A glimpse at what's new in chemistry analyzers

Brendan Dabkowski

In British author Kazuo Ishiguro's novel *The Remains of the Day*, the main character, an elderly butler named Stevens, fails to recognize the obsolescence of his occupation because he is obsessed with perfecting its minutiae. Stevens dismisses anything he thinks might conflict with the dignity of his profession, thereby missing crucial self-realizations and hemming himself in the past. He neither plans for nor embraces change.

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For labs and the companies that develop the assays and platforms they need, change has become routine. That's one reason why Abbott Diagnostics, for instance, is not only working to launch new analyzers for today but also investing to develop solutions labs will need "10 to 15 years from now," says marketing manager Neal Nash. Accuracy and quality come first, but reducing complexity, realizing financial growth, and enhancing patient care drive the ability to compete, says Roche Diagnostics group marketing manager for centralized diagnostics systems Ed Gilligan. "Integrated platforms and automation," he says, "are especially critical in helping labs with a lean-thinking approach overall."

Many of the companies in this month's guide to mid- and high-volume chemistry and chemistry/immunoassay analyzers (pages 19-45) are addressing, with their new and soon-to-be-introduced products, the challenges laboratories face.

Siemens Healthcare Diagnostics' Dimension EXL with LM integrated chemistry system and Dimension Vista 500 intelligent lab system are two of the several solutions you will find in the following pages. Launched in April, the Dimension EXL uses LOCI advanced chemiluminescent technology and provides 10-minute cardiac assay times, says Curt Koehn, the company's director of chemistry/immunoassay instruments. Panels available for the Dimension EXL include cardiac, thyroid disorder, therapeutic drug monitoring, drugs-of-abuse and protein testing, fertility, and routine and specialty chemistry testing. The Dimension Vista 500, which the company was expecting to roll out in time for this month's annual American Association for Clinical Chemistry meeting, features LOCI advanced chemiluminescent technology and onboard automation.

Siemens has also released 13 new concentrated reagents for its Advia line of chemistry analyzers. "These are concentrates of our current reagents that are diluted automatically on-system on a per-test basis to offer the same high-quality results seen with our respective nonconcentrated formulations," says Pamela Curtin, the company's marketing manager for Advia automation and chemistry systems. The reagent kits contain as many as 3,450 tests in 40- or 70-mL containers.

OrthoClinical Diagnostics' vice president of clinical laboratory and donor screening worldwide marketing Betsy S. Hanna says her company's Vitros 5600 Integrated System, which became available last fall, has "Sample-Centered" processing, whereby individual samples are accessed independently and in parallel for chemistry and immunoassay testing. The analyzer can perform more than 100 different chemistry, immunoassay, and infectious-disease assays. HIV combo, syphilis, and intact PTH assays are in the works for the 5600 and other analyzers. The company plans to launch a 24-hour remote monitoring center this summer to manage and maintain its Vitros line of instruments. The center "works to detect problems before they occur," Hanna says.

Abbott is also offering a new combined platform: The Architect ci4100 integrated immunoassay/clinical chemistry system, which can generate up to 900 test results per hour. Also new is its companion product, the Architect c4000 clinical chemistry analyzer, which can generate up to 800 test results per hour. Both systems, says Nash, offer stat capability; the ability to measure hemolysis, icterus, and lipemia levels; clot and bubble detection; and a plug-and-play ICT module that measures Na, K, and Cl and guarantees 45,000 patient determinations. They will be launched at this month's AACC meeting. The Architect line, Nash notes, was designed to offer standardization and scalability to improve lab efficiency and smooth the transition to electronic medical records.

Later this year or in early 2010, Roche plans to add stat capability to its Cobas e 601 immunoassay analyzer. This will result in a nine-minute turnaround time, Gilligan says. And though not yet released, the Cobas 8000 integrated analyzer series will be on display at the AACC meeting. The 8000 series' clinical chemistry modules are the Cobas c 701 and Cobas c 502 analyzers. "The Cobas

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State Dates

When state pathology societies meet

State	Meeting	Date	Contact
SC	22nd Annual South Carolina Society of Pathology Gordon R. Hennigar Lecture	9/12/09	Debbie Shealy 800-327-1021, ext. 223 *debbie@scmanet.org*
AZ	Arizona Society of Pathologists Fall Meeting 2009	10/24/09	Patrice Hand 602-347-6901 *patriceh@azmedassn.org*
NJ	New Jersey Society of Pathology 59th Annual Slide Seminar and Annual Meeting	11/21/09	Zilka Figueroa 973-597-0938, ext. 229 *zfigueroa@successcomgroup.com*
TX	2010 Annual Meeting	1/15/10	Shari Noonan, CMP 512-370-1510 *shari.noonan@texmed.org*

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Chemistry analyzers

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c 701 will offer photometric throughput of up to 2,000 results per hour and includes 70 reagent positions," he says. The Cobas c 502 has a throughput of up to 600 results per hour and can run 60 different assays. The 8000 series' immunoassay module is the Cobas e 602. The company expects to release the 8000 outside the U.S. this year and domestically in 2010. For lower-volume labs, the Cobas c 311 analyzer, introduced this year, is a standalone chemistry solution with stat assay capability and the same reagents and user interface as the Cobas 6000 series. (See the POC chemistry/immunoassay product guide in the October issue of CAP TODAY for more information.)

Carolina Liquid Chemistries' BioLis 24i benchtop chemistry system, introduced last summer, features a menu of more than 100 tests, a no-pretreat HbA1c that correlates 1:1 to high-pressure liquid chromatography, and a water system that eliminates the need for water cubes that have to be transported and stored, says Patricia Gaull Shugart, BS, MT, MBA, the company's vice president of sales and marketing. Joining the 24i later this year will be the BioLis 12i low-volume chemistry analyzer, which is pending FDA 510(k) clearance (and not listed in the following product guide).

Randox Laboratories has added cystatin C and sLDL assays to its RX Imola benchtop analyzer's test menu, says Julia Dunlop, the company's RX series global product manager. This will "continue to raise the profile of the Randox test menu on the RX Imola platform," she says. The company has also added a drugs-of-abuse test panel to the menu, which now includes tests for amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, ecstasy, EDDP, methadone, and opiates.

Remaining available from Awareness Technology is the ChemWell series of analyzers, which includes the 2902 and 2910. "The 2902 is strictly a chemistry analyzer, while the 2910 has the added benefits of being an EIA-capable analyzer along with the chemistry functions," says marketing representative Joe Neal. The company will display at AACC an automated chemistry analyzer prototype targeted for launch in 2010, says sales manager Chris Schneider. Awareness' latest model is the Stat Fax 4500 compact chemistry analyzer for low-volume labs, which has touchscreen technology, onboard curve-fitting software, and an optional flow-cell feature. (You'll find more detail in CAP TODAY's October listing of POC chemistry/immunoassay analyzers.)

Earlier this year Beckman Coulter introduced three new integrated chemistry/immunoassay system solutions: the UniCel DxC 660i, UniCel DxC 680i, and UniCel DxC 860i Synchron Access clinical systems. Each of the integrated systems is configured to meet a different level of throughput and features Beckman Coulter's automated closed-tube aliquotting and sampling ClozCap technology, which frees technologists from the labor-intensive tasks of decapping, recapping, and sorting samples manually.

CAP TODAY's guide to mid- and high-volume chemistry and chemistry/immunoassay analyzers includes products from the aforementioned manufacturers and from Olympus America. Companies supplied the information listed. Readers interested in a particular product should confirm it has the stated features and capabilities. □

Brendan Dabkowski is CAP TODAY *associate editor.*

MID

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Abbott Diagnostics
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Name of instrument/First year sold in U.S.	Architect c4000* and ci4100*/2009 (*in development)
List price/Total No. sold in 2008	c4000: $180,000; ci4100: $275,000/—
No. units in clinical use in U.S./Outside U.S.	—
Country where designed/Manufactured/Where reagents mftd.	U.S., Japan/U.S., Japan/U.S.
Operational type/Reagent type	continuous random access/self-contained multi-use cartridges, open reagent system
Sample handling system/Model type	3-dimensional robotic sample handler/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	c4000: 49 × 63 × 36/21; ci4100: 49 × 111 × 36/37
No. of tests for which analyzer has FDA-cleared applications	75
Tests clinically released in last 12 months	—
Tests cleared but not clinically released	acet, acid phos, Alb BCG, alb BCP, alk phos, ALT, AST, amy, crea, CRP, chol, CK, Ca, ammonia, Cl, K, NA, CO2, gluc, D. bili, gent, GGT, iron, lac acid, LD, LDL, lipase, mag, phos, salicylate, T Bili, TP, trigs, UIBC, HDL, urea, uric acid, urine/CSF protein
Tests not available in U.S. but submitted for 510(k) clearance	—
Tests not available in U.S. but available in other countries	—
Research-use-only assays	—
Tests in development	A1 AT, A1 GP, B2M, cerulo, CRP HS, enz. crea, ferritin, IgA, IgE, IgG, IgM, lith, Lp(a), amikacin, amph/methamph, barbs, benzos, cannab, carb, cocaine, dig, ecstasy, ethanol, HbA1C, meth, microalbumin, opiates, PCP, phenobarb, pheny, propox, quinidine, benzos-serum, TCAs, theo, tobra, vanco, valp acid, apo LP A1, apo LP B, C3, C4, hapto, pre-Alb, RF, transferrin
User-defined methods implemented for what analytes	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/chemiluminescence with flexible protocols
No. of direct ion selective electrode channels	3
No. of different measured assays onboard simultaneously	c4000: 58; ci4100: 83
No. of different assays programmed, calibrated at once	c4000: 220; ci4100: 320
No. of user-definable (open) channels/No. active simultaneously	220/220
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	c4000: varies 50–1,700; ci4100: varies 50 –1,700 chemistry, 100 immunoassay
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/28 days/yes (2° to 8°C)
Multiple reag. configurations supported	yes
Reag. container placed directly on system for use	yes
Instrument has same capabilities when 3rd-party reag. used	yes
Walkaway capacity in minutes/Specimens/Tests-assays	c4000: varies/100/62,000+; ci4100: varies/180/64,000+
System is liquid or dry	liquid
Uses disposable cuvettes/Max. No. stored	no/yes, immunoassay/300
Uses washable cuvettes/Replacement frequency	yes, chemistry/minimum 1-yr guarantee
Minimum sample volume aspirated precisely at one time	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no
Requires dedicated water system/Water consumption per hour	yes/15 L
Noise generated in decibels	normal operation: ≤48; peak: 70 for max 10 sec
Dedicated pediatric sample cup/Dead volume	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes, 2-D bar codes
Bar code placement per CLSI standard Auto2A	yes
Onboard test auto inventory (determines volume in container)	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes
Hemolysis/Turbidity detection-quantitation	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes (for chemistry)
Autocalibration or autocalibration alert	yes
Calibrants stored onboard/Multipoint calibration supported	yes, for chemistry only/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hr/30 days/7 days/14 days
Automatic shutdown/Startup programmable	no/no
Stat time to completion of all analytes, throughput per hr. for:	
• Sodium, potassium, chloride, TCO2	2.5 min, 133 specimens, 532 tests
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	8.4 min, 67 specimens, 469 tests
• Album., bili. direct & total, AST, ALT, ALP	9.6 min, 37 specimens, 469 tests
Typical time delay from ordering stat test to aspiration of sample	<20 sec
How often QC required/Onboard SW capability to review QC	shortest interval: 8 hr; longest: 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes
QC results transferred automatically to LIS	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	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, others
Bidirectional interface capability	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes
LIS interface operates simultaneously with running assays	yes
Uses LOINC to transmit orders & results	—
How labs get LOINC codes for reagent kits	package insert
Interface avail. (or will be) to automated specimen handling system	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	<24 hr/yes
Mean time between failures/To repair failures	>2 months/varies
Average time to complete maintenance by lab personnel	daily: <15 min; weekly: <35 min; monthly: <15 min
Onboard maintenance records/Maint. training demo module	yes/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	flexible options available
Distinguishing features (provided by vendor)	integration of CC and IA w/o compromising stat TAT, results, or throughput; robotic sample handler design w/SmartWash technology allows IA and CC testing in any order for overall TAT; features and benefits standardized across Architect instruments for consistent user experience, reduced variation in operator procedures, less errors, and consistent results; large reagent, routine and stat sample load-up capacity for efficient processing of samples for patient results

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

Survey Editor: Raymond Aller, MD

Chemistry analyzers for mid- and high-volume laboratories

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MID
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HIGH
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	MID	HIGH
Name of instrument/First year sold in U.S.	Architect c8000 and ci8200/2003	Architect c16000 and ci16200/2007
List price/Total No. sold in 2008	c8000: $200,000/15; ci8200: $375,000/25	c16000: $325,000/98; ci16200: $475,000/3
No. units in clinical use in U.S./Outside U.S.	c8000: 266/2,436; ci8200: 294/1,302	c16000: 6/220; ci16200: 5/380
Country where designed/Manufactured/Where reagents mftd.	U.S., Japan/U.S., Japan/U.S.	U.S., Japan/U.S., Japan/U.S.
Operational type/Reagent type	continuous random access/self-contained multi-use cartridges, open reagent system	continuous random access/open reagent system
Sample handling system/Model type	3-dimensional robotic sample handler/floor standing	3-dimensional robotic sample handler and carousel/floor-standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	c8000: 48 × 79 × 49/26; ci8200: 48 × 127 × 49/42	c16000: 48 × 79 × 49/26; ci16200: 48 × 127 × 49/42
No. of tests for which analyzer has FDA-cleared applications	138	138
Tests clinically released in last 12 months	TDMs, tricyclics, benzo-serum, enzymatic creatinine, NextGen creatinine, NextGen calcium	TDMs, tricyclics, benzo-serum, enzymatic creatinine, NextGen creatinine, NextGen calcium
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	CK-MB, myoglobin, ALT activated, AST activated, p-amylase, bile acids, cholinesterase, cholinesterase/dibucaine, copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, enzymatic creatinine	CK-MB, myoglobin, ALT activated, AST activated, p-amylase, bile acids, cholinesterase, cholinesterase/dibucaine, copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, enzymatic creatinine
Research-use-only assays	—	—
Tests in development	NextGen LD, NextGen direct bili	NextGen LD, NextGen direct bili
User-defined methods implemented for what analytes	yes, varies	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/chemiluminescence with flexible protocols	photometry, potentiometry (ISE), turbidmetric/chemiluminescence with flexible protocols (ChemiFlex)
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	c8000: 68; ci8200: 93	c16000: 68; ci16200: 93
No. of different assays programmed, calibrated at once	c8000: 220; ci8200: 320	c16000: 220; ci16200: 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	c8000: 65/50–1,700; ci8200: 90/50–1,170 (chemistry), 100–500 (immunoassay)	c16000: 65/50–1,700 (chemistry); ci16200: 93/50–1,700 (chemistry), 100–500 (immunoassay)
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/28 days/yes (2° to 8°C)	7 days/28 days/yes (2° to 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	c8000: varies/215/69,000+; ci8200: varies/365/81,000–93,000	c16000: varies/215/69,000+; ci16200: varies/365/81,000–93,000
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	c8000: no/—; ci8200: yes/1,200 immunoassay	c16000: no/—; ci16200: yes/1,200 immunoassay
Uses washable cuvettes/Replacement frequency	yes, chemistry/minimum 1-yr guarantee	yes/minimum 1-yr guarantee
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/yes
Requires dedicated water system/Water consumption per hour	yes/30.5 L	yes/59 L
Noise generated in decibels	normal operation: ≤48; peak: 70 for max 10 sec	normal operation: ≤48 peak; 70 for max 10 sec
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/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes, 2-D bar codes	yes, 2-D bar codes
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 aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes (for chemistry)	yes/yes (for chemistry)
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes, for chemistry only/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hr/30 days/7 days/14 days	24 hr/30 days/7 days/14 days
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2.5 min, 200 specimens, 800 tests	2.5 min, 200 specimens, 800 Tests
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	9.6 min, 160 specimens, 1,120 tests	9.6 min, 190 specimens, 1,330 Tests
• Album., bili. direct & total, AST, ALT, ALP	9.6 min, 133 specimens, 800 tests	9.6 min, 200 specimens, 1,200 Tests
Typical time delay from ordering stat test to aspiration 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)	optional add-on (addt'l price varies; SW mftr: Abbott)
Interfaces up and running in active user sites with	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Triple G, CIS, others	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Citation, CHCS, Antek, Orchard, others
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	—
How labs get LOINC codes for reagent kits	package insert	package insert
Interface avail. (or will be) to automated specimen handling system	no	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	>2 months/varies	—/—
Average time to complete maintenance by lab personnel	daily: 15 min; weekly: <45 min; monthly: 15 min	daily: 15 min; weekly: <45 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	yes/yes	yes/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)	flexible options available	flexible options available
Distinguishing features (provided by vendor)	integration of CC and IA without compromising stat TAT, results, or throughput because of the design of the robotic sample handler and SmartWash technology, which minimizes carryover to <0.1 ppm; large reagent capacity of 93 assays, with sample load up to 365; efficiency provided via multiple patented technologies	high-speed integration of CC and IA without compromising stat TAT, results, or throughput because of the design of the robotic sample handler and SmartWash technology, which minimizes carryover to <0.1 ppm; large reagent capacity of 93 assays, with sample load up to 365; Chemiflex and FlexRate technologies deliver assay extended linearities and enhanced sensitivities

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Chemistry analyzers for mid- and high-volume laboratories

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MID

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HIGH

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Name of instrument/First year sold in U.S.	ChemWell 2902, 2910/1999	UniCel DxC 660i Synchron Access Clinical System/2009
List price/Total No. sold in 2008	starts at $20,000/>500	$575,000/—
No. units in clinical use in U.S./Outside U.S.	50+/2,200+	>5/<5 (system release May 2009)
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./open system	U.S./U.S./U.S., France, Ireland
Operational type/Reagent type	batch, random access, continuous random access/open reagent system	batch, random access, continuous random access/immunoassay: self-contained singe-use cartridges, packages, slides; chemistry: open reagent system
Sample handling system/Model type	rack/benchtop	rack closed-tube/floor-standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	19 × 36 × 22/7	68 × 147 × 48/49
No. of tests for which analyzer has FDA-cleared applications	22	>150
Tests clinically released in last 12 months	none	soluble transferrin receptor
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for 510(k) clearance	18 EIA kits manuf. by BioCheck have been submitted	SHBG
Tests not available in U.S. but available in other countries	open system	HIV 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6, CMV IgG, rubella IgM
Research-use-only assays	open system	IL-6, PAPP-A
Tests in development	none	CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH Vitamin D, ultrasensitive estradiol, enzymatic CO2, AAT, AAG, total bile acid, enzymatic creatinine, ceruloplasmin
User-defined methods implemented for what analytes	all colorimetric biochemistry & EIA that read between 340–700 nm	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC
Methods supported/immunoassay methods	photometry/microwell assays	photometry, potentiometry (ISE), turbidimetric/ particle enhanced, turbidimetric, enzyme immunoassay, near infrared particle immunoassay, chemiluminescence, magnetic particle
No. of direct ion selective electrode channels	0	5
No. of different measured assays onboard simultaneously	27 std, 44 optional	115
No. of different assays programmed, calibrated at once	unlimited	115
No. of user-definable (open) channels/No. active simultaneously	unlimited/27 std, 44 optional	100/100
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	27 std, 44 optional/reagent dependent	115/immunoassay: 100 tests/kit; general chemistry: 300 tests/container
Shortest/median onboard reag. stability/Refrigerated onboard	reagent dependent/yes (15°C below ambient) optional	28 days/yes (2° to 10°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	assay mix dependent/—/assay dependent
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	yes (optional)/96	no/125
Uses washable cuvettes/Replacement frequency	yes (optional)/weekly	yes/—
Minimum sample volume aspirated precisely at one time	2 µL	3 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/up to 16 L
Noise generated in decibels	60	64
Dedicated pediatric sample cup/Dead volume	no/—	yes/20
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/yes
Sample bar-code reading capability/Autodiscrimination	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	2 or 5 interl., UPC, Codabar, codes 39 ¶ 128/yes
Reagent bar-code reading capability	no	yes
Bar code placement per CLSI standard Auto2A	no	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/no	yes/yes/yes
Automatic detection of adequate reag. for aspiration & 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	—
Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	user-defined for all	—/—/assay dependent/assay dependent
Automatic shutdown/Startup programmable	yes/yes	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	5.5 min, 28 specimens	—
Typical time delay from ordering stat test to aspiration of sample	15 sec	—
How often QC required/Onboard SW capability to review QC	reagent dependent/yes	24 hours/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 & optional add-on (sw mftr: Beckman Coulter/Normand)/yes (additional cost)
Interfaces up and running in active user sites with	not known	most commercially available LIS
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	no
How labs get LOINC codes for reagent kits	supplied by reagent manufacturer	—
Interface avail. (or will be) to automated specimen handling system	no	yes
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	metro: same day; rural: same or next day/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: <10 min; weekly: <10 min; monthly: <18 min
Onboard maintenance records/Maint. training demo module	no/no	yes, includes audit trai/yes
Training provided with purchase/Advanced oper. training avail.	2 days on site, 3 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	$4,000	contract dependent
Distinguishing features (provided by vendor)	price; one instrument for EIA & biochemistry; open and user programmable; discounts for biochemistry only; calculates indices; flexible formatting of reports	parallel processing of immunoassay & chemistry tests on a single system; ClozCap technology (closed-tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry & immunoassay reagent packs identical across UniCel and Access systems; immunossay: high-throughput analyzer; uses chemiluminescent assay technology and reagent packs for consistent results; loads consumables on the fly; chemistry: closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring w/semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat TAT; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification

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Chemistry analyzers for mid- and high-volume laboratories

Part 4 of 17

HIGH

Beckman Coulter, Inc.
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714-961-6698 www.beckmancoulter.com

HIGH

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Name of instrument/First year sold in U.S.	UniCel DxC 680i Synchron Access Clinical System/2009	UniCel DxC 860i Synchron Access Clinical System/2009
List price/Total No. sold in 2008	$610,000/—	$615,000/—
No. units in clinical use in U.S./Outside U.S.	<5 /<5 (system release May 2009)	1/1 (system release May 2009)
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S., France, Ireland	U.S./U.S./U.S., France, Ireland
Operational type/Reagent type	batch, random access, continuous random access/immunoassay: self-contained single-use cartridges, packages, sides; chemistry: open reagent system	batch, random access, continuous random access/immunoassay: self-contained single-use cartridges, packages, sides; chemistry: open reagent system
Sample handling system/Model type	rack closed-tube/floor-standing	rack closed-tube/floor-standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	68 × 153 × 48/51	68 × 155 × 48/51.7
No. of tests for which analyzer has FDA-cleared applications	>150	>150
Tests clinically released in last 12 months	soluble transferrin receptor	soluble transferrin receptor
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	SHBG	SHBG
Tests not available in U.S. but available in other countries	HIV 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6, CMV IgG, rubella IgM	HIV 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6, CMV IgG, rubella IgM
Research-use-only assays	IL-6, PAPP-A	IL-6, PAPP-A
Tests in development	CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH Vitamin D, ultrasensitive estradiol, enzymatic CO2, AAT, AAG, total bile acid, enzymatic creatinine, ceruloplasmin	CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH Vitamin D, ultrasensitive estradiol, enzymatic CO2, AAT, AAG, total bile acid, enzymatic creatinine, ceruloplasmin
User-defined methods implemented for what analytes	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC
Methods supported/immunoassay methods	photometry, potentiometry (ISE), turbidimetric/ particle enhanced, turbidimetric, enzyme immunoassay, near infrared particle immunoassay, chemiluminescence, magnetic particle	photometry, potentiometry (ISE), turbidimetric/ particle enhanced, turbidimetric, enzyme immunoassay, near infrared particle immunoassay, chemiluminescence, magnetic particle
No. of direct ion selective electrode channels	5	5
No. of different measured assays onboard simultaneously	115	120
No. of different assays programmed, calibrated at once	115	120
No. of user-definable (open) channels/No. active simultaneously	100/100	100/100
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	115/immunoassay: 100 tests/kit; general chemistry: 300 tests/container	120/immunoassay: 100 tests/kit; general chemistry: 300 tests/container
Shortest/median onboard reag. stability/Refrigerated onboard	28 days/yes (2° to 10°C)	28 days/yes (2° to 10°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	assay mix dependent/—/assay dependent	assay mix dependent/—/assay dependent
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/125	no/125
Uses washable cuvettes/Replacement frequency	yes/—	yes/—
Minimum sample volume aspirated precisely at one time	3 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	yes/up to 16 L	yes/up to 16 L
Noise generated in decibels	64	64
Dedicated pediatric sample cup/Dead volume	yes/20	yes/20
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability/Autodiscrimination	2 or 5 interl., UPC, Codabar, codes 39 & 128/yes	2 or 5 interl., UPC, Codabar, codes 39 & 128/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & 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	—	—
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	—/—/assay dependent/assay dependent	—/—/assay dependent/assay dependent
Automatic shutdown/Startup programmable	no/no	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 aspiration of sample	—	—
How often QC required/Onboard SW capability to review QC	24 hours/yes	24 hours/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/Normand)/yes (additional cost)	onboard & optional add-on (sw mftr: Beckman Coulter/Normand)/yes (additional cost)
Interfaces up and running in active user sites with	most commercially available LIS	most commercially available LIS
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	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: <10 min; weekly: <10 min; monthly: <18 min	daily: <10 min; weekly: <10 min; monthly: <18 min
Onboard maintenance records/Maint. training demo module	yes, includes audit trai/yes	yes, includes audit trai/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)	contract dependent	contract dependent
Distinguishing features (provided by vendor)	parallel processing of immunoassay & chemistry tests on a single system; ClozCap technology (closed-tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry & immunoassay reagent packs identical across UniCel and Access systems; immunossay: high-throughput analyzer; uses chemiluminescent assay technology and reagent packs for consistent results; loads consumables on the fly; chemistry: closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring w/semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat TAT; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification	parallel processing of immunoassay & chemistry tests on a single system; ClozCap technology (closed-tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry & immunoassay reagent packs identical across UniCel and Access systems; immunossay: high-throughput analyzer; uses chemiluminescent assay technology and reagent packs for consistent results; loads consumables on the fly; chemistry: closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring w/semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat TAT; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification

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Chemistry analyzers for mid- and high-volume laboratories

Part 5 of 17

	MID	MID
	Beckman Coulter Inc. Leslie Cutter lccutter@beckman.com 200 South Kraemer Blvd. Brea, CA 92821 714-993-8432 www.beckmancoulter.com	Beckman Coulter Inc. Leonard Bachicha LABachicha@beckman.com 200 South Kraemer Blvd. Brea, CA 92821 714-961-6698 www.beckmancoulter.com
Name of instrument/First year sold in U.S.	UniCel DxC 600/2004	Unicel DxC 600i/2006
List price/Total No. sold in 2008	$261,000/—	$400,000/—
No. units in clinical use in U.S./Outside U.S.	>1300 />2500	>350 />700
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. & Ireland	U.S./U.S./U.S., Ireland, France
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, closed-tube/floor-standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	62 × 62 × 41/17.7	62 × 126.5 × 48/42.16
No. of tests for which analyzer has FDA-cleared applications	>100	>150
Tests clinically released in last 12 months	barbiturate serum tox, benzodiazepine serum tox, tricyclics serum tox, oxycodone, ecstasy, amikacin, quinidine, cystatin c	soluble transferrin receptor
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	SHBG
Tests not available in U.S. but available in other countries	—	HIV 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6, CMV IgG, rubella IgM
Research-use-only assays	—	IL-6, PAPP-A
Tests in development	AAG, AAT, buprenorphine, ceruloplasmin, kappa, lambda, total bile acid, enzymatic creatinine, enzymatic CO2, amylase G7	CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH Vitamin D, ultrasensitive estradiol, enzymatic CO2, AAT, AAG, total bile acid, enzymatic creatinine, ceruloplasmin
User-defined methods implemented for what analytes	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC
Methods supported/immunoassay methods	photometry, potentiometry, near-infrared bidentate turbidimetric/ particle enhanced turbidimetric, enzyme immunoassay, near infrared particle immunoassay	photometry, potentiometry (ISE), turbidimetric, enzyme immunoassay/ chemiluminescence
No. of direct ion selective electrode channels	5	5
No. of different measured assays onboard simultaneously	65	89
No. of different assays programmed, calibrated at once	100	>150
No. of user-definable (open) channels/No. active simultaneously	100/65	100/65
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	65/about 3,500 modular; about 600 cartridges	89/about 300 cartridges (chem), 50 per pack (immuno)
Shortest/median onboard reag. stability/Refrigerated onboard	168 hr/30 days/yes (2° to 8°C)	168 hr/28 days/yes (2° to 10°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	no	no
Walkaway capacity in minutes/Specimens/Tests-assays	83/132/5,280	180/96/5,280
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	—	yes/294 (immuno)
Uses washable cuvettes/Replacement frequency	yes/2-yr warranty, semi-permanent	yes/2-yr warranty (chem)
Minimum sample volume aspirated precisely at one time	3 µL	5 µL
Supplied with UPS (backup power)/Requires floor drain	optional/no	optional/yes
Requires dedicated water system/Water consumption per hour	yes/16 L	yes/16 L
Noise generated in decibels	60	—
Dedicated pediatric sample cup/Dead volume	yes/40 µL	yes/—
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & 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	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/up to 90 days/up to 60 days/14 days	1 day/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	6:15 min. from standby, 96 specimens	8:15 min. from standby, 96 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	6:15 min. from standby, 96 specimens	8:15 min. from standby, 96 specimens
• Album., bili. direct & total, AST, ALT, ALP	13:07 min. from standby, 57 specimens	15:07 min. from standby, 57 specimens
Typical time delay from ordering stat test to aspiration of sample	16 sec	2:16
How often QC required/Onboard SW capability to review QC	24 hr/yes	24 hr/—
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes/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)/—
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps
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	yes (Beckman Coulter automation)	no
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day, rural: same or next day/yes	metro: same day; rural: same day or next
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: none; weekly: 7 min (tech time); monthly: 11 min (tech time)	daily: <15 min, weekly: 36 min; monthly: 11 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)/no
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	10 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	—
Distinguishing features (provided by vendor)	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; REMISOL Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification	parallel processing of immunoassay & chemistry tests on a single system; ClozCap technology (closed-tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry & immunoassay reagent packs identical across UniCel and Access systems; immunossay: high-throughput analyzer; uses chemiluminescent assay technology and reagent packs for consistent results; loads consumables on the fly; chemistry: closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring w/semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat TAT; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification

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Chemistry analyzers for mid- and high-volume laboratories

Part 6 of 17

	HIGH	HIGH
	Beckman Coulter Inc. Leslie Cutter lccutter@beckman.com 200 South Kraemer Blvd. Brea, CA 92821 714-993-8432 www.beckmancoulter.com	Beckman Coulter Inc. Leonard Bachicha LABachicha@beckman.com 200 South Kraemer Blvd. Brea, CA 92821 714-961-6698 www.beckmancoulter.com
Name of instrument/First year sold in U.S.	UniCel DxC 800/2005	UniCel DxC 880i Synchron Access Clinical System/2008
List price/Total No. sold in 2008	$340,000/not available	$650,000/—
No. units in clinical use in U.S./Outside U.S.	>475 />900	>20/>50
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. & Ireland	U.S./U.S./U.S., Ireland and France
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system for chemistry; self-contained single use cartridges for immunoassay
Sample handling system/Model type	racks, centrifugable/floor standing	rack closed tube/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	62 × 70 × 41/19.9	68 × 161 × 48/53.66
No. of tests for which analyzer has FDA-cleared applications	>100	>150
Tests clinically released in last 12 months	barbiturate serum tox, benzodiazepine serum tox, tricyclics serum tox, oxycodone, ecstasy, amikacin, quinidine, cystatin c	soluble transferrin receptor
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	SHBG
Tests not available in U.S. but available in other countries	—	HIV 1/2, HBs Ag confirm, HBs Ab, HCV Ab, HAV Ab, HAV IgM, HBcAb, HBc IgM, IL-6, CMV IgG, rubella IgM
Research-use-only assays	—	IL-6, PAPP-A
Tests in development	AAG, AAT, buprenorphine, ceruloplasmin, kappa, lambda, total bile acid, enzymatic creatinine, enzymatic CO2, amylase G7	CMV IgG, CMV IgM, p2PSA, PIGF, sVEGF R1, 25 OH Vitamin D, ultrasensitive estradiol, enzymatic CO2, AAT, AAG, total bile acid, enzymatic creatinine, ceruloplasmin
User-defined methods implemented for what analytes	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC
Methods supported/immunoassay methods	photometry, potentiometry (ISE), near-infrared bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay	photometry, potentiometry (ISE), turbidimetric/enzyme immunoassay, near infrared particle immunoassay, chemiluminescence, magnetic particle/chemiluminescence; magnetic particle
No. of direct ion selective electrode channels	5	5
No. of different measured assays onboard simultaneously	70	120
No. of different assays programmed, calibrated at once	100	120
No. of user-definable (open) channels/No. active simultaneously	100/70	100/100
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	70/approx. 3,500 (modular); 600 cartridges	120/100 tests/kit (immunoassay); 300 test/container (general chem)
Shortest/median onboard reag. stability/Refrigerated onboard	168 hr/30 days/yes (2° to 8°C)	316 hours/28 days/yes (2° to 10°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	no	no
Walkaway capacity in minutes/Specimens/Tests-assays	83/132/5,280	assay mix dependent/112/assay dependent
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no	no/—
Uses washable cuvettes/Replacement frequency	yes/2-yr warranty, semi-permanent	yes/2-year warranty, semi-permanent
Minimum sample volume aspirated precisely at one time	3 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	optional/no	yes/yes
Requires dedicated water system/Water consumption per hour	yes/16 L	yes/up to 16 L
Noise generated in decibels	60	64
Dedicated pediatric sample cup/Dead volume	yes/40 µL (samples directly from bullet)	yes/20 µL (chemistry)
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	—
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & 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	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/up to 90 days/up to 60 days/14 days	every 24 hours/up to 90 days/up to 60 days/up to 90 days
Automatic shutdown/Startup programmable	none required	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2:23 min. (from standby), 91 specimens	<1 min, 90 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	2:22 min. (from standby), 91 specimens	<1 min, 90 specimens
• Album., bili. direct & total, AST, ALT, ALP	12:32 min. (from standby), 76 specimens	approx. 6.5 min, 90 specimens
Typical time delay from ordering stat test to aspiration of sample	16 sec	<1 min
How often QC required/Onboard SW capability to review QC	24 hr/yes	24 hours/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 (additional cost)
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, Citation, Medlab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps	Cerner, Misys, Meditech, Citation, Medlab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps
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	yes, Beckman Coulter automation	yes (If cleaved, DxI and DxC systems can interface w/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	—/—	—/—
Average time to complete maintenance by lab personnel	daily: none; weekly: 10 min (tech time); monthly: 18 min (tech time)	daily: <10 min; weekly: <10 min; monthly: <18 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/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 (provided by vendor)	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; REMISOL Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification	parallel processing of immunoassay & chemistry tests on a single system; ClozCap technology (closed-tube aliquotting & closed-tube sampling) eliminates manual processes; chemistry & immunoassay reagent packs identical across UniCel and Access systems; immunossay: high-throughput analyzer; uses chemiluminescent assay technology and reagent packs for consistent results; loads consumables on the fly; chemistry: serum indices/polychromatic correction; clot detection and correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring w/semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat TAT; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification

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Chemistry analyzers for mid- and high-volume laboratories

Part 7 of 17	MID Carolina Liquid Chemistries Corp. Patti Shugart contactsales@carolinachemistries.com 391 Technology Way Winston-Salem NC 27101 877-722-8910 www.carolinachemistries.com	MID Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com
Name of instrument/First year sold in U.S.	BioLis 24i/2008	AU480/2009
List price/Total No. sold in 2008	45,000/30+	$140,000/—
No. units in clinical use in U.S./Outside U.S.	200/>3,000	—/—
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S.	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	batch, random access, discrete, continuous random access/open reagent system	random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	cup, bar-coded tubes, stat/benchtop	rack & stat carousel/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	20 × 31 × 25/5	47.5 × 57.1 × 30/47
No. of tests for which analyzer has FDA-cleared applications	100	130
Tests clinically released in last 12 months	direct (no-pretreatment) HbA1c and cystatin C	cystatin C, homocysteine, total bile acids, TIBC, master curve cal set (C3, C4, transferrin, ASO)
Tests cleared but not clinically released	Lp-PLA2	—
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
Tests in development	vitamin D, RPR syphilis	—
User-defined methods implemented for what analytes	—	fructosamine, oxycodone, topiramate
Methods supported/immunoassay methods	photometry, potentiometry/—	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	39	up to 63
No. of different assays programmed, calibrated at once	39	120
No. of user-definable (open) channels/No. active simultaneously	39/39	117/60
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	39/300 (3 × 100)	76/100–1,333
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/14 days/yes	5 days/30 days/yes (4° to 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	4 hours/40/39	varies/up to 102/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	yes/6 months	yes/permanent
Minimum sample volume aspirated precisely at one time	3 µL	1 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	no (optional)/yes (no w/ optional water pump)
Requires dedicated water system/Water consumption per hour	no/3.5 L	yes/20 L per hr average peak consumption
Noise generated in decibels	—	60
Dedicated pediatric sample cup/Dead volume	yes/30 µL	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved)/—	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/no	yes/yes
Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hours/14 days/14 days/14 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	12 min, 160 specimens	<5 min, 200 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	1 hour, 60 specimens	<5 min, 80 specimens
• Album., bili. direct & total, AST, ALT, ALP	14 min, 240 specimens	<9 min, 67 specimens
Typical time delay from ordering stat test to aspiration of sample	5 min	<2 min
How often QC required/Onboard SW capability to review QC	2 levels per operational shift; shortest interval: 8 hours; longest: 24 hours/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	yes, onboard/yes (additional cost)	onboard/no (optional)
Interfaces up and running in active user sites with	all common LISs	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
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	no	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	no/no/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	within 24 hours/yes	<24 hr/yes
Mean time between failures/To repair failures	—/—	average 2 calls per yr/<24 hr
Average time to complete maintenance by lab personnel	weekly: 20 min; monthly: visual inspections, <5 min	daily: 5 min; weekly: 12 min; monthly: 45 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/no	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site/yes	3–5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	$5,500	inquire
Distinguishing features (provided by vendor)	small size and large menu; most analyzers with this menu are floor models; 39 onboard chemistries can run general chemistries and special chemistries from CMPs to D-dimer, cystatin C, insulin and more	Olympus SupportVision, an Internet-based, real-time monitoring system for proactive services; standardization with family of chemistry immuno systems— the AU400e, AU640e, AU680, AU2700, and AU5400; broad test menu of 130 methods delivers standardized results for improved patient management and streamlined operation

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Chemistry analyzers for mid- and high-volume laboratories

Part 8 of 17	MID Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com	HIGH Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com
Name of instrument/First year sold in U.S.	AU680/2008	AU2700/2000
List price/Total No. sold in 2008	$213,000/30	$320,000/22
No. units in clinical use in U.S./Outside U.S.	70/>100	120/>600
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 × W × D)/Instrument footprint in sq ft	42.5 × 76.8 × 50/94.5	50 × 79 × 45/92
No. of tests for which analyzer has FDA-cleared applications	130	130
Tests clinically released in last 12 months	HbA1c automated pretreatment, cystatin C, homocysteine, total bile acids, TIBC, master curve cal set (C3, C4, transferrin, ASO)	cystatin C, homocysteine, total bile acids, TIBC, master curve Cal set (C3, C4, transferrin, ASO)
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	—	o
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	none	none
Tests in development		
User-defined methods implemented for what analytes	fructosamine, oxycodone, topiramate	fructosamine, oxycodone, topiramate
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 63	up to 51
No. of different assays programmed, calibrated at once	120	99
No. of user-definable (open) channels/No. active simultaneously	116/60	95/48
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	63/100–1,500	48/100–4,000
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4° to 12°C)	120 hr/30 days/yes (4° to 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/—	no/—
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 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	60	<65
Dedicated pediatric sample cup/Dead volume	no/—	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & 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 aspiration 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 year/<24 hr	<4 calls per year/<24 hr
Average time to complete maintenance by lab personnel	daily: 4 min; weekly: 27 min; monthly: 45 min	daily: 5 min; weekly: 42 min; monthly: 15 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 (provided by vendor)	Olympus SupportVision, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400e, AU480, AU640e, AU2700, and AU5400; broad test menu of 130 methods; designed as a standalone or with direct-track sampling capability; fully automated HbA1c option available; newly reduced sampling volume; laboratory definable enhanced options for reflex, repeat, pre-dilution, auto-calibration, auto-QC, and multi-lot advanced calibration	Olympus SupportVision, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400e, AU480, AU640e, AU2700, and AU5400; broad test menu of 130 methods delivers standardized results for improved patient management and streamlined operation

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Chemistry analyzers for mid- and high-volume laboratories

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	HIGH Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com	HIGH Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com
Name of instrument/First year sold in U.S.	AU5421 with dual ISE/2001	AU5431 with dual ISE/2001
List price/Total No. sold in 2008	$465,000/—	$575,000/—
No. units in clinical use in U.S./Outside U.S.	200/450	200/450
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/floor standing	rack/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	50 × 148 × 45/46.25	50 × 200 × 45/62.5
No. of tests for which analyzer has FDA-cleared applications	130	130
Tests clinically released in last 12 months	HbA1c automated pretreatment, cystatin C, homocysteine, total bile acids, TIBC, master curve cal set (C3, C4, transferrin, ASO)	HbA1c automated pretreatment, cystatin C, homocysteine, total bile acids, TIBC, master curve cal set (C3, C4, transferrin, ASO)
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	—	—
User-defined methods implemented for what analytes	fructosamine, oxycodone, topiramate	fructosamine, oxycodone, topiramate
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 99
No. of different assays programmed, calibrated at once	99	99
No. of user-definable (open) channels/No. active simultaneously	95/95	95/95
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	48 × 2/100–4,000	48 × 3/100–4,000
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4° to 12°C)	120 hr/30 days/yes (4° to 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/—	no/—
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/—	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl.)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & 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 specimens	—, max 600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	—, max 600 specimens	—, max 600 specimens
• Album., bili. direct & total, AST, ALT, ALP	—, max 533 specimens	—, max 800 specimens
Typical time delay from ordering stat test to aspiration 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	<9 calls per year/<24 hr	<9 calls per year/<24 hr
Average time to complete maintenance by lab personnel	daily: 30 min; weekly: 81 min; monthly: 40 min	daily: 30 min; weekly: 81 min; monthly: 40 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 (provided by vendor)	Olympus SupportVision, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400e, AU480, AU640e, AU680, AU2700, and AU5400; broad test menu of 130 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 AU400e, AU480, AU640e, AU680, AU2700, and AU5400; broad test menu of 130 methods delivers standardized results for improved patient management and streamlined operation

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Chemistry analyzers for mid- and high-volume laboratories

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	HIGH	MID
	Ortho-Clinical Diagnostics Jeff Coons jcoons1@its.jnj.com 1001 U.S. Route 202 Raritan, NJ 08869 908-218-8637 www.orthoclinical.com	Ortho-Clinical Diagnostics Bob Geen bgeen@its.jnj.com 1001 U.S. Route 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com
Name of instrument/First year sold in U.S.	VITROS 5600 Integrated System/2008	VITROS 350/2005
List price/Total No. sold in 2008	$410,000/15	$110,000/—
No. units in clinical use in U.S./Outside U.S.	40/30	—/—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. & United Kingdom	U.S./U.S./U.S.
Operational type/Reagent type	random access/self-contained multi-use cartridges, packages, slides	batch, random access, discrete, continuous random access/self-contained single-use cartridges, packages, slides
Sample handling system/Model type	universal sample tray/floor-standing	rack/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	64.5 × 109.7 × 33.5/25.6	47 × 45.5 × 28/8.8
No. of tests for which analyzer has FDA-cleared applications	111	70
Tests clinically released in last 12 months	111	none
Tests cleared but not clinically released	103	—
Tests not available in U.S. but submitted for 510(k) clearance	—	none
Tests not available in U.S. but available in other countries	HBeAg, aHBe, rub IgM, tox IgG, tox IgM, CMV IgG, CMV IgM	none
Research-use-only assays	—	none
Tests in development	HIV Ag/Ab Combo, syphilis TPA, intact PTH, aHBE, HBeAg, pre-eclampsia	none
User-defined methods implemented for what analytes	—	—
Methods supported/immunoassay methods	photometry, potentiometry (ISE), thin film reflectance/homogeneous EMIT, microparticle agglutination, enhanced chemiluminescence	potentiometry, colorimetric, rate, immuno-rate
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	106	up to 60
No. of different assays programmed, calibrated at once	106	up to 60
No. of user-definable (open) channels/No. active simultaneously	20/10	—/—
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	106/100	up to 60/18, 50, 60
Shortest/median onboard reag. stability/Refrigerated onboard	48 hours/30 days/yes (2° to 8°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	no	—
Walkaway capacity in minutes/Specimens/Tests-assays	varies/90/11,440	varies/40/3,600
System is liquid or dry	liquid and dry	dry
Uses disposable cuvettes/Max. No. stored	yes/348	—
Uses washable cuvettes/Replacement frequency	no/—	—
Minimum sample volume aspirated precisely at one time	2	6 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	available (not included)/no
Requires dedicated water system/Water consumption per hour	no/0	no/—
Noise generated in decibels	idle: 60 dB; operational: 65 dB	61
Dedicated pediatric sample cup/Dead volume	yes/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/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	no/no
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	no/no	yes/no
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	reagent lot change/reagent lot change/reagent lot change/reagent lot change	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	5.5 min, 400 specimens	6 min, 240 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.75 min, 625 specimens	6 min 24 sec, 287 specimens
• Album., bili. direct & total, AST, ALT, ALP	7.5 min, 360 specimens	6 min 40 sec, 261 specimens
Typical time delay from ordering stat test to aspiration of sample	approx. 10 seconds	12 sec
How often QC required/Onboard SW capability to review QC	once per 24 hours/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	onboard/no (optional)
Interfaces up and running in active user sites with	all major LIS vendors	all major LIS vendors
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	LOINC database	—
Interface avail. (or will be) to automated specimen handling system	yes, enGEN	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	4–8 hours/yes	varies by location, usually 4–8 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
Onboard maintenance records/Maint. training demo module	yes, includes audit trail/yes	no/yes
Training provided with purchase/Advanced oper. training avail.	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)	varies	varies
Distinguishing features (provided by vendor)	ability to add or remove reagents, consumables, and empty solid and liquid waste while operating; sample-centered processing integration approach eliminates need to move sample trays or aliquote samples between chemistry and immunoassay processing modules; ability to integrate chemistry, immunoassay, and infectious-disease testing, and process them in parrallel; integrated MicroTip technology expands menu availability, such as DATs, TDMs, specific proteins, %hbA1c and user-defined channels. MicroSensor technology detects interfering levels of hemolysis, icterus and turbidity; eConnectivity assists with remote diagostics, software, and test parameter downloads and updates	MicroSlide technology delivers low cost per reportable result and high reagent efficiency without the maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required 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- and high-volume laboratories

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	HIGH	MID
	Ortho-Clinical Diagnostics Bob Geen bgeen@its.jnj.com 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com	Randox Laboratories Ltd marketing@randox.com 4065 Oceanside Blvd., Ste. Q Oceanside, CA 92056 760-639-1506 www.randox.com
Name of instrument/First year sold in U.S.	VITROS 5,1 FS Chemistry System/2004	RX Imola/2006
List price/Total No. sold in 2008	$225,000/—	—/—
No. units in clinical use in U.S./Outside U.S.	>500/—	—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	Japan/Japan/United Kingdom
Operational type/Reagent type	random access, discrete, continuous random access/self-contained single-use cartridges, packages, slides; user-defined assay capability	random access/self-contained multi-use cartridges, packages, slides
Sample handling system/Model type	universal sample tray/floor standing	ring/benchtop
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	52.5 × 92.2 × 33.4/21.4	23 × 38 × 28/3.1 × 2.3 sq ft
No. of tests for which analyzer has FDA-cleared applications	>100	62 different analytes
Tests clinically released in last 12 months	—	—
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	cystatin C, s LDL, amphetamines, barbituates, benzodiazepines, canabinoids, cocaine, ecstasy, EDDP, methadone, opiates
Tests not available in U.S. but available in other countries	none	—
Research-use-only assays	none	acetic acid, Apo E, Apo CIII, Apo CII, Apo AII, α-1-antitrypsin, α-1-acid glycoprotein, bile acids, butyryl cholinesterase, enzymatic chloride, glutamate dehydrogenase, glutathione reductase, haptoglobin, HBDH, leucine arylamidase, L-lactate, L-lactic acid, malic acid, total antioxidant status, α-hydroxybutyrate, glutathione peroxidase, glycerol, NEFA, superoxide dismutase, zinc
Tests in development	—	haptoglobin, oxycodone, propoxyphene, caeruloplasmin, D-dimer, salicylate, paracetomol, cotinine, fully automated HbA1c
User-defined methods implemented for what analytes	—	acetaminophen, drugs of abuse, salicylate, cyclosporin, alcohol, glycerol-3-phosphate, oxidase, phospholipids, maltose, T4, T-uptake
Methods supported/immunoassay methods	photometry, potentiometry, immuno-rate, turbidimetric, colorimetric, spectrophotometeric/—	photometry, potentiometry (ISE), immunoturbidimetric, latex enhanced immunoturbidimetric/—
No. of direct ion selective electrode channels	3 (direct)	3
No. of different measured assays onboard simultaneously	up to 125	60
No. of different assays programmed, calibrated at once	up to 125	60
No. of user-definable (open) channels/No. active simultaneously	20/10	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	up to 125/up to 100	60/50–11,250
Shortest/median onboard reag. stability/Refrigerated onboard	48 hr/14 days/yes (temp: 10°C)	8 hr/28 days/yes (8° to 15°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	664/72/76,115
System is liquid or dry	dry, liquid ready to use	liquid
Uses disposable cuvettes/Max. No. stored	yes/348	no/90
Uses washable cuvettes/Replacement frequency	no/disposable	yes/5 yr
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	available (not included)/no	no/yes
Requires dedicated water system/Water consumption per hour	no/—	yes/18 L
Noise generated in decibels	<60	75
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/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, UPC, Codabar, codes 39 &128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	—
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	system autodilutes	yes/yes
Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	reagent lot changes	daily/28 days/7 days/28 days
Automatic shutdown/Startup programmable	no/no (instrument maintained in ready mode)	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	5.5 min, 400 specimens	13 min 15 sec, 80 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.75 min, 625 specimens	13 min 43 sec, 80 specimens
• Album., bili. direct & total, AST, ALT, ALP	7.5 min, 360 specimens	13 min 15 sec, 67 specimens
Typical time delay from ordering stat test to aspiration of sample	~10 sec	30 sec
How often QC required/Onboard SW capability to review QC	once per 24 hr/yes	recommend 2 levels run per day/shortest: daily; longest: customer's discretion/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes/yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard (optional add-on)/no	onboard/no
Interfaces up and running in active user sites with	all major LIS vendors	no
Bidirectional interface capability	yes (broadcast download & host query)	yes (host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	LOINC database	—
Interface avail. (or will be) to automated specimen handling system	yes (enGen, plus any open point in space systems)	no
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	varies by location; usually 4–8 hr/yes	within 24 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 9 min; weekly: 5 min; monthly: 31 min	daily 5 min; weekly: 15 min
Onboard maintenance records/Maint. training demo module	in development/yes	no/no
Training provided with purchase/Advanced oper. training avail.	yes/yes	3 days on site/yes
Annual service contract cost (24 h/7 d)	varies	—
Distinguishing features (provided by vendor)	MicroSlide technology delivers low cost per reportable result and high reagent efficiency without the maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC required once each day and calibration intervals up to lot change with min. interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides or disposable cuvette; eConnectivity interactive management system onboard	benchtop analyzer offers consolidation of testing in an established compact platform; dedicated multi-speed paddle mixers allow optimum mixing for each assay; direct ISE module prevents pseudohyponatremia

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Chemistry analyzers for mid- and high-volume laboratories

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MID

Roche Diagnostics
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Indianapolis, IN 46250
800-428-5074 www.roche.com

MID

Roche Diagnostics
Sheila Brewer sheila.brewer@roche.com
9115 Hague Rd.
Indianapolis, IN 46250
317-521-2000 us.labsystems.roche.com

Name of instrument/First year sold in U.S.	cobas Integra 800/2001 (cobas Integra introduced 1995)	cobas c501 analyzer/2006
List price/Total No. sold in 2008	$265,000/—	—/>250
No. units in clinical use in U.S./Outside U.S.	>600/>2,000	>550/—
Country where designed/Manufactured/Where reagents mftd.	Switzerland/Switzerland/multiple countries random access, discrete, continuous random access/self-contained multi-use cartridges-packages-slides	Japan/Japan/U.S. & Germany
Operational type/Reagent type	sample racks: RD 5-position rack/floor standing	continuous random access/self-contained multi-use cartridges-packages-slides, open channels available
Sample handling system/Model type	47.3 × 74.8 × 35.4/—	five-position rack/floor-standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	139	49.2 × 71.8 × 40/19.9
No. of tests for which analyzer has FDA-cleared applications	—	88
Tests clinically released in last 12 months	kappa, lambda, cystatin C, homocysteine	lithium, TinaQuant HbA1c, kappa, lambda, cystatin C, HbA1c hemolysate
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for 510(k) clearance	kappa, lambda	—
Tests not available in U.S. but available in other countries	LDH (P›L), ALP (DGKC), AT3, CHE-D, GLDH, HBDH, lipoprotein(a), kappa/lambda light chains	alpha-1 microglobulin, %CDT, HBDH, AT3, ACP, kappa, lambda, GLDH
Research-use-only assays	sirolimus, tacrolimus, EDDP, oxycodone	none
Tests in development	—	trig GB, cyclosporine
User-defined methods implemented for what analytes	photometry	—
Methods supported/immunoassay methods	turbidimetric, potentiometry, fluorescence polarization	photometry, potentiometry (ion selective electrode)/micro-particle
No. of direct ion selective electrode channels	4	3
No. of different measured assays onboard simultaneously	72	up to 63
No. of different assays programmed, calibrated at once	72	>100
No. of user-definable (open) channels/No. active simultaneously	20/20	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	72/50–800	up to 60 (plus 3 ISE)/varies (100–800)
Shortest/median onboard reag. stability/Refrigerated onboard	336 hr/84 days/yes (8°C)	21 days/>60/yes (5° to 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	450/180/4,000	varies/250/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	yes/3,600	no
Uses washable cuvettes/Replacement frequency	no/—	yes/monthly
Minimum sample volume aspirated precisely at one time	2 µL	1.5 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	yes (direct connection, type I CLSI)/5–7 L	yes/40 max, 20 mean
Noise generated in decibels	58.5	<65
Dedicated pediatric sample cup/Dead volume	yes/approx. 50–70 µL	yes/50µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes (on sample transport, shortly before sample is aspirated, 2 of 5 interl., Codabar, code 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & 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/once per lot/varies/once per lot
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	5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	8.6 min, 99 specimens	7 min, 150 specimens
• Album., bili. direct & total, AST, ALT, ALP	9.8, 118 specimens	10 min, 100 specimens
Typical time delay from ordering stat test to aspiration of sample	1 min	<1 min
How often QC required/Onboard SW capability to review QC	typically once per 24 hr/yes	typically once per 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 (included)
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 (both supported)
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	—	Web site
Interface avail. (or will be) to automated specimen handling system	no	yes, Roche Diagnostics MPA system
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
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: <1 min; weekly: <5 min; monthly: none	daily: 20 min; weekly: 25 min; montly: 40 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	days on site varies, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	varies	varies
Distinguishing features (provided by vendor)	comprehensive test menu includ. HbA1c; reagent cassette requires no operator prep. or special handling (from refrigerator to system with no warmup time); 97% of reagents are liquid, ready to use; system auto. reconstitutes if necessary; system forecasts daily reagent requirements based on history; operator maintenance auto. scheduled by system, based on actual use; clot and bubble detection, and accommodates universal 5-position Roche rack for modular systems and Elecsys IA analyzers	flexible/modular system; can be upgraded on site; ready-to-use bar-coded reagents; connectivity to Roche Preanalytics; requires small sample volumes <2–10 µL

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Chemistry analyzers for mid- and high-volume laboratories

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	HIGH	MID
	Roche Diagnostics Leslie Casciato leslie.casciato@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 ext. 3099 us.labsystems.roche.com	Roche Diagnostics Sheila Brewer sheila.brewer@roche.com 9115 Hague Rd. Indianapolis, IN 46250 317-521-2000 us.labsystems.roche.com
Name of instrument/First year sold in U.S.	Integrated Modular Analytics/1998	cobas c501/e601/2006
List price/Total No. sold in 2008	varies	—/>250
No. units in clinical use in U.S./Outside U.S.	>800/>5,000	>880/—
Country where designed/Manufactured/Where reagents mftd.	multiple countries/multiple countries/multiple countries	Japan/Japan/U.S., Germany
Operational type/Reagent type	continuous random access/self-contained multiuse cartridges, packages, slides	continuous random access/self-contained multi-use cartridges, packages, slide
Sample handling system/Model type	5-position rack/floor standing	five-position rack/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	varies per configuration/varies	4.1 ft × variable × 3.3 ft (base = 9.9 ft)/32.67
No. of tests for which analyzer has FDA-cleared applications	>140	127
Tests clinically released in last 12 months	toxo IgG, anti-TSH receptor, rubella IgG, toxo IgG	lithium, TinaQuant HbA1c, toxo IgG, kappa, lambda, cystatin C, PSA (screening), free PSA, HBsAg, HBsAg conf., anti-HBs, anti-TSH receptor, rubella IgG
Tests cleared but not clinically released	—	HbA1c, hemolysate
Tests not available in U.S. but submitted for 510(k) clearance	rubella IgM, toxo IgM, anti-HCV	toxoplasma IgM, rubella IgM, anti-HCV
Tests not available in U.S. but available in other countries	Lp(a), kappa, lambda, P/NP, TG	alpha-1 microglobulin, %cDT, HBDH, AT3, ACP, kappa, lambda, GLDH
Research-use-only assays	none	none
Tests in development	PAPP-A, P1NP, anti-CMV IgG, anti-CMV IgM, homocysteine, mycophenolic acid, tacrolimus, hepatitis A, hepatitis B, HIV combi, IL-6, sCD40 ligand, CA 72-4, cyfra 21-1/NSE, NSE	P1NP, thyroglobulin, CA 72-4, NSE, cyfra 21-1, anti-CMV IgG, anti-CMV IgM, HIV combi, anti-HAV, anti-HAV IgM, anti-Hbc, anti-HBc IgM, anti-HBe, HBeAg, oxycodone, cyclosporine, mycophenolic acid, sirolimus, tacrolimus
User-defined methods implemented for what analytes	yes, varies	—
Methods supported/immunoassay methods	photometry, potentiometry/HbA1c	photometry, potentiometry (ion selective electrode)/micro-particle, ECL
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	47–>100	88
No. of different assays programmed, calibrated at once	47–>100	>100
No. of user-definable (open) channels/No. active simultaneously	varies	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	47–100/100–3,000	up to 85 (plus 3 ISE)/varies (100–800)
Shortest/median onboard reag. stability/Refrigerated onboard	72 hr/28 days/yes (2° to 12°C)	21 days/>60 days/yes (5° to 20°)
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	limited	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/300/varies	varies/250/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	no
Uses washable cuvettes/Replacement frequency	yes/monthly	yes/once per month
Minimum sample volume aspirated precisely at one time	2 µL	1.5 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	yes/varies (50 L/hr/mod)	yes/40 L per hour (e501), 20 L per hour (e601)
Noise generated in decibels	<62	≤65
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/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & 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	24 hr/varies/bottle change/lot change	24 hr/once per lot/varies/once per lot
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2	3.5 min, 300–600 specimens	7 min, 150 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 min, 160–600 specimens	10 min, 100 specimens
• Album., bili. direct & total, AST, ALT, ALP	10.5 min, 133–1,200 specimens	<1 min
Typical time delay from ordering stat test to aspiration of sample	<1 min	typically once per 24 hr
How often QC required/Onboard SW capability to review QC	24 hr/yes	yes/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes
QC results transferred automatically to LIS	yes	onboard/no
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	all major LIS vendors
Interfaces up and running in active user sites with	all major LIS vendors	yes (broadcast download & host query)
Bidirectional interface capability	yes (broadcast download & host query)	yes
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	Website
How labs get LOINC codes for reagent kits	database	yes, Roche MPA system
Interface avail. (or will be) to automated specimen handling system	yes (Roche Pre-Analytical Modular)	yes/yes/yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	≤8 hr/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	8 hr/yes	TBD/TBD
Mean time between failures/To repair failures	260 days/3.5 hr	—/—/—
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 15 min	yes (includes audit trail of who replaced parts)/yes
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	varies on site, 5 days at vendor offices/yes
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	varies
Annual service contract cost (24 h/7 d)	varies	flexible modular system—can be upgraded on-site; second-generation
Distinguishing features (provided by vendor)	Roche Hitachi chemistry and automation reliability and more than 20 years of experience; capable of consolidating 95 percent of test menu on one high-throughput Integrated Modular System; system can be connected directly to preanalytical automation with 12 modules per configuration; flexible, expandable to lab's changing needs; up to four modules per system	integrated platform; ready-to-use bar-coded reagents; automation connectivity; small sample size

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Chemistry analyzers for mid- and high-volume laboratories

Part 14 of 17	MID Siemens Healthcare Diagnostics Inc. Diane Bandy diane.m.bandy@siemens.com 1717 Deerfield Rd. Deerfield, IL 60015 302-631-9435 www.siemens.com/diagnostics	MID Siemens Healthcare Diagnostics Inc. Pamela Curtin pamela.curtin@siemens.com 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics
Name of instrument/First year sold in U.S.	Dimension Vista 500 Intelligent Lab System/2009	ADVIA 1200/2005
List price/Total No. sold in 2008	$278,271/—	$189,000/—
No. units in clinical use in U.S./Outside U.S.	—/—	—/—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S., Germany	Japan/Japan/Ireland
Operational type/Reagent type	continuous random access/self-contained single-use cartridges, packages	random access/open reagent system
Sample handling system/Model type	rack and aliquot plate system	carousel/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	55.5 × 84.75 × 43.875/26	33.5 × 48 × 44/1.04 square meters
No. of tests for which analyzer has FDA-cleared applications	>115, includes vendor-supported applications	>80
Tests clinically released in last 12 months	10	no pretreat HbA1C serum benzo, barb, TCA, cystatin C, concentrated chemistry reagents
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	IgG subclasses	—
Tests not available in U.S. but available in other countries	TPSA, FPSA, IgG subclasses	—
Research-use-only assays	—	—
Tests in development	CA 125, CA 15-3, CA 19-9, additional cancer markers, fertility panel, plasma proteins, hormones, infectious disease	—
User-defined methods implemented for what analytes	specialty chemistry, plasma proteins, some TDMs and DATs	open-system architecture, CK-MB, myoglobin, fructosamine, β-2 microglobulin, D-dimer, caffeine, TCA, Lp(a)
Methods supported/immunoassay methods	nephelometry/ LOCI advanced chemiluminescence, EMIT technology, particle enhanced turbidimetric immunoassay (PETINIA), affinity column mediated immunoassay (ACMIA)	photometry, potentiometry, turbidimetric/—
No. of direct ion selective electrode channels	3 (indirect)	3
No. of different measured assays onboard simultaneously	>100	40 colorimetric, 3 ISE
No. of different assays programmed, calibrated at once	>100	100
No. of user-definable (open) channels/No. active simultaneously	10/>100	100/43
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	144/20–1,200	43/700
Shortest/median onboard reag. stability/Refrigerated onboard	24 hours/30 days/yes (2° to 8°C)	7 days/45 days/yes
Multiple reag. configurations supported	no	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	225/150/3,150	20,000 photometrics
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	yes/>1,600	no/231
Uses washable cuvettes/Replacement frequency	yes/automatic as needed	yes/4 mos
Minimum sample volume aspirated precisely at one time	50 µL	1 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/yes
Requires dedicated water system/Water consumption per hour	yes/10.8 L	yes/20 L
Noise generated in decibels	64	<60
Dedicated pediatric sample cup/Dead volume	no/10 µL, if using small sample cup	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., UPC, Codabar, codes 39 & 128)/yes	yes/—
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & 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	no/no	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	4 hours, automatic/30–90 days/30 days/30 days	daily/45 days/30 days/14 days
Automatic shutdown/Startup programmable	no/no	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2 mins, 166 panels	5 min
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 mins, 125 specimens	10 min
• Album., bili. direct & total, AST, ALT, ALP	9.4 mins, 83 specimens	10 min
Typical time delay from ordering stat test to aspiration of sample	<2 mins	10 sec
How often QC required/Onboard SW capability to review QC	24 hours/yes	per laboratory protocol/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	yes/—
Interfaces up and running in active user sites with	all major LIS vendors	Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens, others
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	no	yes
How labs get LOINC codes for reagent kits	—	yes
Interface avail. (or will be) to automated specimen handling system	yes, StreamLab Automation connectivity is in development	—
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 hours/yes	varies by location, generally <4 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: <10 mins, monthly: 10–20 mins	—
Onboard maintenance records/Maint. training demo module	no/yes	no/yes
Training provided with purchase/Advanced oper. training avail.	4 days at vendor offices/yes	yes/no
Annual service contract cost (24 h/7 d)	—	na
Distinguishing features (provided by vendor)	ultra integrated chemistry platform with LOCI advanced chemiluminescence and nephelometry onboard; enhanced workflow efficiency with automated features, such as autocalibration, auto QC, and system twinning; proactive service and support through RealTime Solutions services	clot detection; serum indices; 1,200 tests per hour; auto reruns, dilutions, repeats, reflex testing; open system for third-party assays; part of family of chemistry systems (ADVIA 2400 & ADVIA 1800) 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- and high-volume laboratories

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	MID	HIGH
	Siemens Healthcare Diagnostics Inc. Pamela Curtin pamela.curtin@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Inc. Pamela Curtin pamela.curtin@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics
Name of instrument/First year sold in U.S.	ADVIA 1800/2006	ADVIA 2400/2003
List price/Total No. sold in 2008	$299,000/—	$305,000/—
No. units in clinical use in U.S./Outside U.S.	—/—	—/—
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/Ireland	Japan/Japan/Ireland
Operational type/Reagent type	random access/open reagent system	random access/open reagent system
Sample handling system/Model type	carousel rack handler option, automation option/floor standing	carousel, rack handler option, automation option/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	45 × 58 × 34/14	1,157 × 1,711 × 934 mm/—
No. of tests for which analyzer has FDA-cleared applications	>80	>80
Tests clinically released in last 12 months	no pretreat HbA1C serum benzo, barb, TCA, Cystatin C, concentrated chemistry reagents	no pretreat HbA1C serum benzo, barb, TCA, Cystatin C, concentrated chemistry reagents
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	neonatal bilirubin, tricyclics, serum benzo, serum barb	none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays	none	none
Tests in development	ecstasy	—
User-defined methods implemented for what analytes	open system architecture, CK-MB, myoglobin, fructosamine, caffeine, TCA, Lp(a), β-2-mincroglobulin, D-dimer	open system architecture, CK-MB, myoglobin, fructosamine, caffeine, TCA, Lp(a), β-2-microglobulin, D-dimer
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetrics	photometry, potentiometry turbidimetric/—
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	52 colorimetric, 3 ISE	46 colormetric, 3 ISE
No. of different assays programmed, calibrated at once	100	100
No. of user-definable (open) channels/No. active simultaneously	100/52 (plus 3 ISE)	100/49
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	52/850	49/850
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/45 days/yes	7 days/45 days/yes
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	32,000 photometrics	32,000 photometric
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/221	no/340
Uses washable cuvettes/Replacement frequency	yes/every 4 months	yes/every 4 months
Minimum sample volume aspirated precisely at one time	2 µL of diluted specimen	2 µL of diluted specimen
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes (or sink)
Requires dedicated water system/Water consumption per hour	yes/25 L	yes/40 L
Noise generated in decibels	<45	<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/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 inter., Codabar, codes 39 & 128)/—	yes/—
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	daily/45 days/30 days/14 days	daily/45 days/30 days/14 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	5 min, —	5 min, —
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	10 min, —	10 min, —
• Album., bili. direct & total, AST, ALT, ALP	10 min, —	10 min, —
Typical time delay from ordering stat test to aspiration of sample	10 sec	10 sec
How often QC required/Onboard SW capability to review QC	per laboratory protocol	per laboratory protocol/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes/—	yes/—
Interfaces up and running in active user sites with	Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Computer Service & Support Q, Fletcher Flora, HDS, PSA consultants, Siemens, others	Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Computer Service & Support Q, Fletcher Flora, HDS, PSA consultants, Siemens, 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	yes	yes
How labs get LOINC codes for reagent kits	via 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	—/yes	varies by location, generally <4 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	automated daily maintenance	automated daily maintenance
Onboard maintenance records/Maint. training demo module	yes/yes	—/yes
Training provided with purchase/Advanced oper. training avail.	yes/yes	yes/yes
Annual service contract cost (24 h/7 d)	na	—
Distinguishing features (provided by vendor)	comprehensive menu; >80 assays, including chemistry, special chemistry, TDMs, TAUs, special proteins; long-life ISEs; 90,000 tests; unlimited open channels; third-party applications available; three-second cycle time; 1,800 tests per hour; automation ready; concentrated reagents available for high-volume chemistries, walkaway capability; clot detect; liquid level sense; auto reruns, dilutions, and repeats	system provides workstation consolidation with a comprehensive menu, including routine chemistry, TDMs, TAUs, special chemistry, and special proteins; offers unlimited open channels and walkaway capability (>450 specimens) when combined with the universal rack handler; offers micro-volume sample and reagent technology, multiple reagent wedge sizes, two-second cycle time; fast throughput; sample-saver technology allows automatic repeats, dilutions, and reflex testing

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Chemistry analyzers for mid- and high-volume laboratories

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MID

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HIGH

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	MID	HIGH
Name of instrument/First year sold in U.S.	Dimension RxL Max/Max Suite Integrated Chemistry System/2003/Dimension RxL Integrated Chemistry System/1997	Dimension Vista Intelligent Lab System 1500/2006
List price/Total No. sold in 2008	—/—	$543,500 (USD)/—
No. units in clinical use in U.S./Outside U.S.	—	200/300
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	U.S./U.S./U.S. and Germany
Operational type/Reagent type	batch, random access, continuous random access/self-contained multi-use flex containers	batch, random access, continuous random access/self-contained multi-use cartridges-packages
Sample handling system/Model type	segmented sample wheel/floor standing	sample rack and aliquot plate system/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	44 × 62.5 × 30.5/13.2	55 × 84 × 43/26 sq ft
No. of tests for which analyzer has FDA-cleared applications	>90	>115
Tests clinically released in last 12 months	iron (plasma), revised CSA, monoclonal NT-proBNP, sirolimus, myeloperoxidase, liquid lipase	10
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	IgG subclasses
Tests not available in U.S. but available in other countries	none	TPSA, FPSA, IgG subclasses
Research-use-only assays	none	—
Tests in development	MPA, oxycodone, buprenorphine, meperidine, tramadol	CA-125, CA15-3, CA19-9, fertility panel, plasma proteins, cardiac, infectious disease, additional cancer markers
User-defined methods implemented for what analytes	propoxyphene, methaqualone, serum tricyclic antidepressant, serum barbiturate, serum benzodiazepine	propoxyphene, methaqualone, serum tricyclic antidepressant, serum barbiturate, serum benzodiazepine, caffeine, amikacin
Methods supported/immunoassay methods	ACMIA, EMIT, PETINIA, photometry, potentiometry/heterogeneous, magnetic particle	photometry, potentiometry (ISE), advanced LOCI chemiluminescence technology, nephelometry, EMIT, PETINIA, PETIA, ACMIA, turbidimetric
No. of direct ion selective electrode channels	3 (indirect) ECO2 photometric	3 (indirect)
No. of different measured assays onboard simultaneously	47/91 with optional inventory management system	>100 methods simultaneously/>100 methods
No. of different assays programmed, calibrated at once	190	120+
No. of user-definable (open) channels/No. active simultaneously	10/10	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	44–88/max. 360	166/20-1,200 tests, flex
Shortest/median onboard reag. stability/Refrigerated onboard	48 hours/30 days/yes (2° to 8°C)	24 hours/30 days/yes
Multiple reag. configurations supported	yes	no
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	can be hours/60/>2,000 or >5,000 (with RMS)	>45 min/150/>8,400
System is liquid or dry	liquid, reconstitutes onboard	liquid
Uses disposable cuvettes/Max. No. stored	yes/12,000	yes/>1,500 washed, disposable cuvettes and 1,000 LOCI vessels
Uses washable cuvettes/Replacement frequency	no/—	yes/automatic
Minimum sample volume aspirated precisely at one time	2 µL	50 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption per hour	yes/3.2 L (3.2 to 5.0 L with optional inventory management system)	no/21.6 L per hour
Noise generated in decibels	<70	67
Dedicated pediatric sample cup/Dead volume	yes/10-20 µL	no (can use routine sample cup)/10-20 µL
Primary tube sampling/Pierces caps on primary tubes	yes, 5, 7, 10 mL/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/no	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/no	no/no
Autocalibration or autocalibration alert	yes (with 7.4 software)	yes
Calibrants stored onboard/Multipoint calibration supported	yes (Na, K, Cl)/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	every 2 hr-autocalibrate/—/60–90 days/30 days	automatic every 4 hr/30-90 days/30 days/30 days
Automatic shutdown/Startup programmable	—/—	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	36 sec (Na, K, Cl)/2 min w/ECO2, 300 ISE or 500 photometric tests/hr, 100 panels	2 min, 166
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 min, 300 ISE or 500 photometric tests/hr, 100 panels	5.5 min, 125
• Album., bili. direct & total, AST, ALT, ALP	9 min, 500 tests/hr or 83 panels	9.4 min, 83
Typical time delay from ordering stat test to aspiration of sample	24 sec	<2 min
How often QC required/Onboard SW capability to review QC	24 hrs/yes	24 hrs/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes
QC results transferred automatically to LIS	yes	yes, via EasyLink
Data mgmt. capability/Instrument vendor supplies LIS interface	optional add-on (EasyLink, Siemens)/yes (addt'l cost)	onboard/—
Interfaces up and running in active user sites with	all major LIS vendors	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	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes, Siemens StreamLab, SpecTrak
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	2–8 hr/yes	2–8 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 15 min	daily: 10 min; weekly: none; monthly: 10–20 min
Onboard maintenance records/Maint. training demo module	no/no	in development/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site, 4 days at vendor offices/yes	4 days on site, 4 days at vendor office/yes (online training available)
Annual service contract cost (24 h/7 d)	multiple types	varies—multiple types
Distinguishing features (provided by vendor)	integrates heterogenous immunoassays onboard with other chemistries; allows single platform for more than 95 percent of most requested tests; eliminates sample splitting between general tests and immunoassays	intelligent lab systems with customer-driven design, ultra-integration of technologies; LOCI advanced chemiluminescence and automation onboard for efficiency, simplicity, sensitivity, and convenience—all to provide a more efficient workflow for the laboratory; autocalibration and auto QC onboard; proactive services and support through RealTime Solutions

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Chemistry analyzers for mid- and high-volume laboratories

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MID

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Name of instrument/First year sold in U.S.	Dimension EXL Integrated Chemistry System (upgradeable w/LOCI Module)/2007	Dimension EXL with LM Integrated Chemistry System/2009
List price/Total No. sold in 2008	—/—	—/—
No. units in clinical use in U.S./Outside U.S.	—/—	—/—
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 multi-use cartridges/packages/slides	batch, random access, continuous random access/self-contained multi-use cartridges/packages/slides
Sample handling system/Model type	segmented sample wheel/floor-standing	segmented sample wheel/floor-standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	49 × 82 × 34 (without monitor)/19.4 (with printer shelf down)	49 × 82 × 44 (without monitor)/25.1 (with printer shelf down)
No. of tests for which analyzer has FDA-cleared applications	>90	>90
Tests clinically released in last 12 months	—	liquid lipase, LOCI cardiac troponin I, LOCI free thyroxine, LOCI thyroid stimulating hormone, LOCI NT-proBNP, LOCI LV NT-proBNP
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	—	—
Tests in development	—	LOCI free T3, LOCI B12, LOCI folate, MPA, sirolimus, total PSA, free PSA
User-defined methods implemented for what analytes	serum TCA, serum barbiturates, serum benzodiazepine, propoxyphene, methaqualone	serum TCA, serum barbiturates, serum benzodiazepine, propoxyphene, methaqualone
Methods supported/immunoassay methods	photometry, potentiometry, others/ACMIA, EMIT, PETINIA and turbidimetric	photometry, potentiometry, others/LOCI, ACMIA, EMIT, PETINIA and turbidimetric
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	91	91
No. of different assays programmed, calibrated at once	190	190
No. of user-definable (open) channels/No. active simultaneously	10/10	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	91/15–360	91/15–360
Shortest/median onboard reag. stability/Refrigerated onboard	24 hours/30 days/yes (2° to 8°C)	24 hours/30 days/yes (2° to 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/60/>2,000	can be hours/60/>2,000
System is liquid or dry	liquid, reconstitutes onboard (no reagent prep required by the operator)	liquid, reconstitutes onboard (no reagent prep required by the operator)
Uses disposable cuvettes/Max. No. stored	yes/12,000	yes/12,000
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/no
Requires dedicated water system/Water consumption per hour	yes/up to 5 L	yes/up to 5 L
Noise generated in decibels	<75	<75
Dedicated pediatric sample cup/Dead volume	yes/30 µL	yes/30 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	—	—
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/no	yes/yes/no
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/no	yes/no
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes (NA, K, Cl)/yes	yes (NA, K, Cl)/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	autocalibration every two hours/60–90 days/30 days	autocalibration every two hours/60–90 days/30 days
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2 min (not TCO2, ECO2 for enzymatic), 62 specimens, 187 ISE and 437 photometric tests	2 min (not TCO2, ECO2 for enzymatic), 62 specimens, 187 ISE and 437 photometric tests
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 min (ECO2 not TCO2 [enzymatic]), 62 specimens, 187 ISE and 437 photometric tests	5.5 min (ECO2 not TCO2 [enzymatic]), 62 specimens, 187 ISE and 437 photometric tests
• Album., bili. direct & total, AST, ALT, ALP	—	—
Typical time delay from ordering stat test to aspiration of sample	24 seconds	24 seconds
How often QC required/Onboard SW capability to review QC	24 hours or with lot change/yes	24 hours or with lot change /yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	no	no
Data mgmt. capability/Instrument vendor supplies LIS interface	yes, onboard, optional add-on (EasyLink Informatics System, SW mftr: Siemens Healthcare Diagnostics)/yes (additional cost)	yes, onboard, optional add-on (EasyLink Informatics System, SW mftr: Siemens Healthcare Diagnostics)/yes (additional cost)
Interfaces up and running in active user sites with	all major LIS vendors	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	—	—
Interface avail. (or will be) to automated specimen handling system	—	—
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 hours/—	2–8 hours/—
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 15 min	daily: 5 min; weekly: 10 min; monthly: 23 min
Onboard maintenance records/Maint. training demo module	no/no	no/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	multiple types
Distinguishing features (provided by vendor)	analyzer integrates general chemistry with heterogeneous immunoassays onboard; upgradeable with LOCI module; allows a single platform for more than 95 percent of most requested tests; eliminates sample splitting between general chemistry tests and immunoassays; fully automated onboard ISD assays; QCC PowerPak onboard; Reagent Management System standard	analyzer integrates general chemistry with homogeneous LOCI and heterogeneous immunoassays onboard; allows a single platform for more than 95 percent of most requested tests; eliminates sample splitting between general chemistry tests and immunoassays; fully automated onboard ISD assays; QCC PowerPak onboard; Reagent Management System standard

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