Chemistry analyzers branching out

Raymond Aller, MD

This month's chemistry survey is presented in two parts—pages 86–90 list analyzers suitable for the mid-volume chemistry laboratory, while pages 92–106 tabulate those intended for high-volume environments.

As this class of devices has evolved, most of the analyzers in this review have become dual chemistry-immunoassay instruments. Virtually all of the instruments read reagent pack bar codes to verify that the correct reagent pack has been loaded. The following tables also highlight other technical capabilities of such instrumentation. We are delighted to see that nearly all of the featured instruments read a specimen bar code close to the time a sample is aspirated. Specimen bar-coding coupled with an interface to the laboratory information system ensures results are filed in the record of the patient identified on that tube. When this is matched with systems for bedside verification of positive patient ID (scanning a wristband, then the specimen tube label), and if we avoid aliquoting, we can prevent the egregious error of reporting a result on the wrong patient.

Previously, instruments would transmit to the LIS a unique proprietary code to identify each test performed. Today, some analyzers (including, in this survey, Bayer and Landmark Scientific) can transmit a standardized LOINC (Logical Observation Identifiers Names and Codes) code with each result. This ensures that results are identified accurately and facilitates transmission of results to the electronic patient record and clinical decision support system. Abbott includes LOINC codes in reagent package inserts; Beckman Coulter provides them on its Web site or at a customer's request; and Roche offers them in a database. Other manufacturers are developing mechanisms to provide reagent LOINC codes as well.

We look forward to the time when the data-standardization capabilities of these impressive analyzers begin to match their analytic sophistication and productivity.

Remember that the information listed on the following pages has been provided by the instrument manufacturers. Talk with users of these systems to verify the accuracy of vendors' claims and to determine users' satisfaction with the manufacturers' service. The most elegant instrument offers little if breakdowns cannot be resolved expeditiously. □

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SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid-volume laboratories)

Part 1 of 10	Abbott Diagnostics **Bob Dupor** nebojsa.dupor@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 800-323-9100 www.abbott.com	Abbott Diagnostics **Suzanne Macaitis** suzanne.macaitis@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 800-323-9100 www.abbott.com
See related comments, page 84		
Name of instrument/first year sold in U.S.	Abbott Architect c8000/2002	Abbott Architect ci8200 (in development)/2002
List price	TBD	TBD
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.	U.S., Japan/U.S., Japan/U.S.
Operational type/reagent type	continuous random access/open reagent system	continuous random access/self-contained multi-use cartridges, packages & slides, open reagent system
Sample handling system/model type	multi-dimensional retest sample handler, carousel/floor-standing	multi-dimensional retest sample handler/floor-standing
Dimensions in inches (H x W x D)/instrument footprint	48 x 79 x 49/~26 sq ft	48 x 127 x 49/42 sq ft
No. of tests for which analyzer has FDA-cleared applications	30	30
Tests clinically released in last 12 months		
Tests cleared but not clinically released	alb. BCG, alb. BCP, ALT ALT-ACT., AST, AST-ACT, amylase, Ca, chol., creat., CK, CO_2, direct-HDL, glu, Na, K, Cl, iron, TIBC, LDH, lactic acid, lipase, Mg, phos., T-prot., trig, UICSF protein, BUN	alb. BCG, alb. BCP, ALT ALT-ACT, AST, AST-ACT, amylase, Ca, chol., creat., CK, CO_2, direct-HDL, glu, Na, K, Cl, iron, TIBC, LDH, lactic acid, lipase, Mg, phos., T-prot., trig, UICSF protein, BUN
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	carb., dig., pheno., pheny., theo., valp. acid, ethanol, amph., barb., benzo., cannab., cocaine, methadone, opiates, PCP, propox., apo A1, apo B, C3, C4, CRP, uCRP, hapt., IgA, IgG, IgM, prealb., RF, transf., D-LDL, GHb	carb., dig., pheno., pheny., theo., valp. acid, ethanol, amph., barb., benzo., THC, cocaine, LSD, methadone, opiates, PCP, propox., apo A1, apo B, ASLO, C3, C4, CRP, uCRP, hapt., IgA, IgG, IgM, microalb., prealb., RF, transf., D-LDL, GHb, thyroid, fertility, metabolic, cardiac, cancer, hepatitis, HIV, GHb, BNP
User-defined methods implemented for what analytes	—	—
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/—	photometry, potentiometry, turbidimetric/chemiluminescence with flexible protocols
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	68	93
No. of different assays programmed, calibrated at once	220	320
No. of user-definable (open) channels/no. active simultaneously	220/220	220/220
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	65/370	90/chem 370, immunoassay 100–500
Shortest/median onboard reag. stability/refrigerated onboard	7 days/28 days/yes (2–8°C)	—/—/yes (2–8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/specimens/tests-assays	varies/217/69,000-68	varies >300/367/81,000-93
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/max. no. stored	no/—	yes, immunoassay/—
Uses washable cuvettes/replacement frequency	yes/minimum 1 yr guarantee	yes, chemistry/minimum 1 yr guaranteed
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/requires floor drain	yes/no	yes/no
Requires dedicated water system/water consumption per hour	yes/25 L	yes/30.5 L
Noise generated in decibels	—	—
Dedicated pediatric sample cup/dead volume	yes/50 µL	yes/50 µL
Primary tube sampling/pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes, 2-D bar codes	yes
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/short sample detection/clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/increased to rerun out-of-linear-range high/low results	yes/yes	—/—
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/multipoint calibration supported	yes/yes	yes, for chemistry only/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	8 hr/30 days/14 days/7–14 days	8 hr/30 days/14 days/7–14 days
Automatic shutdown/startup programmable	no/no	—/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	9.6 min, 200 specimens	9.6 min, 200 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	9.6 min, 160 specimens	9.6 min, 160 specimens
• Album., bili. direct & total, AST, ALT, ALP	9.6 min, 133 specimens	9.6 min, 133 specimens
Typical time delay from ordering stat test to aspir. of sample	<20 sec	<20 sec
How often QC required/onboard SW capability to review QC	shortest interval: 8 hr; longest: 24 hr/yes	shortest interval: 8 hr; longest: 24 hr/yes
Onboard real-time QC/support multiple QC lot nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/instrument vendor supplies LIS interface	yes (addt'l cost, SW mftr: Abbott)	yes (addt'l cost, SW mftr: Abbott)
Interfaces up and running in active user sites with	—	—
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	—
How labs get LOINC codes for reagent kits	package insert	—
Interface avail. (or will be) to automated specimen handling system	yes (Tecan Genesis FE 500)	no
Modem servicing available/can diagnose own malfunctions/ determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/to repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: <15 min; weekly: <45 min; monthly: 15 min	daily: TBD; weekly: TBD; monthly: TBD
Onboard maintenance records/maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes/yes
Training provided with purchase/advanced oper. training avail.	5 days on-site, 5 days at vendor offices/yes	5 days on-site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	TBD	TBD
Distinguishing features	unique multi-dimensional retest sample handler provides exceptional sample management; large reagent and sample capacity; state-of-the-art software; liquid ready-to-use reagents; maximized ease of use with patented ICT chip	unique multi-dimensional retest sample handler provides exceptional sample management; integration of chemistry and immunoassay without compromise to turnaround time; large reagent and sample capacity; <0.1 ppm sample carryover; patented ICT chip and extended linearities

Chemistry analyzers (for mid-volume laboratories)

Part 2 of 10 See related comments, page 84	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com	Landmark Scientific Inc. Valerie Brady vbrady@landmarkscientific.com 101-B Creek Ridge Rd. Greensboro, NC 27406 336-373-0274 www.landmarkscientific.com
Name of instrument/first year sold in U.S.	Synchron CX9 Pro/2001	Vitalab Selectra-E
List price	$220,600	$47,000/2000
No. units in clinical use in U.S./outside U.S.	—/—	13/750+
Country where designed/manufactured/where reagents mftd.	U.S./U.S./U.S. & Ireland	Netherlands/Netherlands/U.S.
Operational type/reagent type	continuous random access/open reagent system	random access, continuous random access/open reagent system
Sample handling system/model type	sectors, centrifugable/floor-standing	wheel/benchtop
Dimensions in inches (H x W x D)/instrument footprint	69 x 74 x 30 in/15.4 sq ft	14 x 45 x 22/8 sq ft
No. of tests for which analyzer has FDA-cleared applications	>100	27
Tests clinically released in last 12 months	p-amylase, vancomycin, direct LDL cholesterol, salicylate	fructosamine, LDL, iron
Tests cleared but not clinically released	none	HgbA1c
Tests not available in U.S. but submitted for 510(k) clearance	none	n/a
Tests not available in U.S. but available in other countries	none	special proteins, drugs of abuse, therapeutic drugs
Research-use-only assays	none	n/a
Tests in development	C3, C4, haptoglobin, homocysteine, D-dimer	n/a
User-defined methods implemented for what analytes	UIBC	n/a
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay	photometry/—
No. of direct ion selective electrode channels	5 (indirect)	ISE unit
No. of different measured assays onboard simultaneously	33	29
No. of different assays programmed, calibrated at once	59	29
No. of user-definable (open) channels/no. active simultaneously	102/33	58/29
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	33/25–2,500	29/83
Shortest/median onboard reag. stability/refrigerated onboard	168 hr/30 days/yes (2–8°C)	6 hr/7 days/yes (2–8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	requires operator prehandling, preparation
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/specimens/tests-assays	400/63/2,079	270/50/800
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/max. no. stored	no/n/a	—/—
Uses washable cuvettes/replacement frequency	yes/permanent–2-yr warranty (80 stored on instrument)	yes/every 10,000 reactions
Minimum sample volume aspirated precisely at one time	3 µL	1 µL
Supplied with UPS (backup power)/requires floor drain	yes/yes	yes/no
Requires dedicated water system/water consumption per hour	yes/7 L	0.5 L
Noise generated in decibels	70	45
Dedicated pediatric sample cup/dead volume	yes/40 µL	yes/50 µL
Primary tube sampling/pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes/by handheld scanner as tubes are loaded onto instrument
Reagent bar-code reading capability	yes	no
Bar code placement per NCCLS 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	no/yes/no
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/automatic rerun capability	yes/yes	no/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	no
Calibrants stored onboard/multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	24 hr/up to 90 days/up to 60 days/14 days	separate unit/n/a/n/a/n/a
Automatic shutdown/startup programmable	none required	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	52 sec, 75 specimens	1 min 17 sec., 60 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	52 sec, 75 specimens	4 min 30 sec, 56 specimens
• Album., bili. direct & total, AST, ALT, ALP	10 min, 32 specimens	11 min 30 sec, 20 specimens
Typical time delay from ordering stat test to aspir. of sample	45 sec	9 min
How often QC required/onboard SW capability to review QC	24 hr/yes	shortest interval: once a day; longest: once a day/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 DL2000)/yes (addt'l cost)	optional (LIS: $8,400–$9,923; Antek, Fletcher Flora)/yes (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Sunquest, Meditech, Citation, MedLab, CHC, SMS, HBOC, Labquest, CCA, VA-Mumps, all LISs	LabPak, LabDaq
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	yes
How labs get LOINC codes for reagent kits	Web site, customer request	do not manufacture reagents
Interface avail. (or will be) to automated specimen handling system	yes (Power Processor)	no
Modem servicing available/can diagnose own malfunctions/ determine malfunctioning component	yes/no/no	no/yes/yes
On-site time of svc. engineer/onboard error codes for troubleshooting	metro: same day, rural: same or next day/yes	24–48 hr/yes
Mean time between failures/to repair failures	—/—	24 mo/1–2 hr
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 15 min; monthly: 25 min	daily: 5 min; weekly: 10 min; monthly: 15 min
Onboard maintenance records/maint. training demo module	no/no	no/no
Training provided with purchase/advanced oper. training avail.	3 days on-site, 5 days at vendor offices/yes	3 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	$5,600 (includes preventive maintenance)
Distinguishing features	serum indices; centrifugable sectors; clot detection; design optimized for automation; continuous random access for samples, controls, reagents, and results; no-maintenance glucose oxygen sensor; no-wait autoloader; polychromatic correction; thermal ring and semipermanent glass cuvettes; pulsed xenon lamp; advanced workflow and results mgmt.; liquid, ready-to-use reagents, calibrators, controls; DL2000 Workflow and Results Manager	Levy-Jennings, low cost per test, liquid level sensing, program-mable autostart, no shutdown required, open reagent system, 10,000 reactions per reusable cuvette rotor, walkaway analyzer

Chemistry analyzers (for mid-volume laboratories)

Part 3 of 10 See related comments, page 84	Olympus America Inc. Susan M. Watanabe, PhD susan.watanabe@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com	Roche Diagnostics Roche Product Manager 9115 Hague Rd., P.O. Box 50457 Indianapolis, IN 46250 800-428-5074 us.labsystems.roche.com
Name of instrument/first year sold in U.S.	AU400/1998; AU400e/2002	Cobas Integra 800/2001 (Integra introduced 1995)
List price	$130,000	$265,000
No. units in clinical use in U.S./outside U.S.	300/1,100	>500/>2,000
Country where designed/manufactured/where reagents mftd.	Japan/Japan/U.S. & Ireland	Switzerland/Switzerland/multiple countries
Operational type/reagent type	random access, discrete, continuous random access/open reagent system	random access, discrete, continuous random access/self-contained multi-use cartridges-packages-slides
Sample handling system/model type	rack & stat carousel/floor-standing	sample racks: RD 5-position rack/floor-standing
Dimensions in inches (H x W x D)/instrument footprint	47.6 x 57.1 x 29.9/62.7 sq ft	46 x 57 x 326 sq ft
No. of tests for which analyzer has FDA-cleared applications	122	137
Tests clinically released in last 12 months	direct HDL & LDL, carbamazepine, digoxin, gentamicin, NAPA, phenobarbital, phenytoin, procainamide, quinidine, theo., barb., benzodiaz., cannabinoid, cocaine, metabolite, ethanol, methadone, methaqualone, opiates, phencyclidine, propoxyphene	—
Tests cleared but not clinically released	ceruloplasmin	—
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	cotinine	LDH (P→L), ALP (DGKC)
Research-use-only assays	none	—
Tests in development	acid phosphatase	IgE, lipoprotein (a), kappa/lambda light chains
User-defined methods implemented for what analytes	HbA1c, fructosamine, cholinesterase	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, fluorescence polarization/turbidimetric, fluorescence polarization
No. of direct ion selective electrode channels	3	4
No. of different measured assays onboard simultaneously	up to 76	72
No. of different assays programmed, calibrated at once	99	72
No. of user-definable (open) channels/no. active simultaneously	95/—	0/n/a
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	76/100–1,333	72/50–800
Shortest/median onboard reag. stability/refrigerated onboard	120 hr/30 days/yes (4–12°C)	336 hr/84 days/yes (8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	no
Walkaway capacity in minutes/specimens/tests-assays	varies/up to 102/varies	450/180/4,500
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/max. no. stored	no/n/a	yes/4,500
Uses washable cuvettes/replacement frequency	yes/permanent	no/n/a
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/requires floor drain	no (optional)/yes (no w/ optional water pump)	yes/yes
Requires dedicated water system/water consumption per hour	yes/26 L per hr peak consumption	no (direct connection, type I NCCLS)/5–7 L
Noise generated in decibels	65	—
Dedicated pediatric sample cup/dead volume	no/n/a	yes/approx. 50–70 µL
Primary tube sampling/pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/short sample detection/clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/increased to rerun out-of-linear-range high/low results	yes/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	5 hr/once per lot/140 days/60 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, 200 specimens	8.6 min, 118 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	<5 min, 80 specimens	8.6 min, 99 specimens
• Album., bili. direct & total, AST, ALT, ALP	<9 min, 67 specimens	9.8 min, 118 specimens
Typical time delay from ordering stat test to aspir. of sample	<2 min	1 min
How often QC required/onboard SW capability to review QC	per CLIA & laboratory's decision/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/no (optional)	onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, SMS, HBOC (Data Innov.), CPSI, Meditech, Sunquest, Citation	Cerner, CHCS, Citation, Compton, CompuLab, DynaMedix, EDS, Fletcher Flora, HBOC (ALG, PathLabs, StarLabs), HMS, Intellilabs, Isys, LabDaq, Labforce, Labfusion, LabSoft, LCI, Meditech, Northern Soft, Orsys, Seacoast, SMS, Soft Computer, Sunquest
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	no
Modem servicing available/can diagnose own malfunctions/determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/onboard error codes for troubleshooting	<24 hr/yes	8 hr or next business day/yes
Mean time between failures/to repair failures	average 2 calls per yr/<24 hr	—/—
Average time to complete maintenance by lab personnel	daily: 3 min; weekly: 7 min; monthly: 45 min	daily: <1 min; weekly: <5 min; monthly: none
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 (onscreen help with diagrams & maintenance wizard)
Training provided with purchase/advanced oper. training avail.	3–5 days on-site, 5 days at vendor offices/yes	1 day on-site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	varies
Distinguishing features	Olympus is a leader in standardization with its family of chemistry immuno systems, the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation; speed, reliability, advanced data management, and unprecedented onboard automation for the best walkaway in industry today	comprehensive test menu including hemoglobin A1c; reagent cassette requires no operator prep. or special handling (can go straight from refrigerator to system with no warmup time); 97 percent of reagents are liquid, ready to use, system automatically reconstitutes if necessary, system forecasts daily reagent requirements based on history; operator maintenance automatically scheduled by system, based on actual use, not by calendar schedule; (800 has clot detection, bubble detection, and can accommodate universal 5-position Roche rack for modular systems and Elecsys IA analyzers)

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

Chemistry analyzers (for high-volume laboratories)

Part 4 of 10	Abbott Diagnostics	Bayer Corp., Diagnostics Div.
	Bob Dupor nebojsa.dupor@abbott.com	**Denise Pastore** denise.pastore.b@bayer.com
	100 Abbott Park Road	511 Benedict Ave.
	Abbott Park, IL 60064	Tarrytown, NY 10591
	800-323-9100	914-333-6162
See related comments, page 84	www.abbott.com	www.bayerds.com

Name of instrument/first year sold in U.S.	Abbott Aeroset/1998	Advia 1650/1999
List price	$345,000	$289,000
No. units in clinical use in U.S./outside U.S.	270/500+	54/550
Country where designed/manufactured/where reagents mftd.	Japan/Japan/U.S.	Japan/Japan/Ireland
Operational type/reagent type	continuous random access/open reagent system	batch, random access, discrete, continuous random access/open reagent system
Sample handling system/model type	rack, carousel/floor-standing	automated rack handler, sample carousel/floor-standing
Dimensions in inches (H x W x D)/instrument footprint	42.7 x 74.4 x 44.1/22.7 sq ft	45 x 59 x 34/14 sq ft

No. of tests for which analyzer has FDA-cleared applications	71	66
Tests clinically released in last 12 months	—	LDL direct, HDL II, glucose II, total protein II, cholinesterase
Tests cleared but not clinically released	none	digoxin, phenytoin, theophylline, carbamazipine, gentamicin, valproic acid
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	none	—
Research-use-only assays	none	none
Tests in development	LDL, CRP, RF, dig, valp. acid, pheny., ferritin, GHb, uCRP	—
User-defined methods implemented for what analytes	TDMs, drugs of abuse, GHb, cholinesterase, uCRP, RF, ASLO, fructosamine, lithium, ammonia	alcohol, C3, C4, acetaminophen, salicylate, CK-MB, myoglobin, fructosamine, β2-microglobulin, DAUs

Methods supported/immunoassay methods	photometry, potentiometry/—	photometry, potentiometry, turbidimetrics/—
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	59	49
No. of different assays programmed, calibrated at once	100	100
No. of user-definable (open) channels/no. active simultaneously	100/59	62/62
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	59/400	49/840
Shortest/median onboard reag. stability/refrigerated onboard	7 days/28 days/yes	72 hr/28 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	60/231/50,000+	90–470/200/20,000+
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/max. no. stored	no/n/a	no/n/a
Uses washable cuvettes/replacement frequency	yes/minimum 1 yr guaranteed	yes/4 mo (221 stored on instrument)
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/requires floor drain	no/no	yes/yes
Requires dedicated water system/water consumption per hour	yes/45 L	yes/25 L
Noise generated in decibels	—	—
Dedicated pediatric sample cup/dead volume	yes/50 µL	yes/50 µL
Primary tube sampling/pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes (2 of 5 interl., Codabar [NW7], codes 39 & 128)/auto-discrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per NCCLS 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 aspir. & analysis	yes	yes
Hemolysis/turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/increased to rerun out-of-linear- range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	8 hr/28 days/28 days/28 days	daily/30 days/30 days/daily
Automatic shutdown/startup programmable	yes/yes	yes/yes

Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	10 min, 200+ specimens	10 min, 150 samples, 600 tests
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	10 min, 200+ specimens	10 min, 150 samples, 1,050 tests
• Album., bili. direct & total, AST, ALT, ALP	10 min, 200+ specimens	10 min, 200 samples, 1,200 tests
Typical time delay from ordering stat test to aspir. of sample	<15 sec	3 sec
How often QC required/onboard SW capability to review QC	shortest interval: 8 hr (ISE); longest: 24 hr/yes	per CLIA and 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	no/yes (addt'l cost)	onboard/no
Interfaces up and running in active user sites with	all major vendors	Soft, Sunquest, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	—	e-mail, software

Interface avail. (or will be) to automated specimen handling system	in development	yes (all systems)

Modem servicing available/can diagnose own malfunctions/ determine malfunctioning component	no/no/no	yes/yes/yes
On-site time of svc. engineer/onboard error codes for troubleshooting	<24 hr/yes	4–8 hr/yes
Mean time between failures/to repair failures	>2 mo/varies	—/4-8 hr
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 30 min	daily: 10 min; weekly: 45 min; monthly: 1 hr
Onboard maintenance records/maint. training demo module	no/no	yes/yes
Training provided with purchase/advanced oper. training avail.	5 days on-site, 5 days at vendor offices/no	ongoing on-site, 5 days at vendor offices/—
Annual service contract cost (24 h/7 d)	$23,700	$21,500

Distinguishing features	workstation consolidation; high throughput; large capacity; reliable; open, flexible system	system will aspirate every 3 sec and retain aliquot onboard; original sample is available to leave system; all testing performed with aliquot of sample remaining on Advia 1650; all reruns/repeats/dilu- tions automatically performed without operator intervention; microvolume technology allows up to 840 tests from a 70-mL-test wedge of reagent; reflex testing available; 99 percent uptime guarantee

SURVEY OF INSTRUMENTS

Chemistry analyzers (for high-volume laboratories)

Part 5 of 10	Beckman Coulter Inc.	Beckman Coulter Inc.
	200 South Kraemer Blvd.	200 South Kraemer Blvd.
	P.O. Box 8000	P.O. Box 8000
	Brea, CA 92822-8000	Brea, CA 92822-8000
	800-526-3821	800-526-3821
See related comments, page 84	www.beckmancoulter.com	www.beckmancoulter.com
Name of instrument/first year sold in U.S.	Synchron LX20; Synchron LX4201/1997	Synchron LX20 Pro; Synchron LX4201 Pro/2001
List price	LX20 $278,000; LX4201 $556,200	LX20 Pro $343,000; LX4201 Pro $685,000
No. units in clinical use in U.S./outside U.S.	LX20 500/200; LX4201 200/50	LX20 Pro 30/15; LX4201 Pro 20/15
Country where designed/manufactured/where reagents mftd.	U.S./U.S./U.S. & Ireland	U.S./U.S./U.S. & Ireland
Operational type/reagent type	continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/model type	racks, centrifugable/floor-standing	racks, centrifugable/floor-standing
Dimensions in inches (H x W x D)/instrument footprint	LX20 60 x 70 x 41/19.9 sq ft; LX4201 60 x 140 x 41/39.8 sq ft	LX20 Pro 60 x 70 x 41/19.9 sq ft; LX 4201 Pro 60 x 140 x 41/39.8 sq ft
No. of tests for which analyzer has FDA-cleared applications	>100	>100
Tests clinically released in last 12 months	p-amylase, vancomycin, salicylate, direct LDL	p-amylase, vancomycin, salicylate, direct LDL, high-sensitivity CRP
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays	none	none
Tests in development	C3, C4, haptoglobin, homocysteine, D-dimer	C3, C4, haptoglobin, homocysteine, D-dimer
User-defined methods implemented for what analytes	UIBC	UIBC
Methods supported/immunoassay methods	photometry, potentiometry, near infrared/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay	photometry, potentiometry, near infrared/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay, near infrared particle immunoassay
No. of direct ion selective electrode channels	5 (indirect)	5 (indirect)
No. of different measured assays onboard simultaneously	LX20 41; LX4201 71	LX20 Pro 41; LX4201 Pro 71
No. of different assays programmed, calibrated at once	LX20 100; LX4201 150	LX20 Pro 100; LX 4201 Pro 150
No. of user-definable (open) channels/no. active simultaneously	LX20 100/41; LX4201 150/71	LX20 Pro 100/41; LX4201 Pro 150/71
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	LX20 41/10,650; LX4201 71/21,300	LX20 Pro 41/10,650; LX4201 Pro 71/21,300
Shortest/median onboard reag. stability/refrigerated onboard	168 hr/30 days/yes (2–8°C)	168 hr/30 days/yes (2–8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	no	no
Walkaway capacity in minutes/specimens/tests-assays	LX20 83/132/5,280; LX4201 83/264/10,560	LX20 Pro 83/132/5,280; LX4201 Pro 83/264/10,560
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/max. no. stored	no/n/a	no/n/a
Uses washable cuvettes/replacement frequency	yes/semipermanent–2-yr warranty (250 stored on instrument)	yes/semipermanent–2-yr warranty (250 stored on instrument)
Minimum sample volume aspirated precisely at one time	3 µL	3 µL
Supplied with UPS (backup power)/requires floor drain	yes/no	yes/no
Requires dedicated water system/water consumption per hour	yes/LX20 16 L; LX4201 32 L	yes/LX20 Pro 16 L; LX4201 Pro 32 L
Noise generated in decibels	65	65
Dedicated pediatric sample cup/dead volume	yes/40 µL (samples directly from pediatric bullet)	yes/40 µL
Primary tube sampling/pierces caps on primary tubes	yes/no	yes/yes
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/short sample detection/clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	24 hr/up to 90 days/up to 60 days/14 days	1 day/up to 90 days/up to 60 days/14 days
Automatic shutdown/startup programmable	none required	none required
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	38 sec, 90 specimens	38 sec, 90 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	38 sec, 90 specimens	38 sec, 90 specimens
• Album., bili. direct & total, AST, ALT, ALP	8 min, 90 specimens	8 min, 90 specimens
Typical time delay from ordering stat test to aspir. of sample	16 sec	16 sec
How often QC required/onboard SW capability to review QC	24 hr/yes	24 hr/yes
Onboard real-time QC/support multiple QC lot nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard & optional add-on (SW mftr: Beckman Coulter DL2000)/yes (addt'l cost)	onboard & optional add-on (DL2000, Beckman Coulter)/yes (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Sunquest, Meditech, Citation, MedLab, CHC, SMS, HBOC, Labquest, CCA, VA-Mumps, all LISs	Cerner, Sunquest, Meditech, Citation, MedLab, CHC, SMS, HBOC, Labquest, CCA, VA-Mumps, all LISs
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	Web site, customer request	Web site, customer request
Interface avail. (or will be) to automated specimen handling system	yes (Power Processor, total lab automation)	yes (Power Processor, total lab automation)
Modem servicing available/can diagnose own malfunctions/ determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/onboard error codes for troubleshooting	metro: same day, rural: same or next day/yes	metro: same day, rural: same or next day/yes
Mean time between failures/to repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: none; weekly: 3.5 min; monthly: 25 min	daily: none; weekly: 3.5 min; monthly: 25 min
Onboard maintenance records/maint. training demo module	no/no	no/no
Training provided with purchase/advanced oper. training avail.	5 days on-site, 5 days at vendor offices/no	5 days on-site, 5 days at vendor offices/no
Annual service contract cost (24 h/7 d)	—	—
Distinguishing features	serum indices; centrifugable racks; clot detection; no-wait autoloader/linear racks; multiple wavelength blanking; smart modules, fiber optics; advanced workflow and data management; thermal ring and semipermanent glass cuvettes; pulsed xenon lamp; electronic stat notification; review by exception; reflex testing; add-on test; DL2000 Workflow and Results Manager	serum indices; centrifugable racks; clot detection; no-wait autoloader/linear racks; multiple wavelength blanking; smart modules, fiber optics; advanced workflow & data management; thermal ring and semipermanent glass cuvettes; pulsed xenon lamp; electronic stat notification; review by exception; reflex testing; add-on test; closed-tube sampling, near infrared detection (for high-sensitivity CRP), DL2000 Workflow and Results Manager

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

Chemistry analyzers (for high-volume laboratories)

| Part 6 of 10

See related comments, page 84 | Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101
800-242-3233
www.dadebehring.com | Olympus America Inc.
Terry Giacomo   terry.giacomo@olympus.com
Two Corporate Center Dr.
Melville, NY 11747
800-223-0125
www.olympus.com |
|---|---|---|
| Name of instrument/first year sold in U.S. | Dimension RxL Integrated Chemistry System w/ Heterogeneous Module (HM)/1997 | AU640/1999; AU640e/2002 |
| List price | $249,000 | $185,000 |
| No. units in clinical use in U.S./outside U.S. | 1,500/600 | 275/1,000 |
| Country where designed/manufactured/where reagents mftd. | U.S./U.S./U.S. | Japan/Japan/U.S. & Ireland |
| Operational type/reagent type | random access, continuous random access/self-contained multi-use cartridges-packages-slides | random access, discrete, continuous random access/open reagent system |
| Sample handling system/model type | segmented sample wheel/floor-standing | rack & stat carousel/floor-standing |
| Dimensions in inches (H x W x D)/instrument footprint | 44 x 62.5 x 30.5/13.2 sq ft | 50 x 74 x 32/68 sq ft |
| No. of tests for which analyzer has FDA-cleared applications | 95 | 122 |
| Tests clinically released in last 12 months | HbA1c, hsCRP, lithium, revised triglyceride | direct HDL & LDL, carbamazepine, digoxin, gentamicin, NAPA, phenobarbital, phenytoin, procainamide, quindine, theophylline, barbiturate, benzodiazepine, cannabinoid, cocaine, metabolite, ethanol, methadone, methaqualone, opiates, phencyclidine, propoxyphene |
| Tests cleared but not clinically released | none | ceruloplasmin |
| Tests not available in U.S. but submitted for 510(k) clearance | none | none |
| Tests not available in U.S. but available in other countries | digitoxin | cotinine |
| Research-use-only assays | none | none |
| Tests in development | CSA, ALDL | acid phosphatase |
| User-defined methods implemented for what analytes | none | HbA1c, fructosamine, cholinesterase |
| Methods supported/immunoassay methods | photometry, potentiometry, Integrated Multisensor Technology (IMT)/heterogeneous EIA using HM, EMIT latex particle turbidimetric, latex turbidimetric | photometry, potentiometry, calculated tests/homogeneous |
| No. of direct ion selective electrode channels | 4 (indirect) | 3 |
| No. of different measured assays onboard simultaneously | 48/95 with optional inventory management system | up to 51 |
| No. of different assays programmed, calibrated at once | 140 | 99 |
| No. of user-definable (open) channels/no. active simultaneously | 10/10 | 95/— |
| No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set | —/max. 240 | 48 x 2/100–1,333 |
| Shortest/median onboard reag. stability/refrigerated onboard | 24 hr open well (30 days sealed)/3 days (30 days sealed)/yes (2–8˚C) | 120 hr/30 days/yes (4–12˚C) |
| Multiple reag. configurations supported | yes | yes |
| Reag. container placed directly on system for use | yes | yes |
| Instrument has same capabilities when 3rd-party reag. used | yes | yes |
| Walkaway capacity in minutes/specimens/tests-assays | 60/1,200/n/a | variable/up to 172/variable |
| System is liquid or dry | liquid, reconstitutes onboard | liquid |
| Uses disposable cuvettes/max. no. stored | yes/12,000 | no/n/a |
| Uses washable cuvettes/replacement frequency | no/n/a | yes/permanent |
| Minimum sample volume aspirated precisely at one time | 2 µL | 2 µL |
| Supplied with UPS (backup power)/requires floor drain | yes/yes | no (optional)/yes (no w/ optional water pump) |
| Requires dedicated water system/water consumption per hour | yes/3.2 L | yes/40 L per hr peak consumption |
| Noise generated in decibels | <70 | 65 |
| Dedicated pediatric sample cup/dead volume | yes/20 µL | no/n/a |
| Primary tube sampling/pierces caps on primary tubes | yes/no | yes/no |
| Sample bar-code reading capability | yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination | yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination |
| Reagent bar-code reading capability | yes | yes |
| Bar code placement per NCCLS standard Auto2A | yes | yes |
| Onboard test auto inventory (determines volume in container) | yes | yes |
| Measures no. tests remaining/short sample detection/clot detection | yes/yes/yes | yes/yes/yes |
| Automatic detection of adequate reag. for aspir. & analysis | no | 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/yes | yes/yes |
| Autocalibration or autocalibration alert | yes | yes |
| Calibrants stored onboard/multipoint calibration supported | no (except for IMT)/yes | yes/yes |
| Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse | every 2 hr-autocalibrate/—/60–90 days/30 days | 1 day/30 days/14 days/14–20 days |
| Automatic shutdown/startup programmable | no/yes | yes/yes |
| Stat time to completion of all analytes, throughput per hr. for: | | |
| • Sodium, potassium, chloride, TCO2 | 50 sec, 288 tests | <4 min, 200 specimens |
| • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine | 4.5 min, 500 tests | <5 min, 160 specimens |
| • Album., bili. direct & total, AST, ALT, ALP | 10–11 min, 500 tests | 9 min, 133 specimens |
| Typical time delay from ordering stat test to aspir. of sample | 24 sec | 1 min |
| How often QC required/onboard SW capability to review QC | 24 hr/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 | optional add-on (SW mftr: Dade Behring–DataFusion)/yes (addt'l cost) | onboard/no (optional) |
| Interfaces up and running in active user sites with | Sunquest, Cerner, LabNet, HBOC, SMS, Meditech | all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, SMS, HBOC (Data Innov.), CPSI, Meditech, Sunquest, Citation |
| Bidirectional interface capability | yes (broadcast download & host query) | yes (broadcast download & host query) |
| Test results transmitted to LIS as soon as chem. time complete | yes | yes |
| LIS interface operates simultaneously with running assays | yes | yes |
| Uses LOINC to transmit orders & results | 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 | 2–8 hr/yes | <24 hr/yes |
| Mean time between failures/to repair failures | 70 days/3 hr | average 2 calls per yr/<24 hr |
| Average time to complete maintenance by lab personnel | daily: 2 min; weekly: 2 min; monthly: 15 min | daily: 3 min; weekly: 27 min; monthly: 45 min |
| Onboard maintenance records/maint. training demo module | yes/no | yes (includes audit trail of who replaced parts)/yes |
| Training provided with purchase/advanced oper. training avail. | 5 days on-site, 4 days at vendor offices/yes | 3–5 days on-site, 5 days at vendor offices/yes |
| Annual service contract cost (24 h/7 d) | $17,500 | inquire |
| Distinguishing features | only instrument available that integrates heterogeneous immunoassays onboard with other chemistries; allows single platform for over 95 percent of most requested tests; eliminates sample splitting between general tests & immunoassays | Olympus is a leader in standardization with its family of chemistry immuno systems, the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation; speed, reliability, advanced data management, and unprecedented onboard automation for the best walkaway in industry today |

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Chemistry analyzers (for high-volume laboratories)

	Olympus America Inc. Terry Giacomo terry.giacomo@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com	Olympus America Inc. Hiro Sekiya hiro.sekiya@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com
Name of instrument/first year sold in U.S.	AU2700/2000	AU5421 with dual ISE/2001
List price	$320,000	$465,000
No. units in clinical use in U.S./outside U.S.	n/a/n/a	24/88
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/floor-standing
Dimensions in inches (H x W x D)/instrument footprint	50 x 79 x 45/92 sq ft	50 x 148 x 45/46.25 sq ft
No. of tests for which analyzer has FDA-cleared applications	122	122
Tests clinically released in last 12 months	direct HDL & LDL, carbamazepine, digoxin, gentamicin, NAPA, phenobarbital, phenytoin, procainamide, quindine, theophylline, barbiturate, benzodiazepine, cannabinoid, cocaine, metabolite, ethanol, methadone, methaqualone, opiates, phencyclidine, propoxyphene	direct HDL & LDL, carbamazepine, digoxin, gentamicin, NAPA, phenobarbital, phenytoin, procainamide, quindine, theophylline, barbiturate, benzodiazepine, cannabinoid, cocaine, metabolite, ethanol, methadone, methaqualone, opiates, phencyclidine, propoxyphene
Tests cleared but not clinically released	ceruloplasmin	ceruloplasmin
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	cotinine	cotinine
Research-use-only assays	none	none
Tests in development	acid phosphatase	acid phosphatase
User-defined methods implemented for what analytes	HbA1c, fructosamine, cholinesterase	HbA1c, fructosamine, cholinesterase
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 51	99
No. of different assays programmed, calibrated at once	99	99
No. of user-definable (open) channels/no. active simultaneously	95/—	95/—
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	48 x 2/100–4,000	48 x 4/100–4,000
Shortest/median onboard reag. stability/refrigerated onboard	120 hr/30 days/yes (4–12˚C)	120 hr/30 days/yes (4–12˚C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/specimens/tests-assays	varies/up to 322/varies	varies/up to 300/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/max. no. stored	no/n/a	no/n/a
Uses washable cuvettes/replacement frequency	yes/permanent	yes/permanent
Minimum sample volume aspirated precisely at one time	1 µL	1 µL
Supplied with UPS (backup power)/requires floor drain	no (optional)/yes	no (optional)/yes
Requires dedicated water system/water consumption per hour	yes/65 L per hr peak consumption	yes/120 L
Noise generated in decibels	—	—
Dedicated pediatric sample cup/dead volume	no/n/a	no/n/a
Primary tube sampling/pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl.)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/short sample detection/clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	1 day/30 days/14 days/14–20 days	1 day/30 days/14 days/14–20 days
Automatic shutdown/startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	<4 min, 267 specimens	—, max 600
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	<4 min, 267 specimens	—, max 600
• Album., bili. direct & total, AST, ALT, ALP	9 min, 267 specimens	—, max 533
Typical time delay from ordering stat test to aspir. of sample	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, SMS, HBOC (Data Innov.), CPSI, Meditech, Sunquest, Citation	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, SMS, HBOC (Data Innov.), CPSI, Meditech, Sunquest, Citation
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/can diagnose own malfunctions/determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/to repair failures	TBD/TBD	TBD/TBD
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 30 min; monthly: 45 min	daily: 5 min; weekly: 30 min; monthly: 45 min
Onboard maintenance records/maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/advanced oper. training avail.	3–5 days on-site, 5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	inquire
Distinguishing features	Olympus is a leader in standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation; speed, reliability, advanced data management, and unprecedented onboard automation for the best walkaway in industry today	Olympus is a leader in standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation; speed, reliability, advanced data management, and unprecedented onboard automation for the best walkaway in industry today

Chemistry analyzers (for high-volume laboratories)

Part 8 of 10	Olympus America Inc. **Hiro Sekiya** hiro.sekiya@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125 www.olympus.com	Ortho-Clinical Diagnostics **Christine Hopkins** 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com
See related comments, page 84		
Name of instrument/first year sold in U.S.	AU5431 with dual ISE/2001	Vitros 950, Vitros 950 AT/1995
List price	$575,000	950: $196,000; 950 AT: $250,000
No. units in clinical use in U.S./outside U.S.	24/88	>1,500/—
Country where designed/manufactured/where reagents mftd.	Japan/Japan/U.S. & Ireland	U.S./—/—
Operational type/reagent type	random access, discrete, continuous random access/open reagent system	batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides
Sample handling system/model type	rack/floor-standing	sample trays/floor-standing
Dimensions in inches (H x W x D)/instrument footprint	50 x 200 x 45/62.5 sq ft	55 x 68 x 38/26 sq ft
No. of tests for which analyzer has FDA-cleared applications	122	69
Tests clinically released in last 12 months	direct HDL & LDL, carbamazepine, digoxin, gentamicin, NAPA, phenobarbital, phenytoin, procainamide, quindine, theophylline, barbiturate, benzodiazepine, cannabinoid, cocaine, metabolite, ethanol, methadone, methaqualone, opiates, phencyclidine, propoxyphene	none
Tests cleared but not clinically released	ceruloplasmin	—
Tests not available in U.S. but submitted for 510(k) clearance	none	—
Tests not available in U.S. but available in other countries	cotinine	—
Research-use-only assays	none	—
Tests in development	acid phosphatase	—
User-defined methods implemented for what analytes	HbA1c, fructosamine, cholinesterase	—
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	potentiometry, colorimetric–rate, potentiometry/—
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 147	75
No. of different assays programmed, calibrated at once	99	75
No. of user-definable (open) channels/no. active simultaneously	95/—	n/a/n/a
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	48 x 6/100–4,000	60/60
Shortest/median onboard reag. stability/refrigerated onboard	120 hr/30 days/yes (4–12˚C)	7 days/14 days/n/a
Multiple reag. configurations supported	yes	n/a
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	n/a
Walkaway capacity in minutes/specimens/tests-assays	varies/up to 300/varies	—/40/900 per hr
System is liquid or dry	liquid	dry
Uses disposable cuvettes/max. no. stored	no/n/a	no/n/a
Uses washable cuvettes/replacement frequency	yes/permanent	no/n/a
Minimum sample volume aspirated precisely at one time	1 µL	6 µL
Supplied with UPS (backup power)/requires floor drain	no (optional)/yes	no/no
Requires dedicated water system/water consumption per hour	yes/180 L	no/none
Noise generated in decibels	—	—
Dedicated pediatric sample cup/dead volume	no/n/a	yes/30 µL
Primary tube sampling/pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/short sample detection/clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/turbidity detection-quantitation	yes/yes	not needed/not needed
Dilution of patient samples onboard/automatic rerun capability	yes/yes	no/no
Sample volume can be reduced/increased to rerun out-of-linear-range high/low results	yes/yes	no/no
Autocalibration or autocalibration alert	yes	n/a
Calibrants stored onboard/multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	1 day/30 days/14 days/14–20 days	6 mo/6 mo/3–6 mo/3–6 mo
Automatic shutdown/startup programmable	yes/yes	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	—, max 600	~6 min, 600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	—, max 600	~6 min, ~700 specimens
• Album., bili. direct & total, AST, ALT, ALP	—, max 800	~7 min, ~700 specimens
Typical time delay from ordering stat test to aspir. of sample	—	8 sec
How often QC required/onboard SW capability to review QC	per CLIA & laboratory's decision/yes	24 hr/yes
Onboard real-time QC/support multiple QC lot nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, SMS, HBOC (Data Innov.), CPSI, Meditech, Sunquest, Citation	—
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	—
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes (Lab-InterLink, Labotix, Coulter IDS, AutoLab)
Modem servicing available/can diagnose own malfunctions/ determine malfunctioning component	yes/yes/yes	—/yes/yes
On-site time of svc. engineer/onboard error codes for troubleshooting	<24 hr/yes	<4 hr/yes
Mean time between failures/to repair failures	TBD/TBD	—/—
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 30 min; monthly: 45 min	daily: 2 min; weekly: 5 min; monthly: 15 min
Onboard maintenance records/maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes/yes
Training provided with purchase/advanced oper. training avail.	5 days at vendor offices/yes	3 days on-site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	—
Distinguishing features	Olympus is a leader in standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 122 methods delivers standardized results for improved patient management and streamlined operation; speed, reliability, advanced data management, and unprecedented onboard automation for the best walkaway in industry today	superior assay precision; minimal interference from hemolysis, lipemia, bilirubin; smart metering; continuous process verification; no infectious waste; no plumbing, water, or drains; highest reportable result efficiency of any chemistry analyzer

Chemistry analyzers (for high-volume laboratories)

Part 9 of 10	Ortho-Clinical Diagnostics Christine Hopkins 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com	Roche Diagnostics Lisa Davis, Product Manager 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 ext. 3531 us.labsystems.roche.com
See related comments, page 84		
Name of instrument/first year sold in U.S.	Vitros 250, Vitros 250 AT/1993	Modular/1998
List price	250 $115,000; 250 AT $130,000	varies
No. units in clinical use in U.S./outside U.S.	>3,000/—	>200/>700
Country where designed/manufactured/where reagents mftd.	U.S./—/—	multiple countries/multiple countries/multiple countries
Operational type/reagent type	batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides	continuous random access/self-contained multiuse cartridges-packages-slides
Sample handling system/model type	rack/floor-standing	5-position rack/floor-standing
Dimensions in inches (H x W x D)/instrument footprint	47 x 45.5 x 28/8.8 sq ft	varies per configuration/varies
No. of tests for which analyzer has FDA-cleared applications	69	>100
Tests clinically released in last 12 months	none	sTFR, D-dimer, acetaminophen
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	none
Tests not available in U.S. but available in other countries	—	apoA, apoB, Lpa, kappa, lambda
Research-use-only assays	—	none
Tests in development	—	—
User-defined methods implemented for what analytes	—	none
Methods supported/immunoassay methods	potentiometry, colorimetric–rate, potentiometry/—	photometry, potentiometry/HbA1c
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	60	47–>100
No. of different assays programmed, calibrated at once	60	47–>100
No. of user-definable (open) channels/no. active simultaneously	n/a/n/a	5/5
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	60/60	47–100/100–3,000
Shortest/median onboard reag. stability/refrigerated onboard	7 days/14 days/n/a	72 hr/28 days/yes (2–12°C)
Multiple reag. configurations supported	n/a	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	n/a	no
Walkaway capacity in minutes/specimens/tests-assays	—/40/200 per hr	varies/300/varies
System is liquid or dry	dry	liquid
Uses disposable cuvettes/max. no. stored	n/a/n/a	no/n/a
Uses washable cuvettes/replacement frequency	n/a/n/a	yes/monthly
Minimum sample volume aspirated precisely at one time	6 µL	2 µL
Supplied with UPS (backup power)/requires floor drain	no/no	yes/yes
Requires dedicated water system/water consumption per hour	no/n/a	yes/varies (50 L/hr/mod)
Noise generated in decibels	—	<62
Dedicated pediatric sample cup/dead volume	yes/30 µL	yes/50 µL
Primary tube sampling/pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/short sample detection/clot detection	yes/yes/yes	yes/yes/no
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/turbidity detection-quantitation	not needed/not needed	yes/yes
Dilution of patient samples onboard/automatic rerun capability	yes/no	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	no	yes
Calibrants stored onboard/multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	6 mo/6 mo/3–6 mo/3–6 mo	24 hr/varies/btl chg/lot chg
Automatic shutdown/startup programmable	no/no	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	7 min, 230 specimens	3.5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	7 min, 277 specimens	5.5 min, 160–600 specimens
• Album., bili. direct & total, AST, ALT, ALP	7 min, 250 specimens	10.5 min, 133–1,200 specimens
Typical time delay from ordering stat test to aspir. of sample	12 sec	—
How often QC required/onboard SW capability to review QC	24 hr/yes	24 hr/yes
Onboard real-time QC/support multiple QC lot nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/no	onboard/no
Interfaces up and running in active user sites with	—	all major LIS vendors
Bidirectional interface capability	yes (broadcast download)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	no
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes (Lab-InterLink, Labotix, Coulter IDS, AutoLab)	yes (Roche Pre-Analytical Modular)
Modem servicing available/can diagnose own malfunctions/determine malfunctioning component	—/yes/yes	yes/yes/yes
On-site time of svc. engineer/onboard error codes for troubleshooting	<4 hr/yes	8 hr/yes
Mean time between failures/to repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 2 min; weekly: 5 min; monthly: 15 min	daily: 5 min; weekly: 10 min; monthly: 15 min
Onboard maintenance records/maint. training demo module	yes/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/advanced oper. training avail.	3 days on-site, 5 days at vendor offices/—	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	varies
Distinguishing features	superior assay precision; minimal interference from hemolysis, lipemia, bilirubin; smart metering; continuous process verification; no infectious waste; no plumbing, water, or drains; highest reportable result efficiency of any chemistry analyzer	Roche Hitachi chemistry and automation proven reliability and more than 20 years of experience; only system on the market today capable of consolidating up to 100 different assays on one high-throughput analyzer; system can be connected directly to preanalytical automation today; flexible, expandable to lab's changing needs; up to four modules per system

CAP CALENDAR

July

29   **LAP Inspector Training Seminar (R) workshop at AACC.** Location TBA, Orlando, Fla. CMEs TBA.

August

13   **Virtual Management College:** Medical Director. Teleconference. 1 CME.

17   **LAP Inspector Training Seminar (N).** Crowne Plaza Rochester (NY). 6 CMEs.

September

10   **Virtual Management College:** Human Resources. Teleconference. 1 CME.

14   **LAP Inspector Training Seminar (Cytopathology only).** Marriott Crabtree Valley, Raleigh, NC. 3 CMEs.

18   **LAP Audioconference:** Calibration/Calibration Verification. Teleconference. 1 CME.

21   **LAP Inspector Training Seminar (N).** Sheraton Portland (Ore.) Airport Hotel. 6 CMEs.

21–22   **Strategic Science II: HPV Testing: Are You Ready for a New Era in Cervical Cancer Screening?** Hotel Sofitel Chicago O'Hare. 10 CMEs.

28   **LAP Inspector Training Seminar (R).** Omni William Penn Hotel, Pittsburgh. 6 CMEs.

October

TBA   **LAP Inspector Training Seminar (R).** Washington State Convention Center, Seattle. 6 CMEs.

5   **LAP Inspector Training Seminar (N).** DoubleTree Hotel Portland (Maine). 6 CMEs.

8   **Virtual Management College:** Laboratory Operations. Teleconference. 1 CME.

11   **LAP Inspector Training Seminar (R).** Washington (DC) Convention Center. 3 CMEs.

Key: **(N)** = national seminar, **(R)** = regional seminar, **(CN)** = cosponsored in name only—CAP does not provide CMEs. For all activities, contact Registration Line at 800-323-4040 ext. 7525; registration@cap.org.

Part 10 of 10	Roche Diagnostics Lisa Davis, Product Manager 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 ext. 3531 us.labsystems.roche.com
See related comments, page 84	

Name of instrument/first year sold in U.S.	Integrated Modular Analytics/2002
List price	varies
No. units in clinical use in U.S./outside U.S.	—/—
Country where designed/manufactured/where reagents mftd.	multiple countries/multiple countries/multiple countries
Operational type/reagent type	continuous random access/self-contained multi-use cartridges-packages-slides
Sample handling system/model type	5-position rack/floor-standing
Dimensions in inches (H x W x D)/instrument footprint	varies with configuration/varies with configuration

No. of tests for which analyzer has FDA-cleared applications	>140
Tests clinically released in last 12 months	HBsAg, sTRF, estradiol II, D-dimer, CA 15-3 II, βHCG, CA 125 II, DHEA-S, tPSA, fPSA
Tests cleared but not clinically released	n/a
Tests not available in U.S. but submitted for 510(k) clearance	n/a
Tests not available in U.S. but available in other countries	proBNP, TG, anti-TG, urine cortisol, SHBG, kappa, lambda, apoA, apoB, Lp(a), acetaminophen
Research-use-only assays	n/a
Tests in development	—
User-defined methods implemented for what analytes	—

Methods supported/immunoassay methods	photometry, potentiometry (ion selective electrode)/ECL
No. of direct ion selective electrode channels	3
No. of different measured assays onboard simultaneously	72–>140
No. of different assays programmed, calibrated at once	72–>140
No. of user-definable (open) channels/no. active simultaneously	5/5
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	72–>140/100–3,000
Shortest/median onboard reag. stability/refrigerated onboard	72 hr/—/yes (2–12˚C)
Multiple reag. configurations supported	yes
Reag. container placed directly on system for use	yes, requires operator prehandling, preparation
Instrument has same capabilities when 3rd-party reag. used	yes
Walkaway capacity in minutes/specimens/tests-assays	6 hr/300/varies
System is liquid or dry	liquid
Uses disposable cuvettes/max. no. stored	no
Uses washable cuvettes/replacement frequency	yes/monthly
Minimum sample volume aspirated precisely at one time	2 µL
Supplied with UPS (backup power)/requires floor drain	yes/yes
Requires dedicated water system/water consumption per hour	yes/50 L
Noise generated in decibels	<62
Dedicated pediatric sample cup/dead volume	yes/50 µL
Primary tube sampling/pierces caps on primary tubes	yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes
Bar code placement per NCCLS standard Auto2A	yes

Onboard test auto inventory (determines volume in container)	yes
Measures no. tests remaining/short sample detection/clot detection	yes/yes/no
Automatic detection of adequate reag. for aspir. & analysis	yes
Hemolysis/turbidity detection-quantitation	yes/yes
Dilution of patient samples onboard/automatic rerun capability	yes/yes
Sample volume can be reduced/increased to rerun out-of-linear-range high/low results	yes/yes
Autocalibration or autocalibration alert	yes
Calibrants stored onboard/multipoint calibration supported	no/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	24 hr/varies from bottle change to lot change/bottle change/—
Automatic shutdown/startup programmable	yes/yes

Stat time to completion of all analytes, throughput per hr. for:	
• Sodium, potassium, chloride, TCO2	3.5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 min, 160–600 specimens
• Album., bili. direct & total, AST, ALT, ALP	10 min, 133–600 specimens
Typical time delay from ordering stat test to aspir. of sample	—
How often QC required/onboard SW capability to review QC	shortest interval: 24 hr; longest: —/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	onboard/no (addt'l cost)
Interfaces up and running in active user sites with	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes
LIS interface operates simultaneously with running assays	yes
Uses LOINC to transmit orders & results	no
How labs get LOINC codes for reagent kits	database

Interface avail. (or will be) to automated specimen handling system	yes (Roche Pre-Analytical Modular)

Modem servicing available/can diagnose own malfunctions/determine malfunctioning component	yes/yes/yes
On-site time of svc. engineer/onboard error codes for troubleshooting	8 hr/yes
Mean time between failures/to repair failures	n/a/n/a
Average time to complete maintenance by lab personnel	daily: 5 min hands-on; weekly: 30 min; monthly: 15 min
Onboard maintenance records/maint. training demo module	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/advanced oper. training avail.	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	varies

Distinguishing features	first combined high-throughput clinical chemistry and immunoassay system; single point of entry, single user interface, and single host connection provides unparallel efficiency and productivity gains; enhanced intelligent process management with optimized sample routing achieves: highest sample throughput, minimal sample dwell times, fastest availability of individual samples, seamless integration of stat samples into routine workflow, efficient integration of rerun and reflex tests into the workflow

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