throughput per hr. for: | |
| Automatic detection of adequiate reag. for aspir. & analysisyesyesHemolysis/Truingno/noyes/yesSample volume can be reduced/increased to rerun out-of-linear- range high/low resultsyes/yesyes/yesAutomatic rerun capabilityyes/yesyes/yesAutomatic reage to able reduced/increased to rerun out-of-linear- range high/low resultsyesyesAutomatic bruing of able reduced/increased to rerun out-of-linear- range high/low resultsyesyesAutomatic bruing of constraintsyes/yesyes/yesAutomatic bruingyes/yesyes/yesyes/yesStatimet to completion of all analytes, throughput per tr. for: • Sodium, potassium, chloride, TOO2n/a2.5 min• Sodium, potassium, chloride, TOO2n/a2.5 min9.5 min, 28 specimens• Altowardis bruing to required/onboard/Multiconse, urea, creatinine • n/an/a10 min• Altowardis for eaglity for origing an analyte • yes/yesyes/yesyes/yes• Sodium, potassium, chloride, TOO2n/a2.5 min, 28 specimens10 min• Altowardis for all analytes, throughput per tr. for: • Sodium, potassium, chloride, TOO2yes/yesyes/yes• Sodium, potassium, chloride, TOO2yes/yesyes/yesyes/yes• Completion of all analytes, throughput per tr. for: • Sodium, potassium, chloride, TOO2yes/yes10 min• Altowardis for and yes of to tas per analyte ves of the otal statest to aspir. of sample15 sec10 sec• Corequired/Onboard/Multical for on super analyte ves of thigh/mor teal-inter G | |
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| Sample volume can be reduced/Increased to rerun out-of-linear- range high/how resultsyes/noyes/yesrange high/how resultsyesyes/yesyes/yesCalibration or autocalibration alert talibration or autocalibration supported typical calib. Trequency for ISC/Metabolites/Ther. drugs/Drugs of abuse user defined for all yes/yesyes/yesyes/yesStat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TGO2 • Sodium, potas | |
| range high/low results Autocalibration or autocalibration alert Autocalibration or autocalibration alert Salibrants stored onboard//Multipoint calibration supported yes/yes user defined for all wes/yes user defined for all yes/yes yes yes/yes yes yes yes yes yes yes yes yes yes | |
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| Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse user defined for all yes/yesyes/yes yes/yesVatomatic shutdown/Startup programmableyes/yesyes/yesStat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • N/an/a2.5 min 10 min 10 min• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • N/an/a10 min 10 min 10 min• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • N/a10 min 10 min 10 min 10 min 10 min 10 min 10 sec 10 sec 10 sec• Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2 • Sodium, otassium, chloride, TCO2 • Sodium, otassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2 • Sodium, potasium, chloride, TCO2 • Sodium, p | |
| Automatic shutdown/Startup programmable yes/yes yes/yes Stat time to completion of all analytes, throughput per hr. for: | |
| 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 So min, 28 specimens 10 min Yopical time delay from ordering stat test to aspir. of sample 15 sec 10 sec per laboratory protocol/yes per laboratory protocol/yes per laboratory protocol/yes yes/yes yes yes<td></td> | |
| Sodium, potassium, chloride, TCO2 n/a Sodium, potassium, chloride, TCO2, glucose, urea, creatinine n/a In min In min Sodium, potassium, chloride, TCO2, glucose, urea, creatinine n/a In min In | |
| Album., bill. direct & total, AST, ALT, ALP 5.5 min, 28 specimens 10 min Typical time delay from ordering stat test to aspir. of sample 15 sec 10 sec | |
| Typical time delay from ordering stat test to aspir. of sample15 sec10 secfow often QC required/Onboard SW capability to review QCreagent dependent/yesper laboratory protocol/yesDoboard real-time QC/Support multiple QC lot Nos. per analyteyes/yesyesQc results transferred automatically to LISonboard/yes (included in price)yesData mgmt. capability/Instrument vendor supplies LIS interfaceonboard/yes (included in price)yes/n/anot knownSoft, Misys, Cerner, Meditech, Multidata, SeacoasGdirectional interface capabilityyes (broadcast download)yes (broadcast download)Fest results transmitted to LIS as soon as chem. time completeyesyesJS interface operates simultaneously with running assaysyesyesJs aget LOINC codes for reagent kitsnon/anetface avail. (or will be) to automated specimen handling systemnon/aModem servicing available/Can diagnose own malfunctions/ Determine malfunctioning componentyes/yes/yesyes/yes/yes | |
| How often QC required/Onboard SW capability to review QCreagent dependent/yesper laboratory protocol/yesOnboard real-time QC/Support multiple QC tot Nos. per analyteyes/yesyes/yesyes/yesQC results transferred automatically to LISvesyesyesData mgmt. capability/Instrument vendor supplies LIS interfaceonboard/yes (included in price)yes/n/aInterfaces up and running in active user sites withon obtaind/yes (included in price)yes/n/aBidirectional interface capabilityyes (broadcast download)yes (broadcast download)YesyesyesBidirectional interface operates simultaneously with running assaysyesyesJose LOINC codes for reagent kitssupplied by reagent manufactureryesnot knownnotn/a | |
| QC results transferred automatically to LIS yes yes Data mgmt. capability/Instrument vendor supplies LIS interface onboard/yes (included in price) yes/n/a Interfaces up and running in active user sites with not known Soft, Misys, Cerner, Meditech, Multidata, Seacoas Sidirectional interface capability yes (broadcast download) yes (broadcast download) yes yes yes Sidirectional interface capability yes (broadcast download) yes (broadcast download & host query) yes yes yes yes IS interface operates simultaneously with running assays yes yes ises LOINC to transmit orders & results no yes not labs get LOINC codes for reagent kits supplied by reagent manufacturer yes nterface avail. (or will be) to automated specimen handling system no n/a Wodem servicing available/Can diagnose own malfunctions/ yes/yes/sometimes yes/yes/yes | |
| Data mgmt. capability/Instrument vendor supplies LIS interface interfaces up and running in active user sites with onboard/yes (included in price) not known yes/n/a Soft, Misys, Cerner, Meditech, Multidata, Seacoas Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Siemens, others Bidirectional interface capability yes (broadcast download) yes (broadcast download) yes yes yes Jist reface operates simultaneously with running assays yes yes yes yes yes Jose LOINC codes for reagent kits no no nterface avail. (or will be) to automated specimen handling system no no Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component yes/yes/yes yes/yes/yes | |
| Interfaces up and running in active user sites with not known Soft, Misys, Cerner, Meditech, Multidata, Seacoas Bidirectional interface capability yes (broadcast download) yes (broadcast download) Sidirectional interface capability yes (broadcast download) yes (broadcast download) Is interface operates simultaneously with running assays yes yes Js bes LOINC to transmit orders & results no yes nov labs get LOINC codes for reagent kits no n/a Modem servicing available/Can diagnose own malfunctions/ yes/yes/sometimes yes/yes/sometimes | |
| Bidirectional interface capability yes (broadcast download) yes (broadcast download & host query) Test results transmitted to LIS as soon as chem. time complete yes yes LIS interface operates simultaneously with running assays yes yes Uses LOINC to transmit orders & results no yes How labs get LOINC codes for reagent kits no n/a Interface avail. (or will be) to automated specimen handling system no n/a Modem servicing available/Can diagnose own malfunctions/ yes/yes/sometimes yes/yes/sometimes | |
| Bidirectional interface capability yes (broadcast download) yes (broadcast download & host query) Fest results transmitted to LIS as soon as chem. time complete yes yes JS interface operates simultaneously with running assays yes yes JS interface operates simultaneously with running assays yes yes JS interface operates simultaneously with running assays yes yes JS interface operates simultaneously with running assays yes yes JS interface operates simultaneously with running assays yes yes IS interface operates simultaneously with running assays yes yes IS interface operates interface avail. (or will be) to automated specimen handling system no yes/yes/yes Interface avail. (or will be) to automated specimen handling system no n/a Wodem servicing available/Can diagnose own malfunctions/ yes/yes/sometimes yes/yes/yes Determine malfunctioning component yes/yes/sometimes yes/yes/yes | is, PSA Consultants, |
| I.IS interface operates simultaneously with running assays yes yes Jses LOINC to transmit orders & results no yes Iow labs get LOINC codes for reagent kits supplied by reagent manufacturer yes Interface avail. (or will be) to automated specimen handling system no n/a Aodem servicing available/Can diagnose own malfunctions/ yes/yes/sometimes yes/yes/yes | |
| Jses LOINC to transmit orders & results no yes How labs get LOINC codes for reagent kits supplied by reagent manufacturer yes Interface avail. (or will be) to automated specimen handling system no n/a Modem servicing available/Can diagnose own malfunctions/ yes/yes/sometimes yes/yes/yes Determine malfunctioning component yes/yes/sometimes yes/yes/yes | |
| How labs get LOINC codes for reagent kits supplied by reagent manufacturer yes Interface avail. (or will be) to automated specimen handling system no n/a Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component yes/yes/sometimes yes/yes/yes | |
| 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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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 |
| 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- | yes/yes yes 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 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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| 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 |
| | | |

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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 | | |

July 2006

CAP TODAY / 35



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 | |

URVEYOFUS

36 / CAP TODAY

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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| • 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

38 / CAP TODAY

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 |
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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 • Onboard real-time QC/Support multiple QC lot Nos. per analyte | yes/yes yes/yes yes/yes -, max 600 -, max 600 -, max 600 -, 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 yes/yes yes onboard/no (optional) in development yes (broadcast download) yes yes no no no/yes/yes <4 hr TBD/TBD daily: 2 min; weekly: 5 min; monthly: 15 min |
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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 |
| 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 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 not needed/not needed yes/no no/no | yes yes/yes/yes yes not needed/not needed yes/no yes/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 | yes yes/yes/yes yes/yes not needed/not needed yes/no no/no no | yes yes/yes/yes yes not needed/not needed yes/no yes/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 | 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 |
| 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 | yes yes/yes/yes yes/yes not needed/not needed yes/no no/no no | yes yes/yes/yes yes not needed/not needed yes/no yes/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 | 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 |
| 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 • 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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| 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, 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 | yes yes yes/yes/yes yes not needed/not needed yes/no no/no no no/no no no/no no no/no no no/no no no/no no no/no no/no no/no no no/no no no/no no no/no no no/no no no/no no no/no no no/no no no/no no no/no no no/no no no no no no no no no no | 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 12 sec 24 hr/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 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/yes yes not needed/not needed yes/no no/no no/no no no/no ~6 min, 600 ~6 min, ~700 ~7 min, ~700 8 sec 24 hr/yes yes/yes yes onboard/no (optional) | 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 12 sec 24 hr/yes yes/yes yes onboard/no (optional) |
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| Bar code placement per ČLSI 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, 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 malfunctions/ | yes yes yes/yes/yes yes not needed/not needed yes/no no/no no no no no no no no no seagent lot changes no/no ~6 min, 600 ~6 min, ~700 ~7 min, ~700 8 sec 24 hr/yes yes yes onboard/no (optional) all common interfaces yes (broadcast download) yes yes | yes yes/yes/yes yes not needed/not needed yes/no no no/yes reagent lot changes no/no 6 min, 240 7 min, 258 7 min 17 sec, 230 12 sec 24 hr/yes yes/yes yes onboard/no (optional) all common interfaces yes (broadcast download) yes yes |
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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 |
| 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. | 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 | 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/yes varies | 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. | 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 |
| 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 |
| 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 and calibration intervals up to lot change with min. interferences from | 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 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, |

July 2006

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Chemistry analyzers (for mid/high volume labs)

| | Sector Se |
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| 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 | |

