Good tidings—the latest in chemistry analyzers

Anne Ford

As any weekend farmers' market can attest, with the hottest, stickiest days of summer come the rewards of winter and spring flowers from bulbs planted months ago, bounty from trees carefully tended in cooler weather. So, too, can laboratories reap the harvest of mid- and high-volume chemistry analyzers and their accompanying assays introduced in the past several months. And as a foretaste of the crop to come, some manufacturers are planning to preview new instruments at this month's AACC meeting. Suddenly summer is looking awfully fruitful.

Last winter, Bayer introduced three cerebrospinal fluid assays: glucose oxidase, glucose hexokinase, and total protein, all of which have been approved for testing on the company's Advia 1650 and Advia 2400 chemistry systems. More recently, Bayer expanded the menu of both instruments with nine new tests for drugs of abuse, such as benzodiazepines, opiates, cocaine, and amphetamines. Marketing manager Alexander Socarras says that both the Advia 1650 and the Advia 2400 are "unique in the marketplace because they do not require a robotic interface to link to automation." Also in the Advia line is the fully automated Advia 1200, introduced last fall. Designed for small- to medium-size labs, the Advia 1200 can also serve in larger laboratories as "a backup analyzer to its Advia system siblings," the company says.

Just a few months ago, Ortho-Clinical Diagnostics released 20 assays for use on its Vitros 5,1 FS chemistry system. The assays among them apolipoproteins A1 and B; immunoglobulins A, G, and M; rheumatoid factor; and a highsensitivity CRP assay for the assessment of cardiovascular riskemploy the company's MicroTip technology, which uses disposable tips and cuvettes. The Vitros 5,1 FS itself was made available last fall. In the spring, the company added the Vitros 350, which features more productivity and a more ergonomic design than its forebear, the Vitros

A smaller analyzer, the Envoy 500, is available from Clinical Data. Called "the fastest benchtop analyzer available" by marketing manager Mark Moran, the Envoy 500 is designed to "deliver the performance capability of a floor model." It performs up to 570 tests per hour and features a built-in LCD touchscreen monitor, automated daily maintenance and shutdown, and positive reagent/sample identification.

Later this year, Beckman Coulter plans to introduce the UniCel DxC 600i, a combination chemistry-immunoassay system. Chemistry marketing manager Dan Siegenthaler reports that the system will offer an onboard capacity of 89 assays. "By the time we launch the system, we expect to have more than 160 chemistry and immunoassay tests available," he says. "The DxC 600i will feature closed-tube sampling as well as automated aliquotting and extensive data management capabilities." Beckman Coulter recently made available the UniCel DxC 600, designed for mid-volume laboratories, and the UniCel DxC 800, designed for high-volume labs. Like the forthcoming 600i, the 800 and 600 feature closed-tube sampling.

One of the companies planning to preview instruments at this month's AACC meeting is Abbott, which intends to display its Architect c16000, ci16200, and i1000 $_{SR}$. U.S. product manager Chris Dillman stresses that the Architect c16000 does *not* consist of two of the company's Architect c8000 instruments hooked together. Rather, it is a high-volume chemistry instrument that offers twice the processing capabilities of the c8000 with the same size footprint. In addition, "we've really expanded Architect's chemistry menu," Dillman says. "Last year we added 30 tests, including several for drugs of abuse. This year, we've added numerous specific protein tests." Forthcoming for the Architect line of instruments are software enhancements and additional assays for routine chemistries and therapeutic drug monitoring.

Also planned for preview at AACC is Olympus America's AU-Connector workcell. The workcell, says senior product manager Hiro Sekiya, "integrates specimen movement between two to four Olympus AU chemistry systems as well as the new Olympus AU3000i immunoassay system." He adds, "The workcell design will support stat processing," as well as feature a single loading area for routine specimens and a single user interface for multiple instruments. (Both the AU-Connector and the AU3000i are currently for research use only; they are not for use in diagnostic procedures.) Meanwhile, Olympus customers have already been introduced to the Support Vision system, which, Sekiya says, "automatically and continuously monitors the vital signs of Olympus analyzers." The system also automatically reports test volume data for laboratories.

Thermo Electron's DataPro, an automated random-access chemistry analyzer, is being launched this year at AACC. "It has FDA 510(k) clearance and is designed to meet the specific demands of both the small- and medium-sized clinical laboratories," says John Mc-Clellan, vice president of sales. The analyzer has a throughput of 230 tests per hour, incorporates reagent inventory management, and offers

unlimited storage capacity for patient and control data. "This unit is designed to be cost-competitive and easy to use, with features you would expect to find on larger systems," McClellan says.

AACC attendees can also check out Dade Behring's Dimension Lynx system. "If you are ready to automate but concerned about complexity and size, the Dimension Lynx is the right choice," says U.S. marketing manager Joseph Meola. "The Dimension Lynx provides smart sample management for laboratories that have two separate floor model chemistry analyzers." Dade Behring also plans to demonstrate its Dimension Vista instrument at the show.

Finally, Roche Diagnostics will preview at AACC its second-generation integrated system, the Cobas 6000, which can be a standalone chemistry system or an integrated chemistry and immunoassay system. "We've taken the reliability of Modular and added the reagent cassettes used on the Integra platform," says Modular Systems pro duct manager Lisa Davis. A dedicated HbA_{1c} system (with cap piercing), also not yet launched, will be on display, too. And, Davis says, Modular Pre-Analytics 7 Plus has new features: a pre-sample sorter and flexible sample sorter module "to enhance the sorting process before and after centrifugation."

CAP TODAY's survey of midand high-volume chemistry analyzers includes products from the manufacturers listed above and from Awareness Technology. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities.

Anne Ford is a writer in Chicago.

Chemistry analyzers (for mid-volume laboratories)

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|---|--|---|--|
| | Part 1 of 16 | Abbott Diagnostics Chris Barton christina.barton@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 | Abbott Diagnostics Chris Barton christina.barton@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 |
| | See related comments, page 62 | 800-323-9100 www.abbott.com | 800-323-9100 www.abbott.com |
| | Name of instrument/First year sold in U.S. List price | Abbott Architect c8000/2003 \$225,000 | Abbott Architect ci8200/2003 \$375,000 |
| | No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. | 104/683 U.S., Japan/U.S., Japan/U.S. | 55/321 U.S., Japan/U.S., Japan/U.S. |
| | Operational type/Reagent type | continuous random access/open reagent system | continuous random access/self-contained multi-use cartridges- packages-slides, open reagent system |
| | Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | multi-dimensional retest sample handler, carousel/floor standing 48 x 79 $$ x 49/~26 sq ft | multi-dimensional retest sample handler/floor standing 48 x 127 x 49/42 sq ft |
| | No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months | 79 microalbumin, apo A1, apo B, C3, C4, IgA, IgG, IgM, prealbumin, transferrin, haptoglobin, ferritin, ASO | 79 microalbumin, apo A1, apo B, C3, C4, IgA, IgG, IgM, prealbumin, transferrin, haptoglobin, ferritin, ASO |
| | Tests cleared but not clinically released | myoglobin, alpha-1-antitrypsin, lipoprotein(a) | myoglobin, alpha-1-antitrypsin, lipoprotein(a) |
| | Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries | — a-1-AGP, β-2-microglobulin, digitoxin, IgE, hsCRP, UIBC, bile acid, P. amylase, HBDH, cholinesterase, kappa & lambda light chain, CK-MB, | a-1-AGP, β -2-microglobulin, digitoxin, lgE, hsCRP, UIBC, bile acid, P. amylase, HBDH, cholinesterase, CK-MB, kappa & lambda light |
| | Research-use-only assays Tests in development | ammonia, ceruloplasmin, copper, fructosamine, D-dimer — direct LDL, ultra HDL, lithium, gentamicin, quinidine, tobramycin, vancomycin, acetaminophen, salicylate, ecstasy, benzodiazepine, | chain, ammonia, ceruloplasmin, copper, fructosamine, D-dimer — direct LDL, ultra HDL, lithium, gentamicin, quinidine, tobramycin, vancomycin, acetaminophen, salicylate, ecstasy, benzodiazepine, |
| | User-defined methods implemented for what analytes | barbiturate, TCA ammonia, lithium | barbiturate, TCA ammonia, lithium |
| | Methods supported/immunoassay methods | photometry, potentiometry, turbidimetric/— | photometry, potentiometry, turbidimetric/chemiluminescence with flexible protocols |
| | No. of direct ion selective electrode channels | 3 68 | 3 |
| | No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once | 68 220 | 93 320 |
| | No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates | 220/220 65/370 | 220/220 90/chem 370, immunoassay 100–500 |
| | reag. containers onboard at once/Tests per container set | | · |
| | Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported | 7 days/28 days/yes (2–8°C) yes | —/—/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 yes |
| | Walkaway capacity in minutes/Specimens/Tests-assays | varies/217/69,000-68 | varies >300/367/81,000-93 |
| | System is liquid or dry Uses disposable cuvettes/Max. No. stored | liquid no/— | liquid yes, immunoassay/— |
| | Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time | yes/minimum 1 yr guarantee 2 μL | yes, chemistry/minimum 1 yr guaranteed 2 μL |
| | Supplied with UPS (backup power)/Requires floor drain | yes/no | yes/no |
| | Requires dedicated water system/Water consumption per hour Noise generated in decibels | yes/25 L — | yes/30.5 L — |
| | Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes | yes/50 µL yes/no | yes/50 µL yes/no |
| | 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, 2-D bar codes yes | interl., Codabar, codes 39 & 128)/autodiscrimination yes |
| ŀ | | • | yes |
| | Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection | yes yes/yes | yes yes/yes |
| | Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation | 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- | 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 Automatic shutdown/Startup programmable | no yes/yes 8 hr/30 days/14 days/7–14 days no/no | no yes, for chemistry only/yes 8 hr/30 days/14 days/7–14 days —/no |
| - | Stat time to completion of all analytes, throughput per hr. for: | | |
| | Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP | 2.5 min, 200 specimens, 800 tests 9.6 min, 160 specimens, 1,120 tests 9.6 min, 133 specimens, 800 tests | 2.5 min, 200 specimens, 800 tests 9.6 min, 160 specimens, 1,120 tests 9.6 min, 133 specimens, 800 tests |
| | 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 | <20 sec shortest interval: 8 hr; longest: 24 hr/yes yes/yes yes |
| ŀ | Data mgmt. capability/Instrument vendor supplies LIS interface | yes (addt'l cost, SW mftr: Abbott) | yes (addt'l cost, SW mftr: Abbott) |
| | Interfaces up and running in active user sites with | Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, | Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, |
| | Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete | Meditech, Siemens, Triple G, CIS, Sunquest, others yes (broadcast download & host query) yes | Meditech, Siemens, Triple G, CIS, Sunquest, others yes (broadcast download & host query) yes |
| | LIS interface operates simultaneously with running assays | yes | yes |
| | Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits | package insert | Ξ |
| ŀ | Interface avail. (or will be) to automated specimen handling system | yes | no |
| | Modem servicing available/Can diagnose own malfunctions/ | yes/yes/yes | yes/yes/yes |
| | Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting | <24 hr/yes | <24 hr/yes |
| | Mean time between failures/To repair failures Average time to complete maintenance by lab personnel | >2 mos/varies daily: <15 min; weekly: <45 min; monthly: 15 min | >2 mos/varies daily: TBD; weekly: TBD; monthly: TBD |
| | Onboard maintenance records/Maint. training demo module | yes (includes audit trail of who replaced parts)/yes | yes/yes |
| | Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d) | 5 days on site, 5 days at vendor offices/yes \$18,500 | 5 days on site, 5 days at vendor offices/yes \$28,500 |
| | Distinguishing features | unique multi-dimensional retest sample handler provides exceptional sample management and ensures stat TAT remains constant regardless of routine workload; large reagent and sample capacity; liquid ready-to-use reagents; maximizes ease of use with patented ICT chip; easy-to-use, intuitive software with state-of-the-art online operation manuals and troubleshooting | integration of CC and IA without compromising stat TAT, results, or throughput because of patented SmartWatch technology, which minimizes carryover to <0.1 ppm; large reagent capacity of 93 assays, with sample load up to 367; efficiency provided via multiple patented technologies |
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Survey editor: Raymond Aller, MD

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|--|---|---|
| Part 2 of 16 | Awareness Technology Inc. Chris Schneider info@awaretech.com | Bayer Healthcare, Diagnostics Division Eric Lafleche eric.lafleche.b@bayer.com |
| | P.O. Box 1679 Palm City, FL 34991 | 511 Benedict Ave. Tarrytown, NY 10591 |
| See related comments, page 62 | 772-283-6540 www.awaretech.com | 914-333-6130 labnews.com |
| Name of instrument/First year sold in U.S. | ChemWell/1999 | ADVIA 1200/2005 |
| List price No. units in clinical use in U.S./Outside U.S. | \$25,000 10/550 | \$189,000 10/50 |
| Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type | U.S./U.S./open system continuous random access/open ragent system | Japan/Japan/Ireland random access/open reagent system |
| | | |
| Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | rack of 96 samples/benchtop 19 x 36 x 22 in/7 sq ft | carousel/floor standing 33.5 x 48 x 44 in/1.04 square meters |
| No. of tests for which analyzer has FDA-cleared applications | 22 | 48 |
| Tests clinically released in last 12 months | none | albumin, ALP (AMP), ALP (DEA), ALT, amylase, AST, dir. & total bilirubin, calcium, CO ₂ (L), cholesterol, chloride, CK, creatinine, creatinine (enzymatic), direct LDL, GGT, glucose (hex), glucose (oxi), HDL, inorganic phosphorus, iron, potassium, sodium, total protein, triglycerides, urea nitrogen, uric acid, CRP, transferrin, lipase, C3, C4, AST (P5P), ALT (P5P), valproic acid, RF, urinary total protein, pancreatic amylase, cholinesterase, prealbumin, c-1-antitrypsin, digoxin, theophylline, phenytoin |
| Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance | none 18 EIA kits manuf. by BroCheck have been submitted | none none |
| Tests not available in U.S. but available in other countries Research-use-only assays | open system open system | none none |
| Tests in development | none | TIBC, ammonia, HbA1C, microalbumin, ASO, ApoA, ApoB, wrCRP, haptoglobin, IgA, IgG, IgM, carbamazepine, gentamicin, lithium, |
| | | phenobarb, tobramycin, vancomycin, acetaminophen, ethanol, |
| User-defined methods implemented for what analytes | all colorimetric biochemistry & EIA that read between 340–700 nm | salicylate, DAUs, lactate open system capability |
| Methods supported/immunoassay methods | photometry/microwell assays | photometry, potentiometry, turbidimetric/— |
| No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously | 0 27 | 3 40 colorimetric, 3 ISE |
| No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously | unlimited unlimited/27 | 100 62/43 |
| No. of different analytes for which system accommodates | unimited/2/ 27/reagent dependent | 43/1,000 |
| reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard | reagent dependent/yes (15°C below ambient) | 96 hr/21 days/yes (6–12°C) |
| Multiple reag. configurations supported Reag. container placed directly on system for use | yes reagent dependent | yes yes |
| Instrument has same capabilities when 3rd-party reag. used Walkaway capacity in minutes/Specimens/Tests-assays | yes not limited/96/not limited | yes —/84/17,000 |
| System is liquid or dry | liquid | liquid |
| Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency | yes (optional)/96 yes (optional)/weekly | no/231 yes/4 mos |
| Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain | 2 μL no/no | 1 μL yes/yes |
| Requires dedicated water system/Water consumption per hour Noise generated in decibels | no/<1 L 60 | yes/20 L <60 |
| Dedicated pediatric sample cup/Dead volume | no no/no | yes/50 μL |
| Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability | yes, by handheld scanner as tubes are loaded onto instrument (2 or 5 | yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 |
| | interl., UPC, Codabar, codes 39 & 128)/autodiscrimination depends on handheld scanner models | interl., Codabar, codes 39 & 128)/autodiscrimination |
| Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A | no no | 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/no yes | yes/yes/yes yes |
| Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability | no/no yes/yes | yes/yes |
| Sample volume can be reduced/Increased to rerun out-of-linear- | yes/no | yes/yes yes/yes |
| range high/low results Autocalibration or autocalibration alert | yes | autocalibration |
| Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | yes/yes user defined for all | yes/yes once per day/14 days/n/a/n/a |
| Automatic shutdown/Startup programmable | yes/yes | yes/yes |
| Stat time to completion of all analytes, throughput per hr. for: | n/a | 11 min 200 |
| Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine | n/a n/a | 11 min, 200 11 min, 160 |
| Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample | 5.5 min, 28 specimens 15 sec | 11 min, 133 30 sec |
| How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte | reagent dependent/yes yes/yes | shortest: 8 hr; longest; 24 hr/yes yes/yes |
| QC results transferred automatically to LIS | 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 | onboard/no Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, |
| Bidirectional interface capability | yes (broadcast download) | Siemens, others 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 | no | via software |
| How labs get LOINC codes for reagent kits | supplied by reagent manufacturer | |
| Interface avail. (or will be) to automated specimen handling system | no | no |
| Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component | yes/yes/sometimes | yes/yes/yes |
| On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures | 48 hr/yes depends on user and varies/depends on problem and varies | varies by location, generally <4 hr/yes —/— |
| Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module | daily: <5 min; weekly: about 15 min; monthly: about 30 min or less no/no | daily: <5 min; weekly: 10 min; monthly: 20 min yes (includes audit trail of who replaced parts)/yes |
| Training provided with purchase/Advanced oper. training avail. | 2 days on site, 3 days at vendor offices/yes | 5 days at vendor offices; ongoing onsite as needed/yes |
| Annual service contract cost (24 h/7 d) | \$4,000 | \$19,000 |
| Distinguishing features | price; one instrument for EIA & biochemistry; completely open and user programmable; special discounts for biochemistry only; calculates indices; very flexible formatting of reports | clot detection; serum indices; 1,200 tests per hour; auto reruns, dilutions, repeats, reflex testing; open-system for 3rd party assays; part of family of chemistry systems (ADVIA 2400 & ADVIA 1650) and uses same reagents; short sample detection; liquid level sensing, refrigerated compartment for calibrators/QC; integration to Centralink |
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Chemistry analyzers (for mid-volume laboratories)

| Part 3 of 16 | Beckman Coulter Inc. 200 South Kraemer Blvd. | Beckman Coulter Inc. Dan Siegenthaler dmsiegenthaler@beckman.com |
|---|---|--|
| | P.O. Box 8000 Brea, CA 92822-8000 | 200 South Kraemer Blvd., P.O. Box 8000 Brea, CA 92822-8000 |
| See related comments, page 62 | 800-526-3821 www.beckmancoulter.com | 800-526-3821 www.beckmancoulter.com |
| ame of instrument/First year sold in U.S. ist price | Synchron CX9 Pro/2001 \$220,600 | UniCel DxC 600/2004 \$340,000 |
| lo. units in clinical use in U.S./Outside U.S. | 1,000/600 | 70/50 |
| ountry where designed/Manufactured/Where reagents mftd. perational type/Reagent type | U.S./U.S./U.S. & Irela nd continuous random access/open reagent system | U.S./U.S. & Ireland continuous random access/open reagent system |
| ample handling system/Model type limensions 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 |
| lo. of tests for which analyzer has FDA-cleared applications ests clinically released in last 12 months | >100 lithium | >100 n/a |
| ests clinically released in last 12 months ests cleared but not clinically released | none | none |
| ests not available in U.S. but submitted for 510(k) clearance ests not available in U.S. but available in other countries | none | none none |
| lesearch-use-only assays ests in development | none none sirolimus, tacrolimus, tricyclics, semiquantitative DATs | none none sirolimus, tacrolimus, tricyclics, IMA, semi-quantitative drugs of |
| ser-defined methods implemented for what analytes | UIBC, cyclosporine, homocysteine | abuse UIBC, cyclosporine, homocysteine |
| Methods supported/Immunoassay methods | photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct | photometry, potentiometry, near-infrared bidentate turbidimetric/ |
| | turbidimetric, particle enhanced turbidimetric, enzyme immunoassay | particle enhanced turbidimetric, enzyme immunoassay, near infrared particle immunoassay |
| lo. of direct ion selective electrode channels lo. of different measured assays onboard simultaneously | 5 (indirect) 33 | 5 65 |
| lo. of different assays programmed, calibrated at once | 59 | 100 |
| lo. of user-definable (open) channels/No. active simultaneously | 102/33 33/25_2 500 | 100/65 |
| lo. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set | 33/25–2,500 | 65/about 3,500 modular; about 600 cartridge |
| hortest/median onboard reag. stability/Refrigerated onboard fultiple reag. configurations supported | 168 hr/30 days/yes (2–8°C) yes | 168 hr/30 days/yes (2–8°C) yes |
| leag. container placed directly on system for use | yes yes | yes |
| nstrument has same capabilities when 3rd-party reag. used Valkaway capacity in minutes/Specimens/Tests-assays | yes 100/63/2,079 | no 83/132/5,280 |
| ystem is liquid or dry | liquid | liquid |
| lses disposable cuvettes/Max. No. stored lses washable cuvettes/Replacement frequency | no/n/a yes/permanent-2-yr warranty (80 stored on instrument) | n/a yes/2-yr warranty, semi-permanent |
| linimum sample volume aspirated precisely at one time | 3 μL | 3 μL |
| upplied with UPS (backup power)/Requires floor drain lequires dedicated water system/Water consumption per hour | yes/yes yes/7 L | optional/no yes/16 L |
| loise generated in decibels | 70 | 60 |
| ledicated pediatric sample cup/Dead volume rimary tube sampling/Pierces caps on primary tubes | yes/40 µL yes/no | yes/40 µL yes/yes |
| ample bar-code reading capability | yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination | yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination |
| leagent bar-code reading capability lar code placement per CLSI standard Auto2A | yes yes | yes yes |
| inboard 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 yes |
| lemolysis/Turbidity detection-quantitation bilution of patient samples onboard/Automatic rerun capability | yes/yes | yes/yes |
| range high/low results | yes/yes yes/yes | yes/yes yes/yes |
| utocalibration or autocalibration alert | yes notice | yes no/woo |
| alibrants stored onboard/Multipoint calibration supported ypical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | no/yes 24 hr/up to 90 days/up to 60 days/14 days | no/yes 1 day/up to 90 days/up to 60 days/14 days |
| utomatic shutdown/Startup programmable | none required | none required |
| tat 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 | 52 sec, 75 specimens | 6:15 from standby, 96 specimens |
| Album., bili. direct & total, AST, ALT, ALP ypical time delay from ordering stat test to aspir. of sample | 10 min, 32 specimens 45 sec | 13:07 from standby, 57 specimens 16 sec |
| low often QC required/Onboard SW capability to review QC | 24 hr/yes | 24 hr/yes |
| Inboard real-time QC/Support multiple QC lot Nos. per analyte IC results transferred automatically to LIS | yes/yes yes | yes/yes yes |
| ata mgmt. capability/Instrument vendor supplies LIS interface | onboard & optional add-on (SW mftr: Beckman Coulter)/yes (addt'l | onboard & optional add-on (SW mftr: Beckman Coulter)/yes (addt'l |
| nterfaces up and running in active user sites with | cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs | cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesso Labquest, CCA, VA-Mumps |
| idirectional interface capability | yes (broadcast download & host query) | yes (broadcast download & host query) |
| est results transmitted to LIS as soon as chem. time complete IS interface operates simultaneously with running assays | yes yes | yes yes |
| ses LOINC to transmit orders & results low labs get LOINC codes for reagent kits | no customer request | yes customer request |
| nterface avail. (or will be) to automated specimen handling system | yes (Power Processor) | yes (Beckman Coulter automation) |
| odem servicing available/Can diagnose own malfunctions/ | yes/no/no | yes/yes/yes |
| Determine malfunctioning component In-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 |
| lean time between failures/To repair failures verage 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) |
| go anno to complete maintenance by lab percellille | no/no 5 days at vendor offices/yes | yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes |
| nboard maintenance records/Maint. training demo module raining provided with purchase/Advanced oper. training avail. | | _ |
| | _ | |
| raining provided with purchase/Advanced oper. training avail. | serum indices; centrifugable sectors; clot detection; design optimized | closed-tube sampling; serum indices/polychromatic correction; clo |
| raining provided with purchase/Advanced oper. training avail. Innual service contract cost (24 h/7 d) | serum indices; centrifugable sectors; clot detection; design optimized for automation; continuous random access for samples, controls, reagents, and results; no-maintenance glucose oxygen sensor; no- | detection and correction; centrifugable racks, no-wait autoloader; |
| raining provided with purchase/Advanced oper. training avail. Innual service contract cost (24 h/7 d) | for automation; continuous random access for samples, controls, reagents, and results; no-maintenance glucose oxygen sensor; no-wait autoloader; polychromatic correction; thermal ring and semi- | detection and correction; centrifugable racks, no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; |
| raining provided with purchase/Advanced oper. training avail. Innual service contract cost (24 h/7 d) | for automation; continuous random access for samples, controls, reagents, and results; no-maintenance glucose oxygen sensor; no- | detection and correction; centrifugable racks, no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent |

| Part 4 of 16 | Clinical Data | Clinical Data |
|---|---|---|
| | slsmktg@cida.com | Joe Vacante |
| | 2 Thurber Blvd. Smithfield, RI 02917 | 2 Thurber Blvd. Smithfield, RI 02917 |
| | Smithleta, ki 02917 800-345-2822 | Smithtield, Ri 02917 401-233-3526 |
| ee related comments, page 62 | www.clda.com | www.clda.com |
| ame of instrument/First year sold in U.S. | Vitalab Selectra XL/2004 | Envoy 500/2005 |
| ist price o. units in clinical use in U.S./Outside U.S. | \$98,750 0/— | \$96,750 —/— |
| ountry where designed/Manufactured/Where reagents mftd. | Netherlands/Netherlands/U.S. | Italy/Italy/U.S. |
| perational type/Reagent type | random access/multi-use bottles | random access/self-contained multi-use cartridges, packages, slides |
| ample handling system/Model type imensions in inches (H x W x D)/Instrument footprint | rotor/floor standing 45 x 46 x 30/12 sq ft | rotor/benchtop —/— |
| o. of tests for which analyzer has FDA-cleared applications | >31 | 28 |
| ests clinically released in last 12 months | _ | albumin, direct & total bilirubin, calcium, creatinine, glucose, total iron, magnesium, phosphorus, total protein, urea nitrogen, uric acid, ALT, ALP, AST, CPK, LDH, GGT, amylase, direct LDL & HDL, triglycerides, cholesterol, CO ₂ , chloride, sodium, potassium |
| ests cleared but not clinically released | _ | n/a |
| ests not available in U.S. but submitted for 510(k) clearance ests not available in U.S. but available in other countries | _ | n/a n/a |
| esearch-use-only assays | T | n/a |
| ests in development ser-defined methods implemented for what analytes | hsCRP n/a | hsCRP n/a |
| ethods supported/Immunoassay methods | photometry, potentiometry (ISE)/immunoturbidimetric | photometry, potentiometry (ISE)/— |
| | | |
| o. of direct ion selective electrode channels o. of different measured assays onboard simultaneously | 4 40 | 4 40 |
| o. of different assays programmed, calibrated at once | 40 | 40 |
| o. of user-definable (open) channels/No. active simultaneously o. of different analytes for which system accommodates | 5/40 70/700 | 40/40 40 |
| reag. containers onboard at once/Tests per container set | | |
| nortest/median onboard reag. stability/Refrigerated onboard | 72 hr/7 days/yes (12°C below ambient) | 40 hr/10 days/yes (12–15°C) |
| ultiple reag. configurations supported eag. container placed directly on system for use | — yes | yes yes |
| strument has same capabilities when 3rd-party reag. used | yes | no |
| alkaway capacity in minutes/Specimens/Tests-assays /stem is liquid or dry | 240/80/2,400 liquid | 240/52/40 liquid |
| ses disposable cuvettes/Max. No. stored | no | no |
| ses washable cuvettes/Replacement frequency | yes/every 10,000 reactions | yes/never |
| inimum sample volume aspirated precisely at one time upplied with UPS (backup power)/Requires floor drain | 1 µL yes/no | — yes/no |
| equires dedicated water system/Water consumption per hour | no/0.8 L | no/— |
| oise generated in decibels edicated pediatric sample cup/Dead volume | yes/20 μL | _ |
| imary tube sampling/Pierces caps on primary tubes | yes/no | yes/no |
| ample bar-code reading capability | yes, as sample is being aspirated (2 of 5 interl., UPC, Codabar, | yes, as sample is being aspirated |
| eagent bar-code reading capability | codes 39 & 128) no | yes |
| ar code placement per CLSI standard Auto2A | yes | _ |
| nboard test auto inventory (determines volume in container) easures no. tests remaining/Short sample detection/Clot detection | yes yes/yes/yes | yes yes/yes/yes |
| utomatic detection of adequate reag. for aspir. & analysis | yes | yes |
| emolysis/Turbidity detection-quantitation ilution of patient samples onboard/Automatic rerun capability | —/— yes/yes | no/no yes/yes |
| ample volume can be reduced/Increased to rerun out-of-linear- | yes/no | yes/yes |
| range high/low results utocalibration or autocalibration alert | VPS | no |
| utocambration or autocambration alert alibrants stored onboard/Multipoint calibration supported | yes no/yes | no no/yes |
| pical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | 4 hr/1–14 days/—/— | 4 hr/7 days/n/a/n/a |
| utomatic shutdown/Startup programmable | yes/yes | yes/yes |
| at time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 | 8 min, — | _ ,_ |
| Sodium, potassium, chloride, TCO2, glucose, urea, creatinine | 10 min, — | |
| Album., bili. direct & total, AST, ALT, ALP visal time delay from ordering stat test to aspir of sample. | 10 min, — | |
| ypical time delay from ordering stat test to aspir. of sample ow often QC required/Onboard SW capability to review QC | 6 min shortest interval: 4 hr; longest: once a day/yes | daily/yes |
| nboard real-time QC/Support multiple QC lot Nos. per analyte | no/yes | yes/yes |
| C results transferred automatically to LIS | yes | yes |
| ata mgmt. capability/Instrument vendor supplies LIS interface terfaces up and running in active user sites with | optional add on/yes — | no/yes (addt'l cost) Antek, Labdaq, Fletcher-Flora, Labpak |
| | | |
| directional interface capability est results transmitted to LIS as soon as chem. time complete | yes | yes (broadcast download & host query) |
| S interface operates simultaneously with running assays | yes yes | yes yes |
| ses LOINC to transmit orders & results ow labs get LOINC codes for reagent kits | ======================================= | _ |
| | | |
| terface avail. (or will be) to automated specimen handling system | | |
| odem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component | no/yes/yes | no/yes/yes |
| n-site time of svc. engineer/Onboard error codes for troubleshooting | within 24 hr/yes | 24 hr/yes |
| lean time between failures/To repair failures verage time to complete maintenance by lab personnel | 6 mo/4 hr | n/a/n/a daily: 5 min; weekly: 15 min; monthly: 30 min |
| verage time to complete maintenance by lab personnel nboard maintenance records/Maint. training demo module | daily: 10 min; weekly: 20 min; monthly: 60 min no/yes | no/no |
| raining provided with purchase/Advanced oper. training avail. | 3 days on site/yes | 5 days on site |
| | n/a | - |
| nnual service contract cost (24 h/7 d) | | |
| nnual service contract cost (24 h/7 d) istinguishing features | 4 parameter dry ISE with CO ₂ ; reusable reaction cuvette rotor; onboard wash system | 4 parameter dry ISE with CO ₂ ; 570 tests per hour benchtop; onboard touch screen LCD monitor |
| nnual service contract cost (24 h/7 d) | 4 parameter dry ISE with CO_2 ; reusable reaction cuvette rotor; onboard wash system | |

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Chemistry analyzers (for mid-volume laboratories)

| , | , (| |
|--|---|---|
| Part 5 of 16 | Olympus America Inc. Susan M. Watanabe, PhD susan.watanabe@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 | Ortho-Clinical Diagnostics Adam Cornfield 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 |
| See related comments, page 62 | www.olympus.com | www.orthoclinical.com |
| Name of instrument/First year sold in U.S. | AU400/1998; AU400e/2002 | VITROS 350/2005 |
| List price No. units in clinical use in U.S./Outside U.S. | \$130,000 >500/>2,000 | \$110,000 —/— |
| Country where designed/Manufactured/Where reagents mftd. | Japan/Japan/U.S. & Ireland | U.S./U.S. |
| Operational type/Reagent type | random access, discrete, continuous random access/open reagent | batch, random access, discrete, continuous random access/self- |
| Sample handling system/Model type | system rack & stat carousel/floor standing | contained single-use cartridges, packages, slides rack/floor standing |
| Dimensions in inches (H x W x D)/Instrument footprint | 47.6 x 57.1 x 29.9/62.7 sq ft | 47 x 45.5 x 28/8.8 sq ft |
| No. of tests for which analyzer has FDA-cleared applications | 122 | 70 |
| Tests clinically released in last 12 months | lactate | none |
| | | |
| | | |
| Tests cleared but not clinically released | _ | dHDL MicroSlide |
| 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 |
| Research-use-only assays | none | none |
| Tests in development User-defined methods implemented for what analytes | D-dimer fructosamine, ammonia | none — |
| | | |
| Methods supported/Immunoassay methods No. of direct ion selective electrode channels | photometry, potentiometry, calculated tests/homogeneous 3 | potentiometry, colorimetric, rate, immuno-rate/— 3 |
| No. of different measured assays onboard simultaneously | up to 76 | up to 60 |
| No. of different assays programmed, calibrated at once | 99 | up to 60 |
| No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates | 95/— 76/100–1,333 | 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 Multiple reag. configurations supported | 120 hr/30 days/yes (4–12°C) ves | 48 hr/14 days/no yes |
| Reag. container placed directly on system for use | yes yes | yes yes |
| Instrument has same capabilities when 3rd-party reag. used | yes | n/a |
| Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry | varies/up to 102/varies liquid | varies/40/200 per hr dry |
| Uses disposable cuvettes/Max. No. stored | no/n/a | n/a |
| Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time | yes/permanent 2 μL | n/a 6 μL |
| Supplied with UPS (backup power)/Requires floor drain | no (optional)/yes (no w/ optional water pump) | available (not included)/no |
| Requires dedicated water system/Water consumption per hour Noise generated in decibels | yes/26 L per hr peak consumption 65 | no/n/a 61 |
| Dedicated pediatric sample cup/Dead volume | no/n/a | no special sample cup required/35 μL |
| Primary tube sampling/Pierces caps on primary tubes | yes/no | yes/no |
| Sample bar-code reading capability | yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination | yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination |
| Reagent bar-code reading capability | yes | yes |
| Bar code placement per CLSI standard Auto2A | yes | yes |
| Onboard test auto inventory (determines volume in container) | yes | yes |
| Measures no. tests remaining/Short sample detection/Clot detection | yes/yes/yes | yes/yes/yes |
| Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation | yes yes/yes | yes not needed/not needed |
| Dilution of patient samples onboard/Automatic rerun capability | yes/yes | yes/no |
| Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results | yes/yes | yes/no |
| Autocalibration or autocalibration alert | yes | no |
| Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | yes/yes 1 day/30 days/14 days/14_20 days | no/yes reagent lot changes |
| Automatic shutdown/Startup programmable | yes/yes | no/no |
| Stat time to completion of all analytes throughout per hr for | | |
| Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 | <5 min, 200 specimens | 6 min, 240 |
| Sodium, potassium, chloride, TCO2, glucose, urea, creatinine | <5 min, 80 specimens | 6 min 24 sec, 287 |
| Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample | <9 min, 67 specimens <2 min | 6 min 40 sec, 261 12 sec |
| How often QC required/Onboard SW capability to review QC | per CLIA & laboratory's decision/yes | 24 hr/yes |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS | yes/yes | yes/yes |
| • | yes | yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard/no (optional) | onboard/no (optional) |
| Interfaces up and running in active user sites with | all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, | in development |
| Didinational interfer | McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC | use (husedensk deurster 1) |
| Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete | yes (broadcast download & host query) yes | yes (broadcast download) yes |
| LIS interface operates simultaneously with running assays | yes | yes |
| Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits | no | no |
| - | | |
| Interface avail. (or will be) to automated specimen handling system | yes | no |
| Modem servicing available/Can diagnose own malfunctions/ | yes/yes/yes | no/yes/yes |
| Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting | <24 hr/yes | <4 hr |
| Mean time between failures/To repair failures | <24 nr/yes average 2 calls per yr/<24 hr | <4 nr TBD/TBD |
| Average time to complete maintenance by lab personnel | daily: 3 min; weekly: 7 min; monthly: 45 min | daily: 2 min; weekly: 5 min; monthly: 15 min |
| Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. | yes (includes audit trail of who replaced parts)/yes 3–5 days on site, 5 days at vendor offices/yes | no/yes 3 days on site, 5 days at vendor offices/yes |
| Annual service contract cost (24 h/7 d) | inquire | varies |
| Distinguishing features | Olympus SUPPORTVISION, an Internet-based, real-time monitoring | cost-effective MicroSlide Technology delivers low cost per |
| Journal of the state of the sta | system for proactive services; standardization with family of | reportable result and high reagent efficiency without the costs, |
| | chemistry immuno systems, the AU400, AU400e, AU600, AU640, | maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC proce- |
| | AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management | with traditional water-based and indirect ISE systems; QC procedures are required just once each day and calibration intervals up |
| | and streamlined operation | to six months with minimal interferences from hemolysis, lipemia; |
| | | no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily |
| | | and and angelood of duty |
| | | |
| | | |

| Part 6 of 16 | Roche Diagnostics Todd Atkinson, Product Manager | Roche Diagnostics Lisa Davis, Product Manager |
|---|---|---|
| | 9115 Hague Rd., P.O. Box 50457 | 9115 Hague Rd. |
| Can valated comments, name 60 | Indianapolis, IN 46250 | Indianapolis, IN 46250 |
| See related comments, page 62 | 800-428-5074 www.roche.com | 800-428-5074 ext. 13531 us.labsystems.roche.com |
| Name of instrument/First year sold in U.S. | Cobas Integra 800/2001 (Integra introduced 1995) | Integrated Modular Analytics/2002 |
| List price No. units in clinical use in U.S./Outside U.S. | \$265,000 >500/>2,000 | varies >50/>200 |
| Country where designed/Manufactured/Where reagents mftd. | Switzerland/Switzerland/multiple countries | multiple countries/multiple countries/multiple countries |
| Operational type/Reagent type | random access, discrete, continuous random access/self- | continuous random access/self-contained, multi-use cartridges-pack- |
| Sample handling system/Model type | contained multi-use cartridges-packages-slides sample racks: RD 5-position rack/floor standing | ages-slides 5-position rack/floor-standing |
| Dimensions in inches (H x W x D)/Instrument footprint | 47.3 x 74.8 x 35.4/— | varies with configuration/varies with configuration |
| No. of tests for which analyzer has FDA-cleared applications | 137 | >140 |
| Tests clinically released in last 12 months | _ | amikacin, quinidine, SHBG, C-peptide |
| Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance | none | n/a n/a |
| Tests not available in U.S. but available in other countries | LDH (P→L), ALP (DGKC) | TG, anti-TG, urine cortisol, kappa, lambda, |
| Research-use-only assays | | apo A, apo B, Lp(a), osteocalcin, P1NP n/a |
| Tests in development | IgE, lipoprotein(a), kappa/lambda light chains, IMA | anti-HBc, anti-HBc IgM, anti-HBe, HBe-Ag, rubella IgG, rubella IgM, |
| | | toxo IgG, toxo IgM, CA 19-9, CA 72-4, Lp PLA ₂ , vancomycin, lidocaine, |
| User-defined methods implemented for what analytes | yes, varies | cyclosporin yes, varies |
| | | |
| Methods supported/Immunoassay methods | photometry, potentiometry, fluorescence polarization/ turbidimetric | photometry, potentiometry (ion selective electrode)/ electrochemiluminescence |
| No. of direct ion selective electrode channels | 4 | 3 |
| No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once | 72 72 | 72->140 72->140 |
| No. of uner-ent assays programmed, cambrated 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 | 72/50–800 | 72->140/100-3,000 |
| reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard | 336 hr/84 days/yes (8°C) | 72 hr/90 days/yes (2-12°C) |
| Multiple reag. configurations supported | yes | yes |
| Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used | yes no | yes limited |
| Walkaway capacity in minutes/Specimens/Tests-assays | 450/180/4,000 | 6 hr/300/varies |
| System is liquid or dry | liquid | liquid |
| Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency | yes/3,600 no/n/a | yes, 1,000 tests yes/monthly |
| Minimum sample volume aspirated precisely at one time | 2 μL | 2 μL |
| Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour | yes/yes no (direct connection, type I NCCLS)/5–7 L | yes/yes yes/50 L |
| Noise generated in decibels | 58.5 | <62 |
| Dedicated pediatric sample cup/Dead volume | yes/approx. 50–70 μL | yes/50 µL |
| Primary tube sampling/Pierces caps on primary tubes 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 |
| Description and made and 19th | | interl., Codabar, codes 39 & 128)/autodiscrimination |
| Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A | yes yes | yes yes |
| <u> </u> | • | • |
| Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection | yes yes/yes/yes | yes ves/yes/ves |
| Automatic detection of adequate reag. for aspir. & analysis | yes | yes |
| Hemolysis/Turbidity detection-quantitation 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 | yes/yes yes/yes |
| range high/low results | | |
| Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported | yes yes/yes | yes no/yes |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | 5 hr/once per lot/140 days/60 days | 24 hr/varies from bottle change to lot change/bottle change/— |
| Automatic shutdown/Startup programmable | yes/yes | yes/yes |
| Stat time to completion of all analytes, throughput per hr. for: | | |
| Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine | 8.6 min, 118 specimens 8.6 min, 99 specimens | 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens |
| Album., bili. direct & total, AST, ALT, ALP | 9.8, 118 specimens | 10 min, 133–600 specimens |
| Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC | 1 min | 50 sec 24 hr/yes |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | typically once per 24 hr/yes yes/yes | yes/yes |
| QC results transferred automatically to LIS | yes | yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard/yes (addt'l cost) | onboard/no (addt'l cost) |
| Interfaces up and running in active user sites with | Cerner, CHCS, Citation, Compton, CompuLab, DynaMedix, EDS, | all major LIS vendors |
| | Fletcher Flora, McKesson (ALG, PathLabs, StarLabs), HMS, Intellilabs, Isys, LabDaq, Labforce, Labfusion, LabSoft, LCI, | |
| | Meditech, Northern Soft, Orsys, Seacoast, Siemens, Soft | |
| Bidirectional interface capability | Computer, Misys yes (broadcast download & host query) | ves (hrnadeast download & host query) |
| Test results transmitted to LIS as soon as chem. time complete | yes (proadcast download & nost query) yes | yes (broadcast download & host query) yes |
| LIS interface operates simultaneously with running assays | yes | yes |
| Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits | no — | no database |
| | | |
| Interface avail. (or will be) to automated specimen handling system | 0 | 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 | —/ — | 260 days/3.5 hr |
| Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module | daily: <1 min; weekly: <5 min; monthly: none | daily: 5 min hands-on; weekly: 30 min; monthly: 15 min |
| onsoard maintenance records/maint, training deino module | yes (includes audit trail of who replaced parts)/yes (onscreen help with diagrams & maintenance wizard) | yes (includes audit trail of who replaced parts)/yes |
| Training provided with purchase/Advanced oper. training avail. | 1 day on site, 5 days at vendor offices/yes | 5 days at vendor offices/yes |
| Annual service contract cost (24 h/7 d) | varies | varies |
| Distinguishing features | comprehensive test menu including hemoglobin A1c; reagent cas- | high-throughput clinical chemistry and immunoassay system with single |
| | sette requires no operator prep. or special handling (can go straight from refrigerator to system with no warmup time); 97 percent of | point of entry; single user interface; single host connection, providing productivity & efficiency gains; system offers flexibility to easily expand |
| | reagents are liquid, ready to use, system automatically reconstitutes | configuration on site; enhanced intelligent process management |
| | if necessary, system forecasts daily reagent requirements based on history; operator maintenance automatically scheduled by system, | achieves optimized sample routing, seamless integration of stat samples |
| | | into routine workflow, automatic rerun and repeat testing selectable by |
| | based on actual use, not by calendar schedule; (800 has clot detec- | test and real-time reflex testing with Middleware Solutions |
| | tion, bubble detection, and can accommodate universal five-position | test and real-time reflex testing with Middleware Solutions |
| | | test and real-time reflex testing with Middleware Solutions |

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Chemistry analyzers (for mid-volume labs)

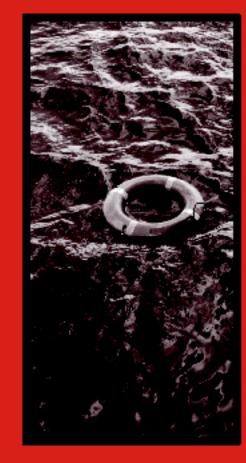
| Part 7 of 16 See related comments, page 62 | Thermo Electron Corp. Technical Support sales.clinicalchemistry@thermo.com 331 S. 104th St. Louisville, CO 80027 800-558-9115 www.thermo.com/clinicalchemistry |
|---|--|
| lame of instrument/First year sold in U.S. | DataPro; DataPro Plus/— |
| List price 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 | — 3/>100 Argentina/Argentina/Australia batch, random access, discrete (separate PC with analyzer), continuous random access/open reagent system ring/benchtop |
| Dimensions in inches (H x W x D)/Instrument footprint | 18.5 x 33.5 x 23/8.25 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 Tests not available in U.S. but available in other countries Tests in development User-defined methods implemented for what analytes | 15 AST, ALT, albumin, total & direct bilirubin, calcium, cholesterol, glucose, creatinine, ALP, phosphorus, total protein, triglycerides, urea nitrogen, uric acid none none CO ₂ , amylase, CK, GGT, HDL, LDL, magnesium, microprotein, ACE, lipase none TDMs, CRP, HbA1c none |
| Methods supported/Immunoassay methods | photometry, turbidimetry/— |
| 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 | photometry, turbidimetry/— — 48 48 Imited to PC memory/48 48/up to 225 —/—/yes (5–7°C below room temperature) |
| 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 | yes requires operator prehandling/preparation yes —/48/48 |
| 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 | liquid yes/80 yes/monitored by instrument 2 µL no/no no/0.58 L |
| Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability | no yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., codes 39 & 128)/— |
| Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A | pending — |
| 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/no/no yes no/no yes/yes yes/yes yes/no yes yes/no yes n/a/TBD/n/a/n/a 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 real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS | |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard/no |
| nterfaces 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 (host query) no yes — — |
| Interface avail. (or will be) to automated specimen handling system | no |
| Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d) | yes/yes/yes /no/ daily: 5 min; weekly: 15 min; monthly: 30 min yes/no 3 days on site, 5 days at vendor offices/no TBD |
| · | |
| Distinguishing features | closed system; compact benchtop; user-friendly Windows software |

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Chemistry analyzers (for high-volume labs)

| | ingri voidino labo) |
|---|--|
| Part 8 of 16 | Abbott Diagnostics Chris Barton christina.barton@abbott.com |
| | 100 Abbott Park Road |
| | Abbott Park, IL 60064 |
| See related comments, page 62 | 800-323-9100 www.abbott.com |
| Name of instrument/First year sold in U.S. | Abbott Aeroset/1998 |
| List price No. units in clinical use in U.S./Outside U.S. | \$345,000 276/650 |
| Country where designed/Manufactured/Where reagents mftd. | Japan/Japan/U.S. |
| Operational type/Reagent type | continuous random access/open reagent system |
| Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | 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 | 79 — |
| Tests cleared but not clinically released | myoglobin, alpha-1-antitrypsin, lipoprotein(a) |
| Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries | - 1 ACD 6 2 microglobulin digitovin IgE boCDD HIDC bile cold D |
| rests not available in 0.3. but available in other countries | a-1-AGP, β -2-microglobulin, digitoxin, IgE, hsCRP, UIBC, bile acid, P. amylase, HBDH, cholinesterase, CK-MB, ammonia, ceruloplasmin, |
| Research-use-only assays | kappa & lambda light chain, copper, fractosamine, D-dimer — |
| Tests in development | ultra HDL, lithium, gentamicin, quinidine, tobramycin, vancomycin, |
| | acetaminophen, salicylate, semi-quantitative DAUs, ecstasy, benzodi- azepine, barbiturate, TCA |
| User-defined methods implemented for what analytes | ammonia, lithium |
| | |
| Methods supported/Immunoassay methods No. of direct ion selective electrode channels | photometry, potentiometry/— 3 |
| No. of different measured assays onboard simultaneously | 59 |
| No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously | 100 100/59 |
| No. of different analytes for which system accommodates | 59/400 |
| reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard | 7 days/28 days/yes |
| Multiple reag. configurations supported | yes |
| Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used | yes |
| Walkaway capacity in minutes/Specimens/Tests-assays | yes 60/231/50,000+ |
| System is liquid or dry Uses disposable cuvettes/Max. No. stored | liquid no/n/a |
| Uses washable cuvettes/Replacement frequency | yes/minimum 1 yr guaranteed |
| Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain | 2 μL no/no |
| Requires dedicated water system/Water consumption per hour | yes/45 L |
| Noise generated in decibels Dedicated pediatric sample cup/Dead volume | — yes/50 μL |
| Primary tube sampling/Pierces caps on primary tubes | yes/no |
| Sample bar-code reading capability | yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination |
| Reagent bar-code reading capability | yes |
| Bar code placement per CLSI standard Auto2A | yes |
| Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection | yes yes/yes/no |
| Automatic detection of adequate reag. for aspir. & analysis | yes |
| Hemolysis/Turbidity detection-quantitation 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 |
| range high/low results Autocalibration or autocalibration alert | yes |
| Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | yes/yes 9 br/99 days/29 days/29 days |
| Automatic shutdown/Startup programmable | 8 hr/28 days/28 days/28 days yes/yes |
| Stat time to completion of all analytes, throughput per hr. for: | |
| Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC03, glucose, uses, grantinine | 10 min, 200+ specimens |
| Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP | 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 | <15 sec shortest interval: 8 hr (ISE); longest: 24 hr/yes |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | yes/yes |
| QC results transferred automatically to LIS | yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | no/yes (addt'l cost) |
| Interfaces up and running in active user sites with | all major vendors |
| Bidirectional interface capability | yes (broadcast download & host query) |
| Test results transmitted to LIS as soon as chem. time complete | yes |
| LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results | yes no |
| How labs get LOINC codes for reagent kits | _ |
| Interface avail. (or will be) to automated specimen handling system | in development |
| Modem servicing available/Can diagnose own malfunctions/ | no/no/no |
| Determine malfunctioning component 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 | >2 mo/varies daily: 5 min; weekly: 10 min; monthly: 30 min |
| Onboard maintenance records/Maint. training demo module | no/no |
| Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d) | 5 days on site, 5 days at vendor offices/no \$18,500 |
| , , | |
| Distinguishing features | 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 canability, low cample volume |
| | module), auto repeat and auto dilution capability, low sample volume (2–35 μ L) |
| | ** |

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



Is Your Lab Drowning In Test Requests?



Chemistry analyzers (for high-volume laboratories)

| Part 9 of 16 | Bayer HealthCare, Diagnostics Division Alexander Socarras alex.socarras.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6162 | Bayer HealthCare, Diagnostics Division Alexander Socarras alex.socarras.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6162 |
|---|--|---|
| See related comments, page 62 | labnews.com | labnews.com |
| Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type | ADVIA 1650/1999 \$279,000 250/600 Japan/Japan/Ireland batch, random access, discrete, continuous random access/open reagent | ADVIA 2400/2003 \$305,000 30/100 Japan/Japan/Ireland random access/open reagent system |
| Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | system automated rack handler, sample carousel/floor standing 45 x 59 x 34/14 sq ft | carousel, rack handler option, automation optionl/floor standing 1,157 x 1,711 x 934 mm/— |
| No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months | 78 DAUs, acetaminophen, ethanol, salicylate, tobramycin, ALT (P5P), AST (P5P) | 77 DAUs, acetaminophen, salicylate, ethanol, wrCRP, lipase, ammonia, HbA1c, lactate, P. amylase, tobramycin, ALT (P5P), AST (P5P) |
| 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 none | none none none |
| Research-use-only assays Tests in development | none lithium, vancomycin | none lithium, vancomycin |
| User-defined methods implemented for what analytes | CK-MB, myoglobin, fructosamine, $\beta\text{-}2\text{-microglobulin}, \text{DAUs}, \text{D-dimer}, \text{lithium}, \text{vancomycin}$ | DAUs, CK-MB, myoglobin, fructosamine, $\beta2\text{-}microglobulin, lithium, vancomycin, D-dimer}$ |
| Methods supported/Immunoassay methods No. of direct ion selective electrode channels | photometry, potentiometry, turbidimetrics/— | photometry, potentiometry (ISE)/homogeneous turbidimetric |
| No. of different measured assays onboard simultaneously | 49 | 46 colormetric, 3 ISE |
| 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 | 100 62/62 49/840 | 100 62/62 —/500 |
| reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard | 72 hr/28 days/yes | 24 hr/14 day/yes (6–12°C) |
| Multiple reag. configurations supported | yes | no |
| Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used | yes yes | yes yes |
| Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry | 90–470/200/32,000 liquid | 3.8 hr max./234/32,000 photometric, +90,000 ISE |
| Uses disposable cuvettes/Max. No. stored | liquid no/221 | liquid no/340 |
| Uses washable cuvettes/Replacement frequency | yes/4 mo (221 stored on instrument) | yes/every 4 months |
| Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain | 2 µL of diluted specimen yes/yes | 2 µL of diluted specimen yes/yes (or sink) |
| Requires dedicated water system/Water consumption per hour | yes/25 L | yes/40 L |
| Noise generated in decibels | | <50 |
| Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability | yes/50 µL yes/no yes (2 of 5 interl., Codabar [NW7], codes 39 & 128)/autodiscrimination | yes/~50 μL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 |
| Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A | yes yes | interl., Codabar, codes 39 & 128) yes yes |
| | ·- | ·- |
| Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection | yes yes/yes | yes yes/yes/yes |
| Automatic detection of adequate reag. for aspir. & analysis | yes | yes |
| Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability | yes/yes yes/yes | yes/yes yes/yes |
| Sample volume can be reduced/Increased to rerun out-of-linear- | yes/yes yes/yes | yes/— |
| range high/low results | | |
| Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported | yes yes/yes | no yes/yes |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable | | once per day/once per month/once per month/once per month yes/yes |
| Stat time to completion of all analytes, throughput per hr. for: | | |
| Sodium, potassium, chloride, TC02 Continue the idea TC02 | 10 min, 150 samples, 600 tests | 11 min, 200 samples |
| Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP | 10 min, 150 samples, 1,050 tests 10 min, 200 samples, 1,200 tests | 11 min, 200 samples 11 min, 300 samples |
| Typical time delay from ordering stat test to aspir. of sample | 3 sec | 30 sec |
| How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte | per CLIA and laboratory's decision/yes yes/yes | shortest interval: 8 hr; long est: 24 hr/yes yes/yes |
| QC results transferred automatically to LIS | yes | yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard/no | onboard/included in system price (TDC Technodata or Bayer |
| Interfaces up and running in active user sites with | Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, | CentraLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation |
| Didirectional interface conshills. | Siemens | |
| Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete | yes (broadcast download & host query) yes | yes (broadcast download & host query) yes |
| LIS interface operates simultaneously with running assays | yes | yes |
| Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits | yes e-mail, software | yes via software |
| Interface avail. (or will be) to automated specimen handling system | yes (all systems) | yes (with ADVIA WorkCell as of October 2003) |
| Modem servicing available/Can diagnose own malfunctions/ | yes/yes/yes | yes/yes/yes |
| Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting | 4–8 hr/yes | varies by location, generally <4 hr/yes |
| Mean time between failures/To repair failures Average time to complete maintenance by lab personnel | —/4-8 hr | daily: «E min: wookly: 10 min: monthly: 90 min |
| Onboard maintenance records/Maint. training demo module | daily: 10 min; weekly: 45 min; monthly: 1 hr yes/yes | daily: <5 min; weekly: 10 min; monthly: 20 min yes/yes |
| Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d) | ongoing on site, 5 days at vendor offices/— \$23,000 | varies according to need on site; 5 days at vendor offices/yes \$23,500 |
| Distinguishing features | system will aspirate every three seconds and retain aliquot onboard; original sample is available to leave system; all testing performed with aliquot of sample remaining on ADVIA 1650; all reruns/repeats/dilutions automatically performed without operator intervention; microvolume technology allows up to 840 tests from a 70-mL test wedge of reagent; reflex testing available; 99 percent uptime guaran- | system provides true workstation consolidation with more than 80 available chemistry and special chemistry methods and application: also offers user-defined methods that equate to cost-effective consolidation; offers unrivaled walkaway capability with an onboard capacity of >450 specimens with the Universal Rack Handler option 32,000 photometric tests and 90,000 ISE tests: sample saver techno |
| | tee | gy allows automatic repeats, dilutions and reflex testing without operator intervention of having to return to the original specimen |

 $\label{thm:condition} \textbf{Tabulation does not represent an endorsement by the College of American Pathologists}$

Chemistry analyzers (for high-volume laboratories)

| | Beckman Coulter Inc. | Beckman Coulter Inc. |
|--|--|---|
| | 200 South Kraemer Blvd. P.O. Box 8000 | 200 South Kraemer Blvd. P.O. Box 8000 |
| | Brea, CA 92822-8000 | Brea, CA 92822-8000 |
| | 800-526-3821 | 800-526-3821 |
| See related comments, page 62 | www.beckmancoulter.com | www.beckmancoulter.com |
| lame of instrument/First year sold in U.S. | Synchron LX20/1997 | Synchron LX20 Pro/2001 |
| ist price lo. units in clinical use in U.S./Outside U.S. | \$278,000 1,000/500 | \$343,000 600/300 |
| country where designed/Manufactured/Where reagents mftd. | U.S./U.S./U.S. & Ireland | U.S./U.S. & Ireland |
| perational type/Reagent type | continuous random access/open reagent system | continuous random access/open reagent system |
| ample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | racks, centrifugable/floor standing LX20 60 x 70 x 41/19.9 sq ft; LX4201 60 x 140 x 41/39.8 sq ft | racks, centrifugable/floor standing 60 x 70 x 41/19.9 sq ft |
| lo. of tests for which analyzer has FDA-cleared applications | >100 | >100 |
| ests clinically released in last 12 months ests cleared but not clinically released | lithium, HbA1c online none | lithium, HbA1c online none |
| ests ofeared but not clinically released ests not available in U.S. but submitted for 510(k) clearance | none | none |
| ests not available in U.S. but available in other countries | none | none |
| lesearch-use-only assays lests in development | none homocysteine, D-dimer, sirolimus, tacrolimus, Lp(a), tricyclics, | none homocysteine, D-dimer, sirolimus, tacrolimus, Lp(a), tricyclics, |
| · | semiquantitative DATs, IMA | semiquantitative DATs, IMA |
| ser-defined methods implemented for what analytes | UIBC, cyclosporine, homocysteine | UIBC, cyclosporine, homocysteine |
| lethods supported/Immunoassay methods | photometry, potentiometry, near infrared/bidentate turbidimetric, direct | photometry, potentiometry, near infrared-bidentate turbidimetric, |
| | turbidimetric, particle enhanced turbidimetric, enzyme immunoassay | direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay |
| lo. of direct ion selective electrode channels | 5 (indirect) | 5 (indirect) |
| lo. of different measured assays onboard simultaneously | 41 | 41 |
| lo. of different assays programmed, calibrated at once lo. of user-definable (open) channels/No. active simultaneously | 100 100/41 | 100 100/41 |
| lo. of different analytes for which system accommodates | 41/10,650 | 41/10,650 |
| reag. containers onboard at once/Tests per container set | 169 hr/20 days/yos /2 990\ | 160 hr/20 days/yos /2 9°C\ |
| hortest/median onboard reag. stability/Refrigerated onboard Aultiple reag. configurations supported | 168 hr/30 days/yes (2–8°C) yes | 168 hr/30 days/yes (2–8°C) yes |
| leag. container placed directly on system for use | yes | yes |
| nstrument has same capabilities when 3rd-party reag. used | NO 92/122/15 200 | NO 92/122/5 200 |
| Valkaway capacity in minutes/Specimens/Tests-assays system is liquid or dry | 83/132/5,280 liquid | 83/132/5,280 liquid |
| ses disposable cuvettes/Max. No. stored | no/n/a | no/n/a |
| ses washable cuvettes/Replacement frequency | yes/semi-permanent—2-yr warranty (250 stored on instrument) | yes/semi-permanent—2-yr warranty (250 stored on instrument) |
| Ainimum sample volume aspirated precisely at one time supplied with UPS (backup power)/Requires floor drain | 3 μL yes/no | 3 μL yes/no |
| equires dedicated water system/Water consumption per hour | yes/16 L | yes/16 L |
| loise generated in decibels ledicated pediatric sample cup/Dead volume | 65 | 65 |
| rimary tube sampling/Pierces caps on primary tubes | yes/40 µL (samples directly from pediatric bullet) yes/no | yes/40 µL yes/yes |
| ample 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 |
| leagent bar-code reading capability | interl., Codabar, codes 39 & 128)/autodiscrimination | interl., Codabar, codes 39 & 128)/autodiscrimination |
| ar code placement per CLSI standard Auto2A | yes yes | yes yes |
| Inboard test auto inventory (determines volume in container) | yes | yes |
| leasures no. tests remaining/Short sample detection/Clot detection | yes/yes | yes/yes/yes |
| automatic detection of adequate reag. for aspir. & analysis | yes | yes |
| lemolysis/Turbidity detection-quantitation bilution of patient samples onboard/Automatic rerun capability | yes/yes yes/yes | yes/yes yes/yes |
| ample volume can be reduced/Increased to rerun out-of-linear- | yes/yes | yes/yes |
| range high/low results | *** | 100 |
| utocalibration or autocalibration alert alibrants stored onboard/Multipoint calibration supported | yes no/yes | yes no/yes |
| ypical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | 24 hr/up to 90 days/up to 60 days/14 days | 1 day/up to 90 days/up to 60 days/14 days |
| utomatic shutdown/Startup programmable | none required | none required |
| tat time to completion of all analytes, throughput per hr. for: | | |
| Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine | 38 sec, 90 specimens 38 sec, 90 specimens | 38 sec, 90 specimens 38 sec, 90 specimens |
| Sodium, potassium, chioride, 1002, glucose, urea, creaunine Album., bili. direct & total, AST, ALT, ALP | 8 min, 90 specimens | 8 min, 90 specimens |
| ypical time delay from ordering stat test to aspir. of sample | 16 sec | 16 sec |
| | 24 hr/yes | 24 hr/yes |
| low often QC required/Onboard SW capability to review QC | | voc/voc |
| | yes/yes yes | yes/yes yes |
| low often QC required/Onboard SW capability to review QC Inboard real-time QC/Support multiple QC lot Nos. per analyte IC results transferred automatically to LIS | yes/yes yes | yes |
| low often QC required/Onboard SW capability to review QC Inboard real-time QC/Support multiple QC lot Nos. per analyte | yes/yes | |
| low often QC required/Onboard SW capability to review QC Inboard real-time QC/Support multiple QC lot Nos. per analyte IC results transferred automatically to LIS | yes/yes yes onboard & optional add-on (Beckman Coulter DL2000)/yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, | onboard & optional add-on (Beckman Coulter DL2000)/ yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson |
| low often QC required/Onboard SW capability to review QC Inboard real-time QC/Support multiple QC lot Nos. per analyte IC results transferred automatically to LIS lata mgmt. capability/Instrument vendor supplies LIS interface interfaces up and running in active user sites with | yes/yes yes onboard & optional add-on (Beckman Coulter DL2000)/yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs | onboard & optional add-on (Beckman Coulter DL2000)/ yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson Labquest, CCA, VA-Mumps, all LISs |
| low often QC required/Onboard SW capability to review QC Inboard real-time QC/Support multiple QC lot Nos. per analyte IC results transferred automatically to LIS Interface | onboard & optional add-on (Beckman Coulter DL2000)/yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) | onboard & optional add-on (Beckman Coulter DL2000)/ yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKessol Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) |
| low often QC required/Onboard SW capability to review QC Inboard real-time QC/Support multiple QC lot Nos. per analyte IC results transferred automatically to LIS lata mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Interface capability lest results transmitted to LIS as soon as chem. time complete IS interface operates simultaneously with running assays | onboard & optional add-on (Beckman Coulter DL2000)/yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes | onboard & optional add-on (Beckman Coulter DL2000)/ yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes |
| low often QC required/Onboard SW capability to review QC Inboard real-time QC/Support multiple QC lot Nos. per analyte IC results transferred automatically to LIS lata mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Interface capability lest results transmitted to LIS as soon as chem. time complete IS interface operates simultaneously with running assays less LOINC to transmit orders & results | onboard & optional add-on (Beckman Coulter DL2000)/yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no | onboard & optional add-on (Beckman Coulter DL2000)/ yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesso Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no |
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Chemistry analyzers (for high-volume laboratories)

| Part 11 of 16 | Beckman Coulter Inc. Kathleen Blount kjblount@beckman.com 200 South Kraemer Blvd. P.O. Box 8000 | Beckman Coulter Inc. Dan Siegenthaler dmsiegenthaler@beckman.com 200 South Kraemer Blvd. P.O. Box 8000 |
|---|--|---|
| See related comments, page 62 | Brea, CA 92822 800-526-3821 www.beckmancoulter.com | Brea, CA 92822 800-526-3821 www.beckmancoulter.com |
| Name of instrument/First year sold in U.S. | Synchron LXi725/2002 | UniCel DxC 800/2005 |
| List price 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 | 350/250 U.S./U.S. continuous random access/open reagent system racks, centrifugable/floor standing 60 x 134.5 x 48/44.8 sq ft | 25/25 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 |
| No. of tests for which analyzer has FDA-cleared applications Fests clinically released in last 12 months | >135 DHEA-S, intrinsic factor Ab, HbA1c online, lithium, fast hTSH, dil AFP | >100 not applicable |
| 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 none none none none intact PTH, EPO, IL6, IMA, dsDNA, D-dimer, TNF- α , soluble transferrin receptor, β -2-gylcoprotein 1 Ab UIBC, homocysteine | none none none sirolimus, tacrolimus, tricyclics, IMA, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine |
| Methods supported/Immunoassay methods | photometry, potentiometry (ISE), near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme | photometry, potentiometry (ISE), near-infrared bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme |
| 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 Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A | immunoassay, chemiluminescence 5 (indirect) 65 124 100/100 65/11,850 168 hr/28 days/yes (2–10°C) yes yes no 180/132/5,280 liquid yes/294 (immuno) yes/2-yr (chemistry) warranty, semi-permanent 3 µL yes/yes yes/16 L n/a — yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes | immunoassay, near infrared particle immunoassay 5 70 100 100/70 70/approx. 3,500 (modular); 600 cartridge 168 hr/30 days/yes (2–8°C) yes yes no 83/132/5,280 liquid no yes/2-yr warranty, semi-permanent 3 µL optional/no yes/16 L 60 yes/40 µL (samples directly from bullet) yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes |
| 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 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 (chemistry)/yes (chemistry) yes/yes yes (chemistry)/yes (chemistry) | yes/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 | yes (chemistry) no/yes 24 hr/up to 90 days/up to 60 days/14 days none required | yes no/yes 1 day/up to 90 days/up to 60 days/14 days none required |
| Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS | 38 sec, 90 specimens 38 sec, 90 specimens 8 min, 90 specimens 36 sec 24 hr/yes yes/yes yes | 2:23 (from standby), 91 specimens 2:22 (from standby), 91 specimens 12:32 (from standby), 76 specimens 16 sec 24 hr/yes yes/yes yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with | onboard & optional add-on (Beckman Coulter)/ yes (addt'l cost) Cerner, Misys | onboard & optional add-on (Beckman Coulter)/ yes (addt'l cost) 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 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 yes customer request | yes (broadcast download & host query) yes yes yes customer request |
| Interface avail. (or will be) to automated specimen handling system | no | yes, Beckman Coulter automation |
| Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d) | yes/yes/yes metro: same day, rural: same or next day/yes n/a/n/a daily: 15 min; weekly: 33.5 min; monthly: 25 min no/no 10 days at vendor offices/yes n/a | yes/yes/yes metro: same day, rural: same or next day/yes n/a/n/a daily: none; weekly: 10 min (tech time); monthly: 18 min (tech time) yes (includes audit trail of who replaced parts/yes 5 days at vendor offices/yes n/a |
| Distinguishing features | workstation consolidation without compromise through single point of sample entry for both chemistry and immunoassay testing; closed-tube sampling; one of fastest stats for chemistry samples; dual scheduling and parallel processing of chemistry and immunoassay samples for optimum throughput; menu equivalence to Synchron and Access product lines | closed-tube sampling; serum indices/polychromatic correction; clot detection & correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; one of the fastest stat TAT; DL2000: stat notification, review by exception, reflex testing, add-on test notification |

| Part 12 of 16 | Dade Behring Inc. P.O. Box 6101 | Dade Behring Inc. Joseph Meola joseph_meola@dadebehring.com |
|--|--|---|
| | Newark, DE 19714-6101 | P.O. Box 6101 |
| See related comments, page 62 | 800-242-3233 www.dadebehring.com | Newark, DE 19714-6101 302-631-6018 www.dadebehring.com |
| See related comments, page 62 | www.dadebelling.com | 302-031-0018 www.dadebelling.com |
| Name of instrument/First year sold in U.S. List price | Dimension RxL Max Integrated Chemistry System/2003 | Dimension Lynx System/2005 |
| No. units in clinical use in U.S./Outside U.S. | RxL: 2,500/—; RxL Max: >600/— | n/a/n/a |
| Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type | U.S./U.S./U.S. batch, random access, continuous random access/self-contained | U.S./U.S./U.S. batch, random access, continuous random access/self-contained |
| | multiuse cartridges-packages-slides | multiuse cartridges-packages-slides, open reagent system |
| Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | segmented sample wheel/floor standing 44 x 62.5 x 30.5/13.2 sq ft | rack & segment/floor standing 64 x 122 x 98/— |
| | • | 04 X 122 X 301— |
| No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months | >90 | — NT-proBNP, microalbumin, triiodothyronine |
| Tests cleared but not clinically released | none | |
| | | |
| Tests not available in U.S. but submitted for 510(k) clearance | none | _ |
| Tests not available in U.S. but available in other countries | none | _ |
| Research-use-only assays Tests in development | none quinidine, sirolimus, tacrolimus | — quinidine, sirolimus, tacrolimus |
| · | | quintants, on ominas, tablominas |
| User-defined methods implemented for what analytes | none | |
| Methods supported/Immunoassay methods | photometry, potentiometry, Integrated Multisensor Technology (IMT)/heterogenous EIA using HM, EMIT latex particle turbidimet- | photometry, potentiometry, Integrated Multisensor Technology (IMT)/heterogenous EIA using HM, EMIT latex particle turbidimet- |
| | ric, latex turbidimetric | ric, latex turbidimetric |
| No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously | 4 (indirect) 48/92 with optional inventory management system | 3 (indirect) 182 |
| No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once | 48/92 with optional inventory management system 190 | 182 182 |
| No. of user-definable (open) channels/No. active simultaneously | 10/10 | 20/20 |
| No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set | 44–88/max. 240 | 182/up to 360 |
| Shortest/median onboard reag. stability/Refrigerated onboard | 72 hr/30 days/yes (2–8°C) | 72 hr/30 days/yes (2-8°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 | yes | yes |
| Walkaway capacity in minutes/Specimens/Tests-assays | can be hours | varies/600/varies |
| System is liquid or dry Uses disposable cuvettes/Max. No. stored | liquid, reconstitutes onboard yes/12,000 | liquid, reconstitutes onboard yes/24,000 |
| Uses washable cuvettes/Replacement frequency | no/— | no/— |
| Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain | 2 μL yes/no | 2 µL yes/yes |
| Requires dedicated water system/Water consumption per hour | yes/3.2 L | yes/6.4 L |
| Noise generated in decibels Dedicated pediatric sample cup/Dead volume | <70 yes/20 μL | <140 yes/15–20 μL |
| Primary tube sampling/Pierces caps on primary tubes | yes, 5, 7, 10 mL/no | yes/no (system automatically decaps sample tube) |
| Sample bar-code reading capability | yes, on sample transport, shortly before sample is aspirated (2 of | yes, on sample transport, shortly before sample is aspirated (2 of |
| Reagent bar-code reading capability | 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes | 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes |
| Bar code placement per CLSI standard Auto2A | yes | yes |
| Onboard test auto inventory (determines volume in container) | yes yes/yes/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/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/no |
| range high/low results | | |
| Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported | yes yes/30–90 days | yes no/yes |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | every 2 hr-autocalibrate/—/60-90 days/30 days | 2 hr autocalibration/most 90 days/60-90 days/30 days |
| Automatic shutdown/Startup programmable | no/no (2 min tech time, 5 min instrument time) | no/no |
| Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 | EO con 200 tacts | |
| Sodium, potassium, chloride, TCO2, glucose, urea, creatinine | 50 sec, 288 tests 4.5 min, 500 tests | |
| Album., bili. direct & total, AST, ALT, ALP | 10–11 min, 500 tests | _ ,_ |
| | 24 sec | |
| Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC | 24 hr/yes | 24 hr/yes |
| How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte | 24 hr/yes no/yes | yes/yes |
| 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 | 24 hr/yes no/yes yes | yes/yes yes |
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Tabulation does not represent an endorsement by the College of American Pathologists

| Part 13 of 16 | Olympus America Inc. | Olympus America Inc. |
|---|---|--|
| | Susan M. Watanabe, PhD susan.watanabe@olympus.com | Susan M. Watanabe, PhD susan.watanabe@olympus.com |
| | Two Corporate Center Dr. Melville, NY 11747 | Two Corporate Center Dr. Melville, NY 11747 |
| | 800-223-0125 | 800-223-0125 |
| See related comments, page 62 | www.olympus.com | www.olympus.com |
| Name of instrument/First year sold in U.S. | AU640/1999; AU640e/2002 | AU2700/2000 |
| List price | \$185,000 | \$320,000 |
| No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. | >300/>1,000 Japan/Japan/U.S. & Ireland | >60/>450 Japan/Japan/U.S. & Ireland |
| Operational type/Reagent type | random access, discrete, continuous random access/open | random access, discrete, continuous random access/open |
| Comple handling quetom/Madel type | reagent system rack & stat carousel/floor standing | reagent system rack & stat carousel/floor standing |
| Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | 50 x 74 x 32/68 sq ft | 50 x 79 x 45/92 sq ft |
| · , , , , , , , , , , , , , , , , , , , | <u> </u> | |
| No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months | 122 lactate | 122 lactate |
| Tests cleared but not clinically released | none | none |
| Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries | _ | _ |
| Research-use-only assays | none | none |
| Tests in development | D-dimer | D-dimer |
| User-defined methods implemented for what analytes | fructosamine, ammonia | fructosamine, ammonia |
| · · · · · · · · · · · · · · · · · · · | · · | , |
| 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 | 3 up to 51 | up to 51 |
| No. of different assays programmed, calibrated at once | 99 | 99 |
| No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates | 95/— 48 x 2/100–1,333 | 95/— 48 x 2/100–4,000 |
| reag. containers onboard at once/Tests per container set | , | · |
| Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported | 120 hr/30 days/yes (4–12°C) | 120 hr/30 days/yes (4–12°C) |
| Reag. container placed directly on system for use | yes yes | yes yes |
| Instrument has same capabilities when 3rd-party reag. used | yes | yes |
| Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry | varies/up to 172/varies liquid | varies/up to 322/varies 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 Supplied with UPS (backup power)/Requires floor drain | 2 μL no (optional)/yes (no w/ optional water pump) | 1 µL no (optional)/yes |
| Requires dedicated water system/Water consumption per hour | yes/40 L per hr peak consumption | yes/65 L per hr peak consumption |
| Noise generated in decibels | 65 no/n/a | <65 no/n/a |
| Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes | yes/no | yes/no |
| Sample bar-code reading capability | yes, on sample transport, shortly before sample is aspirated (2 of | yes, on sample transport, shortly before sample is aspirated (2 of |
| Reagent bar-code reading capability | 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes | 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes |
| Bar code placement per CLSI standard Auto2A | yes | yes |
| Onboard test auto inventory (determines volume in container) | yes | yes |
| Measures no. tests remaining/Short sample detection/Clot detection | yes/yes/yes | yes/yes/yes |
| Automatic detection of adequate reag. for aspir. & analysis | yes | yes |
| Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability | yes/yes yes/yes | 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 | yes | yes |
| Calibrants stored onboard/Multipoint calibration supported | yes/yes | yes/yes |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | 1 day/30 days/14 days/14–20 days | 1 day/30 days/14 days/14–20 days |
| Automatic shutdown/Startup programmable | yes/yes | yes/yes |
| Stat time to completion of all analytes, throughput per hr. for: | | |
| Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine | <4 min, 200 specimens <5 min, 160 specimens | <4 min, 267 specimens <4 min, 267 specimens |
| Sodium, potassium, chioride, 1002, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP | 9 min, 133 specimens | 9 min, 267 specimens |
| Typical time delay from ordering stat test to aspir. of sample | 1 min | 1 min |
| How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte | per CLIA & laboratory's decision/yes yes/yes | per CLIA & laboratory's decision/yes yes/yes |
| QC results transferred automatically to LIS | yes | yes yes |
| | | |
| Data mant, conchility/Instrument warder counties I IO totalises | onhoard/no (ontions!) | onhoard/no (ontional) |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard/no (optional) | onboard/no (optional) |
| | all common interfaces including Cerner, Antrim, CCA, Chemware, | all common interfaces including Cerner, Antrim, CCA, Chemware, |
| | all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, | all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, |
| Interfaces up and running in active user sites with Bidirectional interface capability | all common interfaces including Cerner, Antrim, CCA, Chemware, | all common interfaces including Cerner, Antrim, CCA, Chemware, |
| 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 | 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 | 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 |
| Interfaces up and running in active user sites with Bidirectional interface capability | 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) | 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) |
| 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 | 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 | 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 |
| 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 | 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 | 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 |
| 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 | 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 | 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 yes |
| 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/ | 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 | 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 |
| 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/ Determine malfunctioning component | 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 | 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 yes |
| 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/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures | 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 yes yes/yes/yes <24 hr/yes average 2 calls per yr/<24 hr | 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 yes yes/yes/yes <24 hr/yes TBD/TBD |
| 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/ 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 | 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 — yes yes/yes/yes <24 hr/yes average 2 calls per yr/<24 hr daily: 3 min; weekly: 27 min; monthly: 45 min | 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 — yes yes/yes/yes <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min |
| 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/ 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 | 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 yes yes/yes/yes <24 hr/yes average 2 calls per yr/<24 hr | 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 yes yes/yes/yes <24 hr/yes TBD/TBD |
| 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/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting | 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 — yes 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 | 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 — yes yes/yes/yes <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes |
| 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/ 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) | 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 —— yes 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 | 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 —— yes yes/yes/yes <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 3–5 days on site, 5 days at vendor offices/yes inquire |
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| 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/ 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) | 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 —— yes 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 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 122 methods delivers standardized results for improved patient management | 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 ——————————————————————————————————— |
| 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/ 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) | 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 —— yes 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 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 122 methods delivers standardized results for improved patient management | 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 ——————————————————————————————————— |

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

| Part 14 of 16 | Olympus America Inc. | Olympus America Inc. |
|---|---|---|
| | Hiro Sekiya hiro.sekiya@olympus.com Two Corporate Center Dr. | Hiro Sekiya hiro.sekiya@olympus.com Two Corporate Center Dr. |
| | Melville, NY 11747 | Melville, NY 11747 |
| See related comments, page 62 | 800-223-0125 www.olympus.com | 800-223-0125 www.olympus.com |
| See related comments, page 02 | www.oiyinpus.com | www.oiyinpus.com |
| Name of instrument/First year sold in U.S. List price | AU5421 with dual ISE/2001 | AU5431 with dual ISE/2001 \$575,000 |
| No. units in clinical use in U.S./Outside U.S. | \$465,000 >100/300 | >100/300 |
| Country where designed/Manufactured/Where reagents mftd. | Japan/Japan/U.S. & Ireland | Japan/Japan/U.S. & Ireland |
| Operational type/Reagent type | random access, discrete, continuous random access/open reagent system | random access, discrete, continuous random access/open reagent system |
| Sample handling system/Model type | rack/floor standing | rack/floor standing |
| Dimensions in inches (H x W x D)/Instrument footprint | 50 x 148 x 45/46.25 sq ft | 50 x 200 x 45/62.5 sq ft |
| No. of tests for which analyzer has FDA-cleared applications | 122 | 122 |
| Tests clinically released in last 12 months Tests cleared but not clinically released | lactate none | lactate none |
| Toolo disarca bat not similarly resource | | 1010 |
| Tests not available in U.S. but submitted for 510(k) clearance | _ | _ |
| , | | |
| Tests not available in U.S. but available in other countries Research-use-only assays | none | — none |
| Tests in development | D-dimer | D-dimer |
| User-defined methods implemented for what analytes | fructosamine, ammonia | fructosamine, ammonia |
| | <u> </u> | · |
| 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 | 99 | up to 147 |
| No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously | 99 95/— | 99 95/— |
| No. of different analytes for which system accommodates | 95/— 48 x 4/100–4,000 | 95/— 48 x 6/100–4,000 |
| reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard | 120 hr/20 daye/yee (A_12°C) | 120 hr/30 days/yes (4_12°C) |
| Multiple reag. configurations supported | 120 hr/30 days/yes (4–12°C) yes | 120 hr/30 days/yes (4–12°C) 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 300/varies | yes varies/up to 300/varies |
| System is liquid or dry | liquid . | liquid |
| Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency | no/n/a yes/permanent | no/n/a yes/permanent |
| Minimum sample volume aspirated precisely at one time | 1 µL | ÍμL |
| Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour | no (optional)/yes yes/120 L | no (optional)/yes yes/180 L |
| Noise generated in decibels | <65 | |
| Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes | no/n/a yes/no | no/n/a yes/no |
| Sample bar-code reading capability | yes, on sample transport, shortly before sample is aspirated (2 of | yes, on sample transport, shortly before sample is aspirated (2 of |
| | 5 interl.)/autodiscrimination | 5 interl., Codabar, codes 39 & 128)/autodiscrimination |
| Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A | yes | yes |
| Dai code piacement per ocor standard Autoza | yes | yes |
| | , | |
| Onboard test auto inventory (determines volume in container) | yes | yes ves/ves |
| | <u> </u> | yes yes/yes/yes yes |
| Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation | yes yes/yes/yes yes yes/yes | yes/yes/yes yes yes/yes |
| Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- | yes yes/yes/yes yes | yes/yes/yes yes |
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Chemistry analyzers (for high-volume laboratories)

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| Part 15 of 16 | Ortho-Clinical Diagnostics Adam Cornfield 1001 U.S. Highway 202 Raritan, NJ 08869 | Ortho-Clinical Diagnostics Adam Cornfield 1001 U.S. Highway 202 Raritan, NJ 08869 |
| See related comments, page 62 | 800-826-6316 www.orthoclinical.com | 800-828-6316 www.orthoclinical.com |
| Name of instrument/First year sold in U.S. | VITROS 950, VITROS 950AT/1995 | VITROS 250, VITROS 250AT/1993 |
| List price No. units in clinical use in U.S./Outside U.S. | 950: \$196,000; 950 AT: \$250,000 >1,500/— | 250 \$105,000; 250 AT \$165,000 >3,000/— |
| Country where designed/Manufactured/Where reagents mftd. | U.Ś./U.S./U.S. | U.S./U.S./U.S. |
| Operational type/Reagent type | batch, random access, discrete, continuous random access/self- contained single-use cartridges-packages-slides | batch, random access, discrete, continuous random access/self- contained single-use cartridges-packages-slides |
| Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | sample trays/floor standing 55 x 68 x 38/26 sq ft | rack/floor standing 47 x 45.5 x 28/8.8 sq ft |
| No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months | 70 none | 70 none |
| Tests cleared but not clinically released | dHDL MicroSlide | dHDL MicroSlide |
| Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries | Ξ | none none |
| Research-use-only assays Tests in development | _ | none none |
| User-defined methods implemented for what analytes | _ | none |
| Methods supported/immunoassay methods No. of direct ion selective electrode channels | potentiometry, colorimetric, rate, immuno-rate/— 3 | potentiometry, colorimetric, rate, immuno-rate/— 3 |
| No. of different measured assays onboard simultaneously | 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 reag. containers onboard at once/Tests per container set | up to 75/up to 60 | up to 60/up to 60 |
| Shortest/median onboard reag. stability/Refrigerated onboard | 48 hr/14 days/no | 48 hr/14 days/no |
| Multiple reag. configurations supported 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 System is liquid or dry | —/40/900 per hr dry _ | —/40/200 per hr dry |
| 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 Requires dedicated water system/Water consumption per hour | available (not included)/no no/none | available (not included)/no no/n/a |
| Noise generated in decibels Dedicated pediatric sample cup/Dead volume | — no special sample cup required/35 μL | — no special sample cup required/35 μL |
| Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability | yes/no yes, on sample transport, shortly before sample is aspirated (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) | 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 yes |
| Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability | not needed/not needed yes/no | not needed/not needed yes/no |
| Sample volume can be reduced/Increased to rerun out-of-linear- | no/no | yes/no |
| range high/Low results Autocalibration or autocalibration alert | no | no . |
| Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | no/yes reagent lot changes | no/yes reagent lot changes |
| Automatic shutdown/Startup programmable | no/no | no/no |
| Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 | ~6 min, 600 specimens | 6 min, 240 specimens |
| Sodium, potassium, chloride, TC02, glucose, urea, creatinine | ~6 min, ~700 specimens | 7 min, 258 specimens |
| Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample | ~7 min, ~700 specimens 8 sec | 7 min 17 sec, 230 specimens 12 sec |
| How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot nos. per analyte | 24 hr/yes yes/yes | 24 hr/yes yes/yes |
| QC results transferred automatically to LIS | yes | yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard/no (optional) | onboard/no (optional) |
| Interfaces up and running in active user sites with | all common interfaces | all common interfaces |
| Bidirectional interface capability | yes (broadcast download) | yes (broadcast download) |
| Test results transmitted to LIS as soon as chem. time complete 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 | | _ |
| Interface avail. (or will be) to automated specimen handling system | yes (enGen) | yes (enGen) |
| Modem servicing available/Can diagnose own malfunctions/ | no/yes/yes | no/yes/yes |
| Determine malfunctioning component | • | |
| On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures | <4 hr/yes —/— | <4 hr/yes —/— |
| Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module | daily: 2 min; weekly: 5 min; monthly: 15 min no/yes | daily: 2 min; weekly: 5 min; monthly: 15 min no/yes |
| Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d) | 3 days on site, 5 days at vendor offices/yes | adays on site, 5 days at vendor offices/yes |
| Distinguishing features | cost-effective MicroSlide Technology delivers low cost per reportable result and high reagent efficiency without the costs, maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required just once each day and calibration intervals up to six months with minimal interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily | cost-effective MicroSlide Technology delivers low cost per reportable result and high reagent efficiency without the costs, maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required just once each day and calibration intervals up to six months with minimal interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily |
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 $\label{thm:condition} \textbf{Tabulation does not represent an endorsement by the College of American Pathologists}$

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| Uses washable curettes (Replacement frequency Minimum sampter of precisely of one time supplied precisely of one time washable (or Minimum sampter) washable | System is liquid or dry | dry, liquid ready to use | liquid |
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| Requires dedicated water system/Water consumption per hour follows generated in decidents of partial i | Supplied with UPS (backup power)/Requires floor drain | | |
| Dedicate preliatric sample curplead volume Primary blue sampling/Perces cape on indirect by serving the sample of the property of the sample of the sa | Requires dedicated water system/Water consumption per hour | | yes/varies (50 L/hr/mod) |
| Primary tube sampling/Prieces caps on primary tubes Sample har-code reading capability Bar code placement per CLSI standard AutoZA Per Codebar, codes 39 & 120/autodiscrimination Respent har-code reading capability Bar code placement per CLSI standard AutoZA Discourse caps and placement per CLSI placement per | | | |
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