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 high-sensitivity CRP assay for the assessment of cardiovascular risk—employ 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 250.

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 SupportVision 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 McClellan, 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 product 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 mid- and 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)

Part 1 of 16 *See related comments, page 62*	**Abbott Diagnostics** **Chris Barton** christina.barton@abbott.com **100 Abbott Park Rd.** **Abbott Park, IL 60064** **800-323-9100** www.abbott.com	**Abbott Diagnostics** **Chris Barton** christina.barton@abbott.com **100 Abbott Park Rd.** **Abbott Park, IL 60064** **800-323-9100** www.abbott.com
Name of instrument/First year sold in U.S.	Abbott Architect c8000/2003	Abbott Architect ci8200/2003
List price	$225,000	$375,000
No. units in clinical use in U.S./Outside U.S.	104/683	55/321
Country where designed/Manufactured/Where reagents mftd.	U.S., Japan/U.S., Japan/U.S.	U.S., Japan/U.S., Japan/U.S.
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/self-contained multi-use cartridges-packages-slides, open reagent system
Sample handling system/Model type	multi-dimensional retest sample handler, carousel/floor standing	multi-dimensional retest sample handler/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	48 x 79 x 49/~26 sq ft	48 x 127 x 49/42 sq ft
No. of tests for which analyzer has FDA-cleared applications	79	79
Tests clinically released in last 12 months	microalbumin, apo A1, apo B, C3, C4, IgA, IgG, IgM, prealbumin, transferrin, haptoglobin, ferritin, ASO	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, ammonia, ceruloplasmin, copper, fructosamine, D-dimer	a-1-AGP, β-2-microglobulin, digitoxin, IgE, hsCRP, UIBC, bile acid, P. amylase, HBDH, cholinesterase, CK-MB, kappa & lambda light chain, ammonia, ceruloplasmin, copper, fructosamine, D-dimer
Research-use-only assays	—	—
Tests in development	direct LDL, ultra HDL, lithium, gentamicin, quinidine, tobramycin, vancomycin, acetaminophen, salicylate, ecstasy, benzodiazepine, barbiturate, TCA	direct LDL, ultra HDL, lithium, gentamicin, quinidine, tobramycin, vancomycin, acetaminophen, salicylate, ecstasy, benzodiazepine, barbiturate, TCA
User-defined methods implemented for what analytes	ammonia, lithium	ammonia, lithium
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/—	photometry, potentiometry, turbidimetric/chemiluminescence with flexible protocols
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	68	93
No. of different assays programmed, calibrated at once	220	320
No. of user-definable (open) channels/No. active simultaneously	220/220	220/220
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	65/370	90/chem 370, immunoassay 100–500
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/28 days/yes (2–8°C)	—/—/yes (2–8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/217/69,000-68	varies >300/367/81,000-93
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	yes, immunoassay/—
Uses washable cuvettes/Replacement frequency	yes/minimum 1 yr guarantee	yes, chemistry/minimum 1 yr guaranteed
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption per hour	yes/25 L	yes/30.5 L
Noise generated in decibels	—	—
Dedicated pediatric sample cup/Dead volume	yes/50 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes, 2-D bar codes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	—/—
Autocalibration or autocalibration alert	no	no
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes, for chemistry only/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	8 hr/30 days/14 days/7–14 days	8 hr/30 days/14 days/7–14 days
Automatic shutdown/Startup programmable	no/no	—/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2.5 min, 200 specimens, 800 tests	2.5 min, 200 specimens, 800 tests
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	9.6 min, 160 specimens, 1,120 tests	9.6 min, 160 specimens, 1,120 tests
• Album., bili. direct & total, AST, ALT, ALP	9.6 min, 133 specimens, 800 tests	9.6 min, 133 specimens, 800 tests
Typical time delay from ordering stat test to aspir. of sample	<20 sec	<20 sec
How often QC required/Onboard SW capability to review QC	shortest interval: 8 hr; longest: 24 hr/yes	shortest interval: 8 hr; longest: 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes (addt'l cost, SW mftr: Abbott)	yes (addt'l cost, SW mftr: Abbott)
Interfaces up and running in active user sites with	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Triple G, CIS, Sunquest, others	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Triple G, CIS, Sunquest, others
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	—
How labs get LOINC codes for reagent kits	package insert	—
Interface avail. (or will be) to automated specimen handling system	yes	no
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	>2 mos/varies	>2 mos/varies
Average time to complete maintenance by lab personnel	daily: <15 min; weekly: <45 min; monthly: 15 min	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.	5 days on site, 5 days at vendor offices/yes	5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	$18,500	$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

Chemistry analyzers (for mid-volume laboratories)

Part 2 of 16 *See related comments, page 62*	**Awareness Technology Inc.** **Chris Schneider** info@awaretech.com **P.O. Box 1679** **Palm City, FL 34991** **772-283-6540** www.awaretech.com	**Bayer Healthcare, Diagnostics Division** **Eric Lafleche** eric.lafleche.b@bayer.com **511 Benedict Ave.** **Tarrytown, NY 10591** **914-333-6130** labnews.com
Name of instrument/First year sold in U.S.	ChemWell/1999	ADVIA 1200/2005
List price	$25,000	$189,000
No. units in clinical use in U.S./Outside U.S.	10/550	10/50
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./open system	Japan/Japan/Ireland
Operational type/Reagent type	continuous random access/open ragent system	random access/open reagent system
Sample handling system/Model type	rack of 96 samples/benchtop	carousel/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	19 x 36 x 22 in/7 sq ft	33.5 x 48 x 44 in/1.04 square meters
No. of tests for which analyzer has FDA-cleared applications	22	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, α-1-antitrypsin, digoxin, theophylline, phenytoin
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	18 EIA kits manuf. by BroCheck have been submitted	none
Tests not available in U.S. but available in other countries	open system	none
Research-use-only assays	open system	none
Tests in development	none	TIBC, ammonia, HbA1C, microalbumin, ASO, ApoA, ApoB, wrCRP, haptoglobin, IgA, IgG, IgM, carbamazepine, gentamicin, lithium, phenobarb, tobramycin, vancomycin, acetaminophen, ethanol, salicylate, DAUs, lactate
User-defined methods implemented for what analytes	all colorimetric biochemistry & EIA that read between 340–700 nm	open system capability
Methods supported/Immunoassay methods	photometry/microwell assays	photometry, potentiometry, turbidimetric/—
No. of direct ion selective electrode channels	0	3
No. of different measured assays onboard simultaneously	27	40 colorimetric, 3 ISE
No. of different assays programmed, calibrated at once	unlimited	100
No. of user-definable (open) channels/No. active simultaneously	unlimited/27	62/43
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	27/reagent dependent	43/1,000
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	yes	yes
Reag. container placed directly on system for use	reagent dependent	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	not limited/96/not limited	—/84/17,000
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	yes (optional)/96	no/231
Uses washable cuvettes/Replacement frequency	yes (optional)/weekly	yes/4 mos
Minimum sample volume aspirated precisely at one time	2 µL	1 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/yes
Requires dedicated water system/Water consumption per hour	no/<1 L	yes/20 L
Noise generated in decibels	60	<60
Dedicated pediatric sample cup/Dead volume	no	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	no/no	yes/no
Sample bar-code reading capability	yes, by handheld scanner as tubes are loaded onto instrument (2 or 5 interl., UPC, Codabar, codes 39 & 128)/autodiscrimination depends on handheld scanner models	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	no	yes
Bar code placement per CLSI standard Auto2A	no	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/no	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/no	yes/yes
Autocalibration or autocalibration alert	yes	autocalibration
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	user defined for all	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:		
• Sodium, potassium, chloride, TCO2	n/a	11 min, 200
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	n/a	11 min, 160
• Album., bili. direct & total, AST, ALT, ALP	5.5 min, 28 specimens	11 min, 133
Typical time delay from ordering stat test to aspir. of sample	15 sec	30 sec
How often QC required/Onboard SW capability to review QC	reagent dependent/yes	shortest: 8 hr; longest; 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/yes (included in price)	onboard/no
Interfaces up and running in active user sites with	not known	Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens, others
Bidirectional interface capability	yes (broadcast download)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	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	48 hr/yes	varies by location, generally <4 hr/yes
Mean time between failures/To repair failures	depends on user and varies/depends on problem and varies	—/—
Average time to complete maintenance by lab personnel	daily: <5 min; weekly: about 15 min; monthly: about 30 min or less	daily: <5 min; weekly: 10 min; monthly: 20 min
Onboard maintenance records/Maint. training demo module	no/no	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	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 *See related comments, page 62*	**Beckman Coulter Inc.** **200 South Kraemer Blvd.** **P.O. Box 8000** **Brea, CA 92822-8000** **800-526-3821** www.beckmancoulter.com	**Beckman Coulter Inc.** **Dan Siegenthaler** dmsiegenthaler@beckman.com **200 South Kraemer Blvd., P.O. Box 8000** **Brea, CA 92822-8000** **800-526-3821** www.beckmancoulter.com
Name of instrument/First year sold in U.S.	Synchron CX9 Pro/2001	UniCel DxC 600/2004
List price	$220,600	$340,000
No. units in clinical use in U.S./Outside U.S.	1,000/600	70/50
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. & Irela nd	U.S./U.S./U.S. & Ireland
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/Model type	sectors, centrifugable/floor standing	racks, centrifugable/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	69 x 74 x 30 in/15.4 sq ft	62 x 62 x 41 in/17.7 sq ft
No. of tests for which analyzer has FDA-cleared applications	>100	>100
Tests clinically released in last 12 months	lithium	n/a
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays	none	none
Tests in development	sirolimus, tacrolimus, tricyclics, semiquantitative DATs	sirolimus, tacrolimus, tricyclics, IMA, semi-quantitative drugs of abuse
User-defined methods implemented for what analytes	UIBC, cyclosporine, homocysteine	UIBC, cyclosporine, homocysteine
Methods supported/Immunoassay methods	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay	photometry, potentiometry, near-infrared bidentate turbidimetric/ particle enhanced turbidimetric, enzyme immunoassay, near infrared particle immunoassay
No. of direct ion selective electrode channels	5 (indirect)	5
No. of different measured assays onboard simultaneously	33	65
No. of different assays programmed, calibrated at once	59	100
No. of user-definable (open) channels/No. active simultaneously	102/33	100/65
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	33/25–2,500	65/about 3,500 modular; about 600 cartridge
Shortest/median onboard reag. stability/Refrigerated onboard	168 hr/30 days/yes (2–8°C)	168 hr/30 days/yes (2–8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	no
Walkaway capacity in minutes/Specimens/Tests-assays	100/63/2,079	83/132/5,280
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/n/a	n/a
Uses washable cuvettes/Replacement frequency	yes/permanent–2-yr warranty (80 stored on instrument)	yes/2-yr warranty, semi-permanent
Minimum sample volume aspirated precisely at one time	3 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	optional/no
Requires dedicated water system/Water consumption per hour	yes/7 L	yes/16 L
Noise generated in decibels	70	60
Dedicated pediatric sample cup/Dead volume	yes/40 µL	yes/40 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/yes
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hr/up to 90 days/up to 60 days/14 days	1 day/up to 90 days/up to 60 days/14 days
Automatic shutdown/Startup programmable	none required	none required
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	52 sec, 75 specimens	6:15 from standby, 96 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	52 sec, 75 specimens	6:15 from standby, 96 specimens
• Album., bili. direct & total, AST, ALT, ALP	10 min, 32 specimens	13:07 from standby, 57 specimens
Typical time delay from ordering stat test to aspir. of sample	45 sec	16 sec
How often QC required/Onboard SW capability to review QC	24 hr/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard & optional add-on (SW mftr: Beckman Coulter)/yes (addt'l cost)	onboard & optional add-on (SW mftr: Beckman Coulter)/yes (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	customer request	customer request
Interface avail. (or will be) to automated specimen handling system	yes (Power Processor)	yes (Beckman Coulter automation)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/no/no	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day, rural: same or next day/yes	metro: same day, rural: same or next day/yes
Mean time between failures/To repair failures	—/—	n/a/n/a
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 15 min; monthly: 25 min	daily: none; weekly: 7 min (tech time); monthly: 11 min (tech time)
Onboard maintenance records/Maint. training demo module	no/no	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	—
Distinguishing features	serum indices; centrifugable sectors; clot detection; design optimized for automation; continuous random access for samples, controls, reagents, and results; no-maintenance glucose oxygen sensor; no-wait autoloader; polychromatic correction; thermal ring and semi-permanent glass cuvettes; pulsed xenon lamp; advanced workflow and results mgmt.; liquid, ready-to-use reagents, calibrators, controls; DL2000 Workflow and Results Manager	closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks, no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; DL2000: stat notification, review by exception, reflex testing, add-on test notification

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Chemistry analyzers (for mid-volume laboratories)

Part 4 of 16 *See related comments, page 62*	**Clinical Data** slsmktg@clda.com **2 Thurber Blvd.** **Smithfield, RI 02917** **800-345-2822** www.clda.com	**Clinical Data** **Joe Vacante** **2 Thurber Blvd.** **Smithfield, RI 02917** **401-233-3526** www.clda.com
Name of instrument/First year sold in U.S.	Vitalab Selectra XL/2004	Envoy 500/2005
List price	$98,750	$96,750
No. units in clinical use in U.S./Outside U.S.	0/—	—/—
Country where designed/Manufactured/Where reagents mftd.	Netherlands/Netherlands/U.S.	Italy/Italy/U.S.
Operational type/Reagent type	random access/multi-use bottles	random access/self-contained multi-use cartridges, packages, slides
Sample handling system/Model type	rotor/floor standing	rotor/benchtop
Dimensions in inches (H x W x D)/Instrument footprint	45 x 46 x 30/12 sq ft	—/—
No. of tests for which analyzer has FDA-cleared applications	>31	28
Tests 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
Tests cleared but not clinically released	—	n/a
Tests not available in U.S. but submitted for 510(k) clearance	—	n/a
Tests not available in U.S. but available in other countries	—	n/a
Research-use-only assays	—	n/a
Tests in development	hsCRP	hsCRP
User-defined methods implemented for what analytes	n/a	n/a
Methods supported/Immunoassay methods	photometry, potentiometry (ISE)/immunoturbidimetric	photometry, potentiometry (ISE)/—
No. of direct ion selective electrode channels	4	4
No. of different measured assays onboard simultaneously	40	40
No. of different assays programmed, calibrated at once	40	40
No. of user-definable (open) channels/No. active simultaneously	5/40	40/40
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	70/700	40
Shortest/median onboard reag. stability/Refrigerated onboard	72 hr/7 days/yes (12°C below ambient)	40 hr/10 days/yes (12–15°C)
Multiple reag. configurations supported	—	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	no
Walkaway capacity in minutes/Specimens/Tests-assays	240/80/2,400	240/52/40
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no	no
Uses washable cuvettes/Replacement frequency	yes/every 10,000 reactions	yes/never
Minimum sample volume aspirated precisely at one time	1 µL	—
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption per hour	no/0.8 L	no/—
Noise generated in decibels	—	—
Dedicated pediatric sample cup/Dead volume	yes/20 µL	—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, as sample is being aspirated (2 of 5 interl., UPC, Codabar, codes 39 & 128)	yes, as sample is being aspirated
Reagent bar-code reading capability	no	yes
Bar code placement per CLSI standard Auto2A	yes	—
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	—/—	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/no	yes/yes
Autocalibration or autocalibration alert	yes	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	4 hr/1–14 days/—/—	4 hr/7 days/n/a/n/a
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	8 min, —	—, —
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	10 min, —	—, —
• Album., bili. direct & total, AST, ALT, ALP	10 min, —	—, —
Typical time delay from ordering stat test to aspir. of sample	6 min	—
How often QC required/Onboard SW capability to review QC	shortest interval: 4 hr; longest: once a day/yes	daily/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	optional add on/yes	no/yes (addt'l cost)
Interfaces up and running in active user sites with	—	Antek, Labdaq, Fletcher-Flora, Labpak
Bidirectional interface capability	yes	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	—
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	—	—
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	within 24 hr/yes	24 hr/yes
Mean time between failures/To repair failures	6 mo/4 hr	n/a/n/a
Average time to complete maintenance by lab personnel	daily: 10 min; weekly: 20 min; monthly: 60 min	daily: 5 min; weekly: 15 min; monthly: 30 min
Onboard maintenance records/Maint. training demo module	no/yes	no/no
Training provided with purchase/Advanced oper. training avail.	3 days on site/yes	5 days on site
Annual service contract cost (24 h/7 d)	n/a	—
Distinguishing features	4 parameter dry ISE with CO_2; reusable reaction cuvette rotor; onboard wash system	4 parameter dry ISE with CO_2; 570 tests per hour benchtop; onboard touch screen LCD monitor

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SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid-volume laboratories)

Part 5 of 16 *See related comments, page 62*	**Olympus America Inc.** **Susan M. Watanabe, PhD** susan.watanabe@olympus.com **Two Corporate Center Dr.** **Melville, NY 11747** **800-223-0125** www.olympus.com	**Ortho-Clinical Diagnostics** **Adam Cornfield** **1001 U.S. Highway 202** **Raritan, NJ 08869** **800-828-6316** www.orthoclinical.com
Name of instrument/First year sold in U.S.	**AU400/1998; AU400e/2002**	**VITROS 350/2005**
List price	**$130,000**	**$110,000**
No. units in clinical use in U.S./Outside U.S.	**>500/>2,000**	**—/—**
Country where designed/Manufactured/Where reagents mftd.	**Japan/Japan/U.S. & Ireland**	**U.S./U.S./U.S.**
Operational type/Reagent type	**random access, discrete, continuous random access/open reagent system**	**batch, random access, discrete, continuous random access/self-contained single-use cartridges, packages, slides**
Sample handling system/Model type	**rack & stat carousel/floor standing**	**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	**—**	**none**
Tests not available in U.S. but available in other countries	**—**	**none**
Research-use-only assays	**none**	**none**
Tests in development	**D-dimer**	**none**
User-defined methods implemented for what analytes	**fructosamine, ammonia**	**—**
Methods supported/Immunoassay methods	**photometry, potentiometry, calculated tests/homogeneous**	**potentiometry, colorimetric, rate, immuno-rate/—**
No. of direct ion selective electrode channels	**3**	**3**
No. of different measured assays onboard simultaneously	**up to 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	**95/—**	**n/a/n/a**
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	**76/100–1,333**	**up to 60/18, 50, 60**
Shortest/median onboard reag. stability/Refrigerated onboard	**120 hr/30 days/yes (4–12°C)**	**48 hr/14 days/no**
Multiple reag. configurations supported	**yes**	**yes**
Reag. container placed directly on system for use	**yes**	**yes**
Instrument has same capabilities when 3rd-party reag. used	**yes**	**n/a**
Walkaway capacity in minutes/Specimens/Tests-assays	**varies/up to 102/varies**	**varies/40/200 per hr**
System is liquid or dry	**liquid**	**dry**
Uses disposable cuvettes/Max. No. stored	**no/n/a**	**n/a**
Uses washable cuvettes/Replacement frequency	**yes/permanent**	**n/a**
Minimum sample volume aspirated precisely at one time	**2 µL**	**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	**yes/26 L per hr peak consumption**	**no/n/a**
Noise generated in decibels	**65**	**61**
Dedicated pediatric sample cup/Dead volume	**no/n/a**	**no special sample cup required/35 µL**
Primary tube sampling/Pierces caps on primary tubes	**yes/no**	**yes/no**
Sample bar-code reading capability	**yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination**	**yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination**
Reagent bar-code reading capability	**yes**	**yes**
Bar code placement per CLSI standard Auto2A	**yes**	**yes**
Onboard test auto inventory (determines volume in container)	**yes**	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/yes/yes**	**yes/yes/yes**
Automatic detection of adequate reag. for aspir. & analysis	**yes**	**yes**
Hemolysis/Turbidity detection-quantitation	**yes/yes**	**not needed/not needed**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/no**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes/yes**	**yes/no**
Autocalibration or autocalibration alert	**yes**	**no**
Calibrants stored onboard/Multipoint calibration supported	**yes/yes**	**no/yes**
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	**1 day/30 days/14 days/14–20 days**	**reagent lot changes**
Automatic shutdown/Startup programmable	**yes/yes**	**no/no**
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	**<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	**<9 min, 67 specimens**	**6 min 40 sec, 261**
Typical time delay from ordering stat test to aspir. of sample	**<2 min**	**12 sec**
How often QC required/Onboard SW capability to review QC	**per CLIA & laboratory's decision/yes**	**24 hr/yes**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
QC results transferred automatically to LIS	**yes**	**yes**
Data mgmt. capability/Instrument vendor supplies LIS interface	**onboard/no (optional)**	**onboard/no (optional)**
Interfaces up and running in active user sites with	**all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC**	**in development**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes (broadcast download)**
Test results transmitted to LIS as soon as chem. time complete	**yes**	**yes**
LIS interface operates simultaneously with running assays	**yes**	**yes**
Uses LOINC to transmit orders & results	**no**	**no**
How labs get LOINC codes for reagent kits	**—**	**—**
Interface avail. (or will be) to automated specimen handling system	**yes**	**no**
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	**yes/yes/yes**	**no/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**<24 hr/yes**	**<4 hr**
Mean time between failures/To repair failures	**average 2 calls per yr/<24 hr**	**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	**yes (includes audit trail of who replaced parts)/yes**	**no/yes**
Training provided with purchase/Advanced oper. training avail.	**3–5 days on site, 5 days at vendor offices/yes**	**3 days on site, 5 days at vendor offices/yes**
Annual service contract cost (24 h/7 d)	**inquire**	**varies**
Distinguishing features	**Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with family of chemistry immuno systems, the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation**	**cost-effective MicroSlide Technology delivers low cost per reportable result and high reagent efficiency without the costs, maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required just once each day and calibration intervals up to six months with minimal interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily**

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Chemistry analyzers (for mid-volume laboratories)

Part 6 of 16 *See related comments, page 62*	Roche Diagnostics Todd Atkinson, Product Manager 9115 Hague Rd., P.O. Box 50457 Indianapolis, IN 46250 800-428-5074 www.roche.com	Roche Diagnostics Lisa Davis, Product Manager 9115 Hague Rd. Indianapolis, IN 46250 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	$265,000	varies
No. units in clinical use in U.S./Outside U.S.	>500/>2,000	>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-contained multi-use cartridges-packages-slides	continuous random access/self-contained, multi-use cartridges-packages-slides
Sample handling system/Model type	sample racks: RD 5-position rack/floor standing	5-position rack/floor-standing
Dimensions in inches (H x W x D)/Instrument footprint	47.3 x 74.8 x 35.4/—	varies with configuration/varies with configuration
No. of tests for which analyzer has FDA-cleared applications	137	>140
Tests clinically released in last 12 months	—	amikacin, quinidine, SHBG, C-peptide
Tests cleared but not clinically released	—	n/a
Tests not available in U.S. but submitted for 510(k) clearance	none	n/a
Tests not available in U.S. but available in other countries	LDH (P→L), ALP (DGKC)	TG, anti-TG, urine cortisol, kappa, lambda, apo A, apo B, Lp(a), osteocalcin, P1NP
Research-use-only assays	—	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, cyclosporin
User-defined methods implemented for what analytes	yes, varies	yes, varies
Methods supported/Immunoassay methods	photometry, potentiometry, fluorescence polarization/turbidimetric	photometry, potentiometry (ion selective electrode)/electrochemiluminescence
No. of direct ion selective electrode channels	4	3
No. of different measured assays onboard simultaneously	72	72–>140
No. of different assays programmed, calibrated at once	72	72–>140
No. of user-definable (open) channels/No. active simultaneously	0/n/a	varies
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	72/50–800	72–>140/100–3,000
Shortest/median onboard reag. stability/Refrigerated onboard	336 hr/84 days/yes (8°C)	72 hr/90 days/yes (2–12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	no	limited
Walkaway capacity in minutes/Specimens/Tests-assays	450/180/4,000	6 hr/300/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	yes/3,600	yes, 1,000 tests
Uses washable cuvettes/Replacement frequency	no/n/a	yes/monthly
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	no (direct connection, type I NCCLS)/5–7 L	yes/50 L
Noise generated in decibels	58.5	<62
Dedicated pediatric sample cup/Dead volume	yes/approx. 50–70 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	5 hr/once per lot/140 days/60 days	24 hr/varies from bottle change to lot change/bottle change/—
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	8.6 min, 118 specimens	3.5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	8.6 min, 99 specimens	5.5 min, 160–600 specimens
• Album., bili. direct & total, AST, ALT, ALP	9.8, 118 specimens	10 min, 133–600 specimens
Typical time delay from ordering stat test to aspir. of sample	1 min	50 sec
How often QC required/Onboard SW capability to review QC	typically once per 24 hr/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/yes (addt'l cost)	onboard/no (addt'l cost)
Interfaces up and running in active user sites with	Cerner, CHCS, Citation, Compton, CompuLab, DynaMedix, EDS, Fletcher Flora, McKesson (ALG, PathLabs, StarLabs), HMS, Intellilabs, Isys, LabDaq, Labforce, Labfusion, LabSoft, LCI, Meditech, Northern Soft, Orsys, Seacoast, Siemens, Soft Computer, Misys	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	database
Interface avail. (or will be) to automated specimen handling system	no	yes (Roche Pre-Analytical Modular)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	8 hr or next business day/yes	8 hr/yes
Mean time between failures/To repair failures	—/—	260 days/3.5 hr
Average time to complete maintenance by lab personnel	daily: <1 min; weekly: <5 min; monthly: none	daily: 5 min hands-on; weekly: 30 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes (onscreen help with diagrams & maintenance wizard)	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	1 day on site, 5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	varies	varies
Distinguishing features	comprehensive test menu including hemoglobin A1c; reagent cassette requires no operator prep. or special handling (can go straight from refrigerator to system with no warmup time); 97 percent of reagents are liquid, ready to use, system automatically reconstitutes if necessary, system forecasts daily reagent requirements based on history; operator maintenance automatically scheduled by system, based on actual use, not by calendar schedule; (800 has clot detection, bubble detection, and can accommodate universal five-position Roche rack for modular systems and Elecsys IA analyzers)	high-throughput clinical chemistry and immunoassay system with single point of entry; single user interface; single host connection, providing productivity & efficiency gains; system offers flexibility to easily expand configuration on site; enhanced intelligent process management achieves optimized sample routing, seamless integration of stat samples into routine workflow, automatic rerun and repeat testing selectable by test and real-time reflex testing with Middleware Solutions

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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
Name of instrument/First year sold in U.S.	**DataPro; DataPro Plus/—**
List price	**—**
No. units in clinical use in U.S./Outside U.S.	**3/>100**
Country where designed/Manufactured/Where reagents mftd.	**Argentina/Argentina/Australia**
Operational type/Reagent type	**batch, random access, discrete (separate PC with analyzer), continuous random access/open reagent system**
Sample handling system/Model type	**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	**15**
Tests clinically released in last 12 months	**AST, ALT, albumin, total & direct bilirubin, calcium, cholesterol, glucose, creatinine, ALP, phosphorus, total protein, triglycerides, urea nitrogen, uric acid**
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	**CO_2, amylase, CK, GGT, HDL, LDL, magnesium, microprotein, ACE, lipase**
Research-use-only assays	**none**
Tests in development	**TDMs, CRP, HbA1c**
User-defined methods implemented for what analytes	**none**
Methods supported/Immunoassay methods	**photometry, turbidimetry/—**
No. of direct ion selective electrode channels	**—**
No. of different measured assays onboard simultaneously	**48**
No. of different assays programmed, calibrated at once	**48**
No. of user-definable (open) channels/No. active simultaneously	**limited to PC memory/48**
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	**48/up to 225**
Shortest/median onboard reag. stability/Refrigerated onboard	**—/—/yes (5–7°C below room temperature)**
Multiple reag. configurations supported	**yes**
Reag. container placed directly on system for use	**requires operator prehandling/preparation**
Instrument has same capabilities when 3rd-party reag. used	**yes**
Walkaway capacity in minutes/Specimens/Tests-assays	**—/48/48**
System is liquid or dry	**liquid**
Uses disposable cuvettes/Max. No. stored	**yes/80**
Uses washable cuvettes/Replacement frequency	**yes/monitored by instrument**
Minimum sample volume aspirated precisely at one time	**2 µL**
Supplied with UPS (backup power)/Requires floor drain	**no/no**
Requires dedicated water system/Water consumption per hour	**no/0.58 L**
Noise generated in decibels	**—**
Dedicated pediatric sample cup/Dead volume	**no**
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., codes 39 & 128)/—**
Reagent bar-code reading capability	**pending**
Bar code placement per CLSI standard Auto2A	**—**
Onboard test auto inventory (determines volume in container)	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/no/no**
Automatic detection of adequate reag. for aspir. & analysis	**yes**
Hemolysis/Turbidity detection-quantitation	**no/no**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes/no**
Autocalibration or autocalibration alert	**yes**
Calibrants stored onboard/Multipoint calibration supported	**yes/yes**
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	**n/a/TBD/n/a/n/a**
Automatic shutdown/Startup programmable	**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	**<60 sec**
How often QC required/Onboard SW capability to review QC	**daily/yes**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**
QC results transferred automatically to LIS	**no**
Data mgmt. capability/Instrument vendor supplies LIS interface	**onboard/no**
Interfaces up and running in active user sites with	**—**
Bidirectional interface capability	**yes (host query)**
Test results transmitted to LIS as soon as chem. time complete	**no**
LIS interface operates simultaneously with running assays	**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	**no**
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	**yes/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**—/no**
Mean time between failures/To repair failures	**—/—**
Average time to complete maintenance by lab personnel	**daily: 5 min; weekly: 15 min; monthly: 30 min**
Onboard maintenance records/Maint. training demo module	**yes/no**
Training provided with purchase/Advanced oper. training avail.	**3 days on site, 5 days at vendor offices/no**
Annual service contract cost (24 h/7 d)	**TBD**
Distinguishing features	**closed system; compact benchtop; user-friendly Windows software**

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SURVEY OF INSTRUMENTS

Chemistry analyzers (for high-volume labs)

Part 8 of 16

Abbott Diagnostics
Chris Barton christina.barton@abbott.com
100 Abbott Park Road
Abbott Park, IL 60064
800-323-9100
www.abbott.com

See related comments, page 62

Name of instrument/First year sold in U.S.	Abbott Aeroset/1998
List price	$345,000
No. units in clinical use in U.S./Outside U.S.	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	rack, carousel/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	42.7 x 74.4 x 44.1/22.7 sq ft
No. of tests for which analyzer has FDA-cleared applications	79
Tests clinically released in last 12 months	—
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	a-1-AGP, β-2-microglobulin, digitoxin, IgE, hsCRP, UIBC, bile acid, P. amylase, HBDH, cholinesterase, CK-MB, ammonia, ceruloplasmin, kappa & lambda light chain, copper, fractosamine, D-dimer
Research-use-only assays	—
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	photometry, potentiometry/—
No. of direct ion selective electrode channels	3
No. of different measured assays onboard simultaneously	59
No. of different assays programmed, calibrated at once	100
No. of user-definable (open) channels/No. active simultaneously	100/59
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	59/400
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	yes
Instrument has same capabilities when 3rd-party reag. used	yes
Walkaway capacity in minutes/Specimens/Tests-assays	60/231/50,000+
System is liquid or dry	liquid
Uses disposable cuvettes/Max. No. stored	no/n/a
Uses washable cuvettes/Replacement frequency	yes/minimum 1 yr guaranteed
Minimum sample volume aspirated precisely at one time	2 µL
Supplied with UPS (backup power)/Requires floor drain	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)	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/no
Automatic detection of adequate reag. for aspir. & analysis	yes
Hemolysis/Turbidity detection-quantitation	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes
Autocalibration or autocalibration alert	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	8 hr/28 days/28 days/28 days
Automatic shutdown/Startup programmable	yes/yes
Stat time to completion of all analytes, throughput per hr. for:	
• Sodium, potassium, chloride, TCO2	10 min, 200+ specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	10 min, 200+ specimens
• Album., bili. direct & total, AST, ALT, ALP	10 min, 200+ specimens
Typical time delay from ordering stat test to aspir. of sample	<15 sec
How often QC required/Onboard SW capability to review QC	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	yes
Uses LOINC to transmit orders & results	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/Determine malfunctioning component	no/no/no
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes
Mean time between failures/To repair failures	>2 mo/varies
Average time to complete maintenance by lab personnel	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.	5 days on site, 5 days at vendor offices/no
Annual service contract cost (24 h/7 d)	$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 capability, low sample volume (2–35 µL)

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Chemistry analyzers (for high-volume laboratories)

Part 9 of 16

See related comments, page 62

Bayer HealthCare, Diagnostics Division
Alexander Socarras alex.socarras.b@bayer.com
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914-333-6162
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Name of instrument/First year sold in U.S.	ADVIA 1650/1999	ADVIA 2400/2003
List price	$279,000	$305,000
No. units in clinical use in U.S./Outside U.S.	250/600	30/100
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/Ireland	Japan/Japan/Ireland
Operational type/Reagent type	batch, random access, discrete, continuous random access/open reagent system	random access/open reagent system
Sample handling system/Model type	automated rack handler, sample carousel/floor standing	carousel, rack handler option, automation optionl/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	45 x 59 x 34/14 sq ft	1,157 x 1,711 x 934 mm/—
No. of tests for which analyzer has FDA-cleared applications	78	77
Tests clinically released in last 12 months	DAUs, acetaminophen, ethanol, salicylate, tobramycin, ALT (P5P), AST (P5P)	DAUs, acetaminophen, salicylate, ethanol, wrCRP, lipase, ammonia, HbA1c, lactate, P. amylase, tobramycin, ALT (P5P), AST (P5P)
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays	none	none
Tests in development	lithium, vancomycin	lithium, vancomycin
User-defined methods implemented for what analytes	CK-MB, myoglobin, fructosamine, β-2-microglobulin, DAUs, D-dimer, lithium, vancomycin	DAUs, CK-MB, myoglobin, fructosamine, β-2-microglobulin, lithium, vancomycin, D-dimer
Methods supported/Immunoassay methods	photometry, potentiometry, turbidimetrics/—	photometry, potentiometry (ISE)/homogeneous turbidimetric
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	49	46 colormetric, 3 ISE
No. of different assays programmed, calibrated at once	100	100
No. of user-definable (open) channels/No. active simultaneously	62/62	62/62
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	49/840	—/500
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	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	90–470/200/32,000	3.8 hr max./234/32,000 photometric, +90,000 ISE
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/221	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	2 µL of diluted specimen	2 µL of diluted specimen
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes (or sink)
Requires dedicated water system/Water consumption per hour	yes/25 L	yes/40 L
Noise generated in decibels	—	<50
Dedicated pediatric sample cup/Dead volume	yes/50 µL	yes/~50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes (2 of 5 interl., Codabar [NW7], codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/—
Autocalibration or autocalibration alert	yes	no
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	daily/30 days/30 days/daily	once per day/once per month/once per month/once per month
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	10 min, 150 samples, 600 tests	11 min, 200 samples
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	10 min, 150 samples, 1,050 tests	11 min, 200 samples
• Album., bili. direct & total, AST, ALT, ALP	10 min, 200 samples, 1,200 tests	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	per CLIA and laboratory's decision/yes	shortest interval: 8 hr; longest: 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	onboard/included in system price (TDC Technodata or Bayer CentraLink)
Interfaces up and running in active user sites with	Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens	Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	yes	yes
How labs get LOINC codes for reagent kits	e-mail, software	via software
Interface avail. (or will be) to automated specimen handling system	yes (all systems)	yes (with ADVIA WorkCell as of October 2003)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	4–8 hr/yes	varies by location, generally <4 hr/yes
Mean time between failures/To repair failures	—/4-8 hr	—
Average time to complete maintenance by lab personnel	daily: 10 min; weekly: 45 min; monthly: 1 hr	daily: <5 min; weekly: 10 min; monthly: 20 min
Onboard maintenance records/Maint. training demo module	yes/yes	yes/yes
Training provided with purchase/Advanced oper. training avail.	ongoing on site, 5 days at vendor offices/—	varies according to need on site; 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	$23,000	$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 guarantee	system provides true workstation consolidation with more than 80 available chemistry and special chemistry methods and applications; also offers user-defined methods that equate to cost-effective consolidation; offers unrivaled walkaway capability with an onboard capacity of >450 specimens with the Universal Rack Handler option; 32,000 photometric tests and 90,000 ISE tests; sample saver technology allows automatic repeats, dilutions and reflex testing without operator intervention of having to return to the original specimen

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Chemistry analyzers (for high-volume laboratories)

Part 10 of 16 *See related comments, page 62*	**Beckman Coulter Inc.** **200 South Kraemer Blvd.** **P.O. Box 8000** **Brea, CA 92822-8000** **800-526-3821** www.beckmancoulter.com	**Beckman Coulter Inc.** **200 South Kraemer Blvd.** **P.O. Box 8000** **Brea, CA 92822-8000** **800-526-3821** www.beckmancoulter.com
Name of instrument/First year sold in U.S.	**Synchron LX20/1997**	**Synchron LX20 Pro/2001**
List price	**$278,000**	**$343,000**
No. units in clinical use in U.S./Outside U.S.	**1,000/500**	**600/300**
Country where designed/Manufactured/Where reagents mftd.	**U.S./U.S./U.S. & Ireland**	**U.S./U.S./U.S. & Ireland**
Operational type/Reagent type	**continuous random access/open reagent system**	**continuous random access/open reagent system**
Sample handling system/Model type	**racks, centrifugable/floor standing**	**racks, centrifugable/floor standing**
Dimensions in inches (H x W x D)/Instrument footprint	**LX20 60 x 70 x 41/19.9 sq ft; LX4201 60 x 140 x 41/39.8 sq ft**	**60 x 70 x 41/19.9 sq ft**
No. of tests for which analyzer has FDA-cleared applications	**>100**	**>100**
Tests clinically released in last 12 months	**lithium, HbA1c online**	**lithium, HbA1c online**
Tests cleared but not clinically released	**none**	**none**
Tests not available in U.S. but submitted for 510(k) clearance	**none**	**none**
Tests not available in U.S. but available in other countries	**none**	**none**
Research-use-only assays	**none**	**none**
Tests in development	**homocysteine, D-dimer, sirolimus, tacrolimus, Lp(a), tricyclics, semiquantitative DATs, IMA**	**homocysteine, D-dimer, sirolimus, tacrolimus, Lp(a), tricyclics, semiquantitative DATs, IMA**
User-defined methods implemented for what analytes	**UIBC, cyclosporine, homocysteine**	**UIBC, cyclosporine, homocysteine**
Methods supported/Immunoassay methods	**photometry, potentiometry, near infrared/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay**	**photometry, potentiometry, near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay**
No. of direct ion selective electrode channels	**5 (indirect)**	**5 (indirect)**
No. of different measured assays onboard simultaneously	**41**	**41**
No. of different assays programmed, calibrated at once	**100**	**100**
No. of user-definable (open) channels/No. active simultaneously	**100/41**	**100/41**
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	**41/10,650**	**41/10,650**
Shortest/median onboard reag. stability/Refrigerated onboard	**168 hr/30 days/yes (2–8°C)**	**168 hr/30 days/yes (2–8°C)**
Multiple reag. configurations supported	**yes**	**yes**
Reag. container placed directly on system for use	**yes**	**yes**
Instrument has same capabilities when 3rd-party reag. used	**no**	**no**
Walkaway capacity in minutes/Specimens/Tests-assays	**83/132/5,280**	**83/132/5,280**
System is liquid or dry	**liquid**	**liquid**
Uses disposable cuvettes/Max. No. stored	**no/n/a**	**no/n/a**
Uses washable cuvettes/Replacement frequency	**yes/semi-permanent—2-yr warranty (250 stored on instrument)**	**yes/semi-permanent—2-yr warranty (250 stored on instrument)**
Minimum sample volume aspirated precisely at one time	**3 µL**	**3 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes/no**	**yes/no**
Requires dedicated water system/Water consumption per hour	**yes/16 L**	**yes/16 L**
Noise generated in decibels	**65**	**65**
Dedicated pediatric sample cup/Dead volume	**yes/40 µL (samples directly from pediatric bullet)**	**yes/40 µL**
Primary tube sampling/Pierces caps on primary tubes	**yes/no**	**yes/yes**
Sample bar-code reading capability	**yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination**	**yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination**
Reagent bar-code reading capability	**yes**	**yes**
Bar code placement per CLSI standard Auto2A	**yes**	**yes**
Onboard test auto inventory (determines volume in container)	**yes**	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/yes/yes**	**yes/yes/yes**
Automatic detection of adequate reag. for aspir. & analysis	**yes**	**yes**
Hemolysis/Turbidity detection-quantitation	**yes/yes**	**yes/yes**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/yes**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes/yes**	**yes/yes**
Autocalibration or autocalibration alert	**yes**	**yes**
Calibrants stored onboard/Multipoint calibration supported	**no/yes**	**no/yes**
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	**24 hr/up to 90 days/up to 60 days/14 days**	**1 day/up to 90 days/up to 60 days/14 days**
Automatic shutdown/Startup programmable	**none required**	**none required**
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	**38 sec, 90 specimens**	**38 sec, 90 specimens**
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	**38 sec, 90 specimens**	**38 sec, 90 specimens**
• Album., bili. direct & total, AST, ALT, ALP	**8 min, 90 specimens**	**8 min, 90 specimens**
Typical time delay from ordering stat test to aspir. of sample	**16 sec**	**16 sec**
How often QC required/Onboard SW capability to review QC	**24 hr/yes**	**24 hr/yes**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
QC results transferred automatically to LIS	**yes**	**yes**
Data mgmt. capability/Instrument vendor supplies LIS interface	**onboard & optional add-on (Beckman Coulter DL2000)/yes (addt'l cost)**	**onboard & optional add-on (Beckman Coulter DL2000)/ yes (addt'l cost)**
Interfaces up and running in active user sites with	**Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs**	**Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes (broadcast download & host query)**
Test results transmitted to LIS as soon as chem. time complete	**yes**	**yes**
LIS interface operates simultaneously with running assays	**yes**	**yes**
Uses LOINC to transmit orders & results	**no**	**no**
How labs get LOINC codes for reagent kits	**customer request**	**customer request**
Interface avail. (or will be) to automated specimen handling system	**yes (Power Processor, total lab automation)**	**yes (Power Processor, total lab automation)**
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	**yes/yes/yes**	**yes/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**metro: same day, rural: same or next day/yes**	**metro: same day, rural: same or next day/yes**
Mean time between failures/To repair failures	**—/—**	**—/—**
Average time to complete maintenance by lab personnel	**daily: none; weekly: 5 min; monthly: 25 min**	**daily: none; weekly: 5 min; monthly: 25 min**
Onboard maintenance records/Maint. training demo module	**no/no**	**no/no**
Training provided with purchase/Advanced oper. training avail.	**5 days at vendor offices/yes**	**5 days at vendor offices/yes**
Annual service contract cost (24 h/7 d)	**—**	**—**
Distinguishing features	**serum indices; centrifugable racks; clot detection; no-wait autoloader/linear racks; multiple wavelength blanking; smart modules, fiber optics; advanced workflow and data management; thermal ring and semipermanent glass cuvettes; pulsed xenon lamp; electronic stat notification; review by exception; reflex testing; add-on test, DL2000 Workflow and Results Manager**	**serum indices; centrifugable racks; clot detection; no-wait autoloader/linear racks; multiple wavelength blanking; smart modules, fiber optics; advanced workflow & data management; thermal ring and semipermanent glass cuvettes; pulsed xenon lamp; electronic stat notification; review by exception; reflex testing; add-on test; closed-tube sampling, near infrared detection (for high-sensitivity CRP), DL2000 Workflow and Results Manager**

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SURVEY OF INSTRUMENTS

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** **Brea, CA 92822**	**Beckman Coulter Inc.** **Dan Siegenthaler** dmsiegenthaler@beckman.com **200 South Kraemer Blvd.** **P.O. Box 8000** **Brea, CA 92822**
See related comments, page 62	**800-526-3821** www.beckmancoulter.com	**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.	**350/250**	**25/25**
Country where designed/Manufactured/Where reagents mftd.	**U.S./U.S./U.S.**	**U.S./U.S./U.S. & Ireland**
Operational type/Reagent type	**continuous random access/open reagent system**	**continuous random access/open reagent system**
Sample handling system/Model type	**racks, centrifugable/floor standing**	**racks, centrifugable/floor standing**
Dimensions in inches (H x W x D)/Instrument footprint	**60 x 134.5 x 48/44.8 sq ft**	**62 x 70 x 41/19.9 sq ft**
No. of tests for which analyzer has FDA-cleared applications	**>135**	**>100**
Tests clinically released in last 12 months	**DHEA-S, intrinsic factor Ab, HbA1c online, lithium, fast hTSH, dil AFP**	**not applicable**
Tests cleared but not clinically released	**none**	**—**
Tests not available in U.S. but submitted for 510(k) clearance	**none**	**none**
Tests not available in U.S. but available in other countries	**none**	**none**
Research-use-only assays	**none**	**none**
Tests in development	**intact PTH, EPO, IL6, IMA, dsDNA, D-dimer, TNF-α, soluble transferrin receptor, β-2-gylcoprotein 1 Ab**	**sirolimus, tacrolimus, tricyclics, IMA, semi-quantitative drugs of abuse**
User-defined methods implemented for what analytes	**UIBC, homocysteine**	**UIBC, cyclosporine, homocysteine**
Methods supported/Immunoassay methods	**photometry, potentiometry (ISE), near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, chemiluminescence**	**photometry, potentiometry (ISE), near-infrared bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay**
No. of direct ion selective electrode channels	**5 (indirect)**	**5**
No. of different measured assays onboard simultaneously	**65**	**70**
No. of different assays programmed, calibrated at once	**124**	**100**
No. of user-definable (open) channels/No. active simultaneously	**100/100**	**100/70**
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	**65/11,850**	**70/approx. 3,500 (modular); 600 cartridge**
Shortest/median onboard reag. stability/Refrigerated onboard	**168 hr/28 days/yes (2–10°C)**	**168 hr/30 days/yes (2–8°C)**
Multiple reag. configurations supported	**yes**	**yes**
Reag. container placed directly on system for use	**yes**	**yes**
Instrument has same capabilities when 3rd-party reag. used	**no**	**no**
Walkaway capacity in minutes/Specimens/Tests-assays	**180/132/5,280**	**83/132/5,280**
System is liquid or dry	**liquid**	**liquid**
Uses disposable cuvettes/Max. No. stored	**yes/294 (immuno)**	**no**
Uses washable cuvettes/Replacement frequency	**yes/2-yr (chemistry) warranty, semi-permanent**	**yes/2-yr warranty, semi-permanent**
Minimum sample volume aspirated precisely at one time	**3 µL**	**3 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes/yes**	**optional/no**
Requires dedicated water system/Water consumption per hour	**yes/16 L**	**yes/16 L**
Noise generated in decibels	**n/a**	**60**
Dedicated pediatric sample cup/Dead volume	**—**	**yes/40 µL (samples directly from bullet)**
Primary tube sampling/Pierces caps on primary tubes	**yes/yes**	**yes/yes**
Sample bar-code reading capability	**yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination**	**yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination**
Reagent bar-code reading capability	**yes**	**yes**
Bar code placement per CLSI standard Auto2A	**yes**	**yes**
Onboard test auto inventory (determines volume in container)	**yes**	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/yes/yes**	**yes/yes/yes**
Automatic detection of adequate reag. for aspir. & analysis	**yes**	**yes**
Hemolysis/Turbidity detection-quantitation	**yes (chemistry)/yes (chemistry)**	**yes/yes**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/yes**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes (chemistry)/yes (chemistry)**	**yes/yes**
Autocalibration or autocalibration alert	**yes (chemistry)**	**yes**
Calibrants stored onboard/Multipoint calibration supported	**no/yes**	**no/yes**
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	**24 hr/up to 90 days/up to 60 days/14 days**	**1 day/up to 90 days/up to 60 days/14 days**
Automatic shutdown/Startup programmable	**none required**	**none required**
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	**38 sec, 90 specimens**	**2:23 (from standby), 91 specimens**
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	**38 sec, 90 specimens**	**2:22 (from standby), 91 specimens**
• Album., bili. direct & total, AST, ALT, ALP	**8 min, 90 specimens**	**12:32 (from standby), 76 specimens**
Typical time delay from ordering stat test to aspir. of sample	**36 sec**	**16 sec**
How often QC required/Onboard SW capability to review QC	**24 hr/yes**	**24 hr/yes**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
QC results transferred automatically to LIS	**yes**	**yes**
Data mgmt. capability/Instrument vendor supplies LIS interface	**onboard & optional add-on (Beckman Coulter)/yes (addt'l cost)**	**onboard & optional add-on (Beckman Coulter)/yes (addt'l cost)**
Interfaces up and running in active user sites with	**Cerner, Misys**	**Cerner, Misys, Meditech, Citation, Medlab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes (broadcast download & host query)**
Test results transmitted to LIS as soon as chem. time complete	**yes**	**yes**
LIS interface operates simultaneously with running assays	**yes**	**yes**
Uses LOINC to transmit orders & results	**yes**	**yes**
How labs get LOINC codes for reagent kits	**customer request**	**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	**yes/yes/yes**	**yes/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**metro: same day, rural: same or next day/yes**	**metro: same day, rural: same or next day/yes**
Mean time between failures/To repair failures	**n/a/n/a**	**n/a/n/a**
Average time to complete maintenance by lab personnel	**daily: 15 min; weekly: 33.5 min; monthly: 25 min**	**daily: none; weekly: 10 min (tech time); monthly: 18 min (tech time)**
Onboard maintenance records/Maint. training demo module	**no/no**	**yes (includes audit trail of who replaced parts/yes**
Training provided with purchase/Advanced oper. training avail.	**10 days at vendor offices/yes**	**5 days at vendor offices/yes**
Annual service contract cost (24 h/7 d)	**n/a**	**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**

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

Chemistry analyzers (for high-volume laboratories)

Part 12 of 16 *See related comments, page 62*	**Dade Behring Inc.** **P.O. Box 6101** **Newark, DE 19714-6101** **800-242-3233** www.dadebehring.com	**Dade Behring Inc.** **Joseph Meola** joseph_meola@dadebehring.com **P.O. Box 6101** **Newark, DE 19714-6101** **302-631-6018** www.dadebehring.com
Name of instrument/First year sold in U.S.	**Dimension RxL Max Integrated Chemistry System/2003**	**Dimension Lynx System/2005**
List price	**—**	**—**
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.	**U.S./U.S./U.S.**	**U.S./U.S./U.S.**
Operational type/Reagent type	**batch, random access, continuous random access/self-contained multiuse cartridges-packages-slides**	**batch, random access, continuous random access/self-contained multiuse cartridges-packages-slides, open reagent system**
Sample handling system/Model type	**segmented sample wheel/floor standing**	**rack & segment/floor standing**
Dimensions in inches (H x W x D)/Instrument footprint	**44 x 62.5 x 30.5/13.2 sq ft**	**64 x 122 x 98/—**
No. of tests for which analyzer has FDA-cleared applications	**>90**	**—**
Tests clinically released in last 12 months	**—**	**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	**none**	**—**
Tests in development	**quinidine, sirolimus, tacrolimus**	**quinidine, sirolimus, tacrolimus**
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 turbidimetric, latex turbidimetric**	**photometry, potentiometry, Integrated Multisensor Technology (IMT)/heterogenous EIA using HM, EMIT latex particle turbidimetric, latex turbidimetric**
No. of direct ion selective electrode channels	**4 (indirect)**	**3 (indirect)**
No. of different measured assays onboard simultaneously	**48/92 with optional inventory management system**	**182**
No. of different assays programmed, calibrated at once	**190**	**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	**yes**	**yes**
Reag. container placed directly on system for use	**yes**	**yes**
Instrument has same capabilities when 3rd-party reag. used	**yes**	**yes**
Walkaway capacity in minutes/Specimens/Tests-assays	**can be hours**	**varies/600/varies**
System is liquid or dry	**liquid, reconstitutes onboard**	**liquid, reconstitutes onboard**
Uses disposable cuvettes/Max. No. stored	**yes/12,000**	**yes/24,000**
Uses washable cuvettes/Replacement frequency	**no/—**	**no/—**
Minimum sample volume aspirated precisely at one time	**2 µL**	**2 µL**
Supplied with UPS (backup power)/Requires floor drain	**yes/no**	**yes/yes**
Requires dedicated water system/Water consumption per hour	**yes/3.2 L**	**yes/6.4 L**
Noise generated in decibels	**<70**	**<140**
Dedicated pediatric sample cup/Dead volume	**yes/20 µL**	**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 5 interl., Codabar, codes 39 & 128)/autodiscrimination**	**yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination**
Reagent bar-code reading capability	**yes**	**yes**
Bar code placement per CLSI standard Auto2A	**yes**	**yes**
Onboard test auto inventory (determines volume in container)	**yes**	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/yes/yes**	**yes/yes/yes**
Automatic detection of adequate reag. for aspir. & analysis	**yes**	**yes**
Hemolysis/Turbidity detection-quantitation	**yes/yes**	**yes/yes**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/yes**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes/yes**	**yes/no**
Autocalibration or autocalibration alert	**yes**	**yes**
Calibrants stored onboard/Multipoint calibration supported	**yes/30–90 days**	**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, TCO2	**50 sec, 288 tests**	**—, —**
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	**4.5 min, 500 tests**	**—, —**
• Album., bili. direct & total, AST, ALT, ALP	**10–11 min, 500 tests**	**—, —**
Typical time delay from ordering stat test to aspir. of sample	**24 sec**	**—**
How often QC required/Onboard SW capability to review QC	**24 hr/yes**	**24 hr/yes**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**no/yes**	**yes/yes**
QC results transferred automatically to LIS	**yes**	**yes**
Data mgmt. capability/Instrument vendor supplies LIS interface	**optional add-on (DBNet, Dade Behring)/yes (addt'l cost)**	**onboard (optional add-on)/yes (addt'l cost)**
Interfaces up and running in active user sites with	**all major LIS vendors**	**Cerner, Meditech, SCC, Horus, Misys, SwissLab, Medicom, Izasa, Confidentia, Saudi Bus. Machines**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes (broadcast download & host query)**
Test results transmitted to LIS as soon as chem. time complete	**yes**	**yes**
LIS interface operates simultaneously with running assays	**yes**	**yes**
Uses LOINC to transmit orders & results	**no**	**no**
How labs get LOINC codes for reagent kits	**—**	**n/a**
Interface avail. (or will be) to automated specimen handling system	**yes**	**yes**
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	**yes/yes/yes**	**yes/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**2–8 hr/yes**	**2–8 hr/yes**
Mean time between failures/To repair failures	**—/—**	**n/a/n/a**
Average time to complete maintenance by lab personnel	**daily: 5 min; weekly: 10 min; monthly: 15 min**	**daily: 5 min; weekly: 10 min; monthly: 15 min**
Onboard maintenance records/Maint. training demo module	**yes/no**	**yes (includes audit trail of who replaced parts)/no**
Training provided with purchase/Advanced oper. training avail.	**5 days on site, 4 days at vendor offices/yes**	**5 days on site, 4 days at vendor offices/yes**
Annual service contract cost (24 h/7 d)	**multiple types**	**—**
Distinguishing features	**integrates heterogenous immunoassays onboard with other chemistries; allows single platform for over 95 percent of most requested tests; eliminates sample splitting between general tests and immunoassays**	**entry level automation without the complexity; customized and scalable; power packed space efficient platform**

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

Chemistry analyzers (for high-volume laboratories)

Part 13 of 16 *See related comments, page 62*	Olympus America Inc. Susan M. Watanabe, PhD susan.watanabe@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com	Olympus America Inc. Susan M. Watanabe, PhD susan.watanabe@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 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.	>300/>1,000	>60/>450
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S. & Ireland	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	random access, discrete, continuous random access/open reagent system	random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	rack & stat carousel/floor standing	rack & stat carousel/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	50 x 74 x 32/68 sq ft	50 x 79 x 45/92 sq ft
No. of tests for which analyzer has FDA-cleared applications	122	122
Tests clinically released in last 12 months	lactate	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	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 51	up to 51
No. of different assays programmed, calibrated at once	99	99
No. of user-definable (open) channels/No. active simultaneously	95/—	95/—
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	48 x 2/100–1,333	48 x 2/100–4,000
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4–12°C)	120 hr/30 days/yes (4–12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/up to 172/varies	varies/up to 322/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/n/a	no/n/a
Uses washable cuvettes/Replacement frequency	yes/permanent	yes/permanent
Minimum sample volume aspirated precisely at one time	2 µL	1 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes (no w/ optional water pump)	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	<65
Dedicated pediatric sample cup/Dead volume	no/n/a	no/n/a
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/30 days/14 days/14–20 days	1 day/30 days/14 days/14–20 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	<4 min, 200 specimens	<4 min, 267 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	<5 min, 160 specimens	<4 min, 267 specimens
• 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	per CLIA & laboratory's decision/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	average 2 calls per yr/<24 hr	TBD/TBD
Average time to complete maintenance by lab personnel	daily: 3 min; weekly: 27 min; monthly: 45 min	daily: 5 min; weekly: 30 min; monthly: 45 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	3–5 days on site, 5 days at vendor offices/yes	3–5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	inquire
Distinguishing features	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with 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 and streamlined operation	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation

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Chemistry analyzers (for high-volume laboratories)

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	Olympus America Inc. **Hiro Sekiya** hiro.sekiya@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com	Olympus America Inc. **Hiro Sekiya** hiro.sekiya@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com
Name of instrument/First year sold in U.S.	AU5421 with dual ISE/2001	AU5431 with dual ISE/2001
List price	$465,000	$575,000
No. units in clinical use in U.S./Outside U.S.	>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	lactate	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	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	99	up to 147
No. of different assays programmed, calibrated at once	99	99
No. of user-definable (open) channels/No. active simultaneously	95/—	95/—
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	48 x 4/100–4,000	48 x 6/100–4,000
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4–12°C)	120 hr/30 days/yes (4–12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/up to 300/varies	varies/up to 300/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/n/a	no/n/a
Uses washable cuvettes/Replacement frequency	yes/permanent	yes/permanent
Minimum sample volume aspirated precisely at one time	1 µL	1 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes	no (optional)/yes
Requires dedicated water system/Water consumption per hour	yes/120 L	yes/180 L
Noise generated in decibels	<65	—
Dedicated pediatric sample cup/Dead volume	no/n/a	no/n/a
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl.)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/Low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/30 days/14 days/14–20 days	1 day/30 days/14 days/14–20 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	—, max 600	—, max 600
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	—, max 600	—, max 600
• Album., bili. direct & total, AST, ALT, ALP	—, max 533	—, max 800
Typical time delay from ordering stat test to aspir. of sample	—	—
How often QC required/Onboard SW capability to review QC	per CLIA & laboratory's decision/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	TBD/TBD	TBD/TBD
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 30 min; monthly: 45 min	daily: 5 min; weekly: 30 min; monthly: 45 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	inquire
Distinguishing features	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation

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Chemistry analyzers (for high-volume laboratories)

Part 15 of 16

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	Ortho-Clinical Diagnostics Adam Cornfield 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com	Ortho-Clinical Diagnostics Adam Cornfield 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com
Name of instrument/First year sold in U.S.	VITROS 950, VITROS 950AT/1995	VITROS 250, VITROS 250AT/1993
List price	950: $196,000; 950 AT: $250,000	250 $105,000; 250 AT $165,000
No. units in clinical use in U.S./Outside U.S.	>1,500/—	>3,000/—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	U.S./U.S./U.S.
Operational type/Reagent type	batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides	batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides
Sample handling system/Model type	sample trays/floor standing	rack/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	55 x 68 x 38/26 sq ft	47 x 45.5 x 28/8.8 sq ft
No. of tests for which analyzer has FDA-cleared applications	70	70
Tests clinically released in last 12 months	none	none
Tests cleared but not clinically released	dHDL MicroSlide	dHDL MicroSlide
Tests not available in U.S. but submitted for 510(k) clearance	—	none
Tests not available in U.S. but available in other countries	—	none
Research-use-only assays	—	none
Tests in development	—	none
User-defined methods implemented for what analytes	—	none
Methods supported/immunoassay methods	potentiometry, colorimetric, rate, immuno-rate/—	potentiometry, colorimetric, rate, immuno-rate/—
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 75	up to 60
No. of different assays programmed, calibrated at once	up to 75	up to 60
No. of user-definable (open) channels/No. active simultaneously	n/a/n/a	n/a/n/a
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	up to 75/up to 60	up to 60/up to 60
Shortest/median onboard reag. stability/Refrigerated onboard	48 hr/14 days/no	48 hr/14 days/no
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	n/a	n/a
Walkaway capacity in minutes/Specimens/Tests-assays	—/40/900 per hr	—/40/200 per hr
System is liquid or dry	dry	dry
Uses disposable cuvettes/Max. No. stored	no/n/a	n/a/n/a
Uses washable cuvettes/Replacement frequency	no/n/a	n/a/n/a
Minimum sample volume aspirated precisely at one time	6 µL	6 µL
Supplied with UPS (backup power)/Requires floor drain	available (not included)/no	available (not included)/no
Requires dedicated water system/Water consumption per hour	no/none	no/n/a
Noise generated in decibels	—	—
Dedicated pediatric sample cup/Dead volume	no special sample cup required/35 µL	no special sample cup required/35 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	not needed/not needed	not needed/not needed
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/no
Sample volume can be reduced/Increased to rerun out-of-linear-range high/Low results	no/no	yes/no
Autocalibration or autocalibration alert	no	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	reagent lot changes	reagent lot changes
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	~6 min, 600 specimens	6 min, 240 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	~6 min, ~700 specimens	7 min, 258 specimens
• Album., bili. direct & total, AST, ALT, ALP	~7 min, ~700 specimens	7 min 17 sec, 230 specimens
Typical time delay from ordering stat test to aspir. of sample	8 sec	12 sec
How often QC required/Onboard SW capability to review QC	24 hr/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces	all common interfaces
Bidirectional interface capability	yes (broadcast download)	yes (broadcast download)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	—
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes (enGen)	yes (enGen)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	no/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<4 hr/yes	<4 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 2 min; weekly: 5 min; monthly: 15 min	daily: 2 min; weekly: 5 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	no/yes	no/yes
Training provided with purchase/Advanced oper. training avail.	3 days on site, 5 days at vendor offices/yes	3 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	—
Distinguishing features	cost-effective MicroSlide Technology delivers low cost per reportable result and high reagent efficiency without the costs, maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required just once each day and calibration intervals up to six months with minimal interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily	cost-effective MicroSlide Technology delivers low cost per reportable result and high reagent efficiency without the costs, maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required just once each day and calibration intervals up to six months with minimal interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily

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Chemistry analyzers (for high-volume laboratories)

Part 16 of 16	Ortho-Clinical Diagnostics Adam Cornfield 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316	Roche Diagnostics Lisa Davis, Product Manager 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 ext. 13531
See related comments, page 62	www.orthoclinical.com	us.labsystems.roche.com
Name of instrument/First year sold in U.S.	VITROS 5,1 FS Chemistry System/2004	Modular/1998
List price	$305,000	varies
No. units in clinical use in U.S./Outside U.S.	>150	>400/>3,000
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	multiple countries/multiple countries/multiple countries
Operational type/Reagent type	random access, discrete, continuous random access/ self-contained single-use cartridges-packages-slides; open reagent system (post-launch)	continuous random access/self-contained multiuse cartridges-packages-slides
Sample handling system/Model type	universal sample tray/floor standing	5-position rack/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	52.5 x 92.2 x 33.4/21.4 sq ft	varies per configuration/varies
No. of tests for which analyzer has FDA-cleared applications	90	>100
Tests clinically released in last 12 months	20	urine cortisol
Tests cleared but not clinically released	dHDL MicroSlide	anti-TG
Tests not available in U.S. but submitted for 510(k) clearance	none	CA 19-9, osteocalcin
Tests not available in U.S. but available in other countries	none	apo A, apo B, Lpa, kappa, lambda, P/NP, TG
Research-use-only assays	none	none
Tests in development	ASO, haptoglobin, direct TIBC, homocysteine, opiates, PCP, cocaine, barbiturate, benzodiazapine, cannabinoid, methadone, α-1-antitrysin, HbA1c, amphetamine	lidocaine, cyclosporin, vancomycin, anti-HBc, anti-HBe, HBe-AG, rubella IgG, rubella IgM, toxo IgG, toxo TgM, CA 72-4
User-defined methods implemented for what analytes	—	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry, immuno-rate, turbidimetric, colorimetric, spectrophotometer/—	photometry, potentiometry/HbA1c
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 125	47–>100
No. of different assays programmed, calibrated at once	up to 125	47–>100
No. of user-definable (open) channels/No. active simultaneously	20/10	varies
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	up to 125/up to 100	47–100/100–3,000
Shortest/median onboard reag. stability/Refrigerated onboard	48 hr/14 days/yes (temp: 10°C)	72 hr/28 days/yes (2–12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	no
Walkaway capacity in minutes/Specimens/Tests-assays	varies/160/8,940 per hr	varies/300/varies
System is liquid or dry	dry, liquid ready to use	liquid
Uses disposable cuvettes/Max. No. stored	yes/348	no/n/a
Uses washable cuvettes/Replacement frequency	no/disposable	yes/monthly
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	available (not included)/no	yes/yes
Requires dedicated water system/Water consumption per hour	no/n/a	yes/varies (50 L/hr/mod)
Noise generated in decibels	<60	<62
Dedicated pediatric sample cup/Dead volume	no special sample cup required/35 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	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/no
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/Low results	system autodilutes	yes/yes
Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	reagent lot changes	24 hr/varies/bottle change/lot change
Automatic shutdown/Startup programmable	no/no	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	5.5 min, 400 specimens	3.5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.75 min, 625 specimens	5.5 min, 160–600 specimens
• Album., bili. direct & total, AST, ALT, ALP	7.5 min, 360 specimens	10.5 min, 133–1,200 specimens
Typical time delay from ordering stat test to aspir. of sample	~10 sec	<1 min
How often QC required/Onboard SW capability to review QC	once per 24 hr/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard (optional add-on)/no	onboard/no
Interfaces up and running in active user sites with	all common interfaces	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	no
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	database
Interface avail. (or will be) to automated specimen handling system	yes (enGen, any open point in space systems)	yes (Roche Pre-Analytical Modular)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<4 hr/yes	8 hr/yes
Mean time between failures/To repair failures	TBD/TBD	260 days/3.5 hr
Average time to complete maintenance by lab personnel	daily: 9 min; weekly: 5 min; monthly: 31 min	daily: 5 min; weekly: 10 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	in development/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	varies 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	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; eConnectivity interactive management system	Roche Hitachi chemistry and automation proven reliability and more than 20 years of experience; capable of consolidating up to 100 different assays on one high-throughput analyzer; system can be connected directly to preanalytical automation; flexible, expandable to lab's changing needs; up to four modules per system

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