Much to look forward to in chemistry analyzers

Anne Ford

rom the "Obvious Technological Statement of the Year" files: If you bought your cell phone in 1998, it's almost certainly time to get a new one. With all the sleek, streamlined models on the market that can do everything but shine your shoes, weighing yourself down with an old clunker just seems silly. The same may go for mid- and high-volume chemistry analyzers. "There are a lot of five- to 10-year-old chemistry systems in the field that are in need of replacement," says Gus Gardner, Clinical Data chief operating officer. "Many of them have DOS operating systems and are having obsolescence problems."

Fortunately, several new models have recently been or are about to be launched from a range of companies. They don't exactly offer text messaging or videophone capabilities, but—as Denise Pastore, Bayer clinical chemistry marketing manager, points out—their benefits may sound even more exciting to laboratory technologists and technicians, who "simply put, want things to be smaller, faster, easier."

Abbott Laboratories' Keith Chaitoff, director of global marketing for chemistry, sums up the strength

of his company's new Architect c8000 analyzer in three words: "integration without compromise." He says that while the benefits of integrated systems have been apparent for a while—"reduced workstations in the face of labor shortages, improved workflow for faster turnaround time, reduced errors due to less sample handling, less blood drawn"—some integrated systems of the past required some laboratories to make "significant tradeoffs" because of carryover issues, limited menu, or turnaround times. The Architect c8000, when combined with the i2000 SR immunoassay analyzer, is known as the ci8200 and processes stat samples within 20 seconds because of the retest sample handler, which has no in- or out-queues.

Meanwhile, Clinical Data has just launched the Selectra XL mid- to high-volume chemistry analyzer, which performs up to 480 tests an hour. It features integrated four-parameter dry ISE, a reusable cuvette rotor, positive sample identification, and onboard reagent cooling. And, Gardner adds, "High-tech user features like touch-screen interfaces, flat-screen monitors, and wireless keyboards are all available for users who want them." After all, clean lines and sleek styling are just as attractive in a chemistry analyzer as they are in a cell phone.

As shoppers for any kind of technology know, the only thing more exciting than buying shiny new equipment is the prospect of buying even shinier, newer equipment in the future. In the works at Ortho-Clinical Diagnostics is the Vitros 5,1 FS chemistry system. It will feature several proprietary technologies, such as Intellicheck technology for advanced clot and bubble detection and MicroSensor technology for reagentless and fully automated sample interference monitoring. It will also, says worldwide product director Robert Geen, offer the new MicroTip technology, which "simplifies workflow in the lab by eliminating the water, plumbing, drains, fixed probes, and mixing assemblies characteristic of alternative technologies while doubling the available test menu at the same time."

Chemistry analyzer customers interested in combining their instruments with immunoassay systems can get an early look at Olympus America's AU3000i, scheduled for display at the AACC meeting this month. The AU3000i will be able to be used as a standalone immunoassay system or integrated with an Olympus AU-Connector lab automation workcell in combination with one or more AU chemistry systems. That kind of standardization of systems, says senior product manager Susan Watanabe, is "a relatively new lab strategy

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Chemistry analyzers (for mid-volume laboratories)

Chemistry analyzers

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for lowering operational costs." She adds, "With Olympus standardization, lab personnel can easily move from one AU model used as a primary chemistry analyzer to another AU model used for specialty testing or immunoassay."

New instruments on the horizon from other companies include Bayer's Advia 1200 chemistry system, to be introduced later this year, and Roche's Cobas 6000, which will be introduced in 2005. Already available from Roche are the Integrated Modular Analytics clinical chemistry and immunoassay systems, which, says marketing communications consultant Stacey Bogardus, "can be configured for mid- to high-volume labs."

Labs can look forward to a host of new assays as well. Beckman Coulter is focusing on expanding the menu of its Synchron LXi 725 clinical system, which already features more than 140 assays. "Already we've released a number of new chemistry assays this year, including homocysteine for cardiac as well as tests for key proteins like C3, C4 and haptoglobin," says David Heibel, director of product management marketing.

"Other assays we plan to release within the next few months include an improved HDLD assay, lithium, an improved benzo-diazepine test, online hemoglobin A_{1c}, and an improved phosphorus assay." Dade Behring, too, is developing several new tests for its Dimension line of instruments, among them assays for NT-proBNP, microalbumin, N-acetyl procainamide, procainamide, tacrolimus, and cyclosporine. Bayer plans to add Li, TIBC, and wrCRP to its menu. And Abaxis will soon introduce a lipid panel that includes liver enzymes and an oncologist profile.

Awareness Technology offers economy to the 200-test-per-hour laboratory with its user-programmable ChemWell. "All new assays and systems require validation anyway," says Awareness president Mary Freeman, "so why not allow yourself the freedom to choose, optimize, and change your own test menu?" ChemWell can be used for biochemistry or for microwell EIA.

The appeal of all these instruments and assays, of course, lies not in the inherent charm of innovation, but in what they can offer laboratories that are struggling to keep up with increasing health care demands. "The needs of laboratorians in five, 10, or even 20 years are going to be far more intense," Heibel says. "They're going to need systems and processes that can accommodate increasing test volumes. They're going to want to deliver test results faster with greater accuracy. And, in the midst of all this, labs are going to have even less people to meet all the demand. Workstation consolidation and automation systems take away tedious manual steps and are a solution that's available today."

CAP TODAY's lineup of chemistry analyzers begins on this page. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities.

Anne Ford is a freelance writer in Chicago.

Part 1 of 13	ABAXIS Ron Blasig ron.blasig@abaxis.com 3240 Whipple Road
See related comments, page 62	Union City, CA 94587 510-675-6505 www.abaxis.com
lame of instrument/First year sold in U.S.	Piccolo/1995
ist price lo. units in clinical use in U.S./Outside U.S.	\$18,000 500/300
country where designed/Manufactured/Where reagents mftd. perational type/Reagent type	U.S./U.S./U.S. discrete/self-contained single-use cartridges-packages-slides
ample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	n/a/benchtop 9.5 x 6 x 11.5/1 sq. ft.
lo. of tests for which analyzer has FDA-cleared applications ests clinically released in last 12 months	<u>27</u>
ests cleared but not clinically released	_
ests not available in U.S. but submitted for 510(k) clearance ests not available in U.S. but available in other countries	_
iesearch-use-only assays iests in development	 lipid plus liver enzymes panel
ser-defined methods implemented for what analytes	_
Methods supported/immunoassay methods	photometry/—
lo. of direct ion selective electrode channels	
lo. of different measured assays onboard simultaneously lo. of different assays programmed, calibrated at once	27 27
lo. of user-definable (open) channels/No. active simultaneously lo. of different analytes for which system accommodates	n/a/27 14/14
reag. containers onboard at once/Tests per container set	
hortest/median onboard reag. stability/Refrigerated onboard Nultiple reag. configurations supported	n/a/n/a yes
leag. container placed directly on system for use	yes n/a
nstrument has same capabilities when 3rd-party reag. used Valkaway capacity in minutes/Specimens/Tests-assays	n/a <13 min/1/14
ystem is liquid or dry Ises disposable cuvettes/Max. No. stored	dry uses reagent disks/n/a
ses washable cuvettes/Replacement frequency	no
finimum sample volume aspirated precisely at one time supplied with UPS (backup power)/Requires floor drain	n/a no/—
equires dedicated water system/Water consumption per hour	no/—
loise generated in decibels ledicated pediatric sample cup/Dead volume	none no
rimary tube sampling/Pierces caps on primary tubes iample bar-code reading capability	n/a/n/a yes, by handheld scanner as tubes are loaded onto instrument
leagent bar-code reading capability lar code placement per NCCLS standard Auto2A	yes —
inboard test auto inventory (determines volume in container)	no
Measures no. tests remaining/Short sample detection/Clot detection automatic detection of adequate reag. for aspir. & analysis	no/yes/yes yes
emolysis/Turbidity detection-quantitation	yes/yes
ilution of patient samples onboard/Automatic rerun capability	no/yes
ample volume can be reduced/Increased to rerun out-of-linear-	no/no
range high/low results utocalibration or autocalibration alert	yes
alibrants stored onboard/Multipoint calibration supported	n/a/yes
ypical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse automatic shutdown/Startup programmable	—/—/— no/no
tat time to completion of all analytes, throughput per hr. for:	
Sodium, potassium, chloride, TC02	POC: <13 min, ~4 specimens
 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP 	same as above for all analytes same as above for all analytes
	·
ypical time delay from ordering stat test to aspir. of sample low often QC required/Onboard SW capability to review QC	n/a every 30 days/yes
nboard real-time QC/Support multiple QC lot Nos. per analyte IC results transferred automatically to LIS	yes/yes
·	yes ve/es
lata mgmt. capability/Instrument vendor supplies LIS interface	no/no
nterfaces up and running in active user sites with	contact vendor
idirectional interface capability est results transmitted to LIS as soon as chem. time complete	no yes
IS interface operates simultaneously with running assays lses LOINC to transmit orders & results	yes —
low labs get LOINC codes for reagent kits	_
nterface avail. (or will be) to automated specimen handling system	no
Nodem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes
n-site time of svc. engineer/Onboard error codes for troubleshooting	Piccolo is compact and lightweight and can be returned to mfg. with
lean time between failures/To repair failures	replacement in 24 hrs 3 yr/—
verage time to complete maintenance by lab personnel Inboard maintenance records/Maint. training demo module	n/a no/—
raining provided with purchase/Advanced oper. training avail.	2 hr on site/no
	2 nr on site/no \$1,200

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

Survey editor: Raymond Aller, MD

Chemistry analyzers (for mid-volume laboratories)

	aryzera (for filla-volum	c laboratorics)
Part 2 of 13 See related comments, page 62	Abbott Diagnostics Brian Michalski brian.michalski@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 800-323-9100 www.abbott.com	Abbott Diagnostics Brian Michalski brian.michalski@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 800-323-9100 www.abbott.com
,,, ,		
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Abbott Architect c8000/2003 \$225,000 0/30 U.S., Japan/U.S., Japan/U.S. continuous random access/open reagent system	Abbott Architect ci8200/2003 \$375,000 1/50 U.S., Japan/U.S., Japan/U.S. continuous random access/self-contained multi-use cartridges-
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	multi-dimensional retest sample handler, carousel/floor standing 48 x 79 x 49/~26 sq ft	packages-slides, open reagent system multi-dimensional retest sample handler/floor standing 48 x 127 x 49/42 sq ft
No. of tests for which analyzer has FDA-cleared applications	62	62
Tests clinically released in last 12 months Tests cleared but not clinically released	digoxin, valproic acid, ethanol, amp./meth., barbs., benzo., cannab., cocaine, methadone, opiates, PCP, propox., CRP, RF, HbA1c, carbs, pheno., phenytoin, theo. microalbumin, apo A1, apo B, C3, C4, IgA, IgG, IgM, prealbumin,	digoxin, valproic acid, ethanol, amp./meth., barbs., benzo., cannab., cocaine, methadone, opiates, PCP, propox., CRP, RF, HbA1 c, carbs, pheno., phenytoin, theo. microalbumin, apo A1, apo B, C3, C4, IgA, IgG, IgM, prealbumin,
Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	transferrin, haptoglobin — A-1-AGP, ASP, β2-microglobulin, digitoxin, ferritin, IgE, myoglobin, hsCRP, alpha amylase pancreatic, alpha HBDH, cholinesterase,	transferrin, haptoglobin — A-1-AGP, ASP, β2-microglobulin, digitoxin, ferritin, lgE, myoglobin, hsCRP, alpha amylase pancreatic, alpha HBDH, cholinesterase,
Research-use-only assays Tests in development	CK-MB — direct LDL, ultra HDL, ammonia, ceruloplasmin, iron (UIBC), A-1 antitrypsin	CK-MB — direct LDL, ultra HDL, ammonia, ceruloplasmin, iron (UIBC), A-1 antitrypsin
User-defined methods implemented for what analytes	ammonia, lithium	ammonia, lithium
·	<u> </u>	<u> </u>
Methods supported/Immunoassay methods	photometry, potentiometry, turbidimetric/—	photometry, potentiometry, turbidimetric/chemiluminescence with flexible protocols
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously	3 68	3 93
No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously	220 220/220	320 220/220
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 Reag. container placed directly on system for use	yes yes	yes yes
Instrument has same capabilities when 3rd-party reag. used Walkaway capacity in minutes/Specimens/Tests-assays	yes varies/217/69,000-68	yes varies >300/367/81,000-93
System is liquid or dry	liquid no/—	liquid yes, immunoassay/—
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	yes/minimum 1 yr guarantee	yes, chemistry/minimum 1 yr guaranteed
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain	2 μL yes/no	2 μL yes/no
Requires dedicated water system/Water consumption per hour Noise generated in decibels	yes/25 L	yes/30.5 L
Dedicated pediatric sample cup/Dead volume	yes/50 μL	yes/50 μL
Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5	yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A	interl., Codabar, codes 39 & 128)/autodiscrimination yes, 2-D bar codes yes	interl., Codabar, codes 39 & 128)/autodiscrimination yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection	yes yes/yes/yes	yes yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes/yes yes/yes	yes/yes yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results	yes/yes	_/_
Autocalibration or autocalibration alert	yes year/yea	yes
Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	yes/yes 8 hr/30 days/14 days/7–14 days	yes, for chemistry only/yes 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 Typical time delay from ordering stat test to aspir. of sample	9.6 min, 133 specimens <20 sec	9.6 min, 133 specimens <20 sec
How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte	shortest interval: 8 hr; longest: 24 hr/yes yes/yes	shortest interval: 8 hr; longest: 24 hr/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 LIS interface operates simultaneously with running assays	yes yes	yes yes
Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	package insert	
Interface avail. (or will be) to automated specimen handling system	ves (Tecan Genesis FE 500)	no
, , ,	, , ,	
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 Mean time between failures/To repair failures	<24 hr/yes —/—	<24 hr/yes —/—
Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module	daily: <15 min; weekly: <45 min; monthly: 15 min yes (includes audit trail of who replaced parts)/yes	daily: TBD; weekly: TBD; monthly: TBD 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 3 of 13	Awareness Technology Inc. Chris Schneider info@awaretech.com P.O. Box 1679	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Proc. CA 03933 8000
See related comments, page 62	Palm City, FL 34991 772-283-6540 www.awaretech.com	Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com
ame of instrument/First year sold in U.S.	ChemWell/1999	Synchron CX9 Pro/2001
ist price lo. units in clinical use in U.S./Outside U.S.	\$25,000 10/480	\$220,600 900/500
ountry where designed/Manufactured/Where reagents mftd. perational type/Reagent type	U.S./U.S./open system continuous random access/open ragent system	U.S./U.S. & Ireland continuous random access/open reagent system
ample handling system/Model type imensions in inches (H x W x D)/Instrument footprint	rack of 96 samples/benchtop 19 x 36 x 22 in/7 sq ft	sectors, centrifugable/floor standing 69 x 74 x 30 in/15.4 sq ft
o. of tests for which analyzer has FDA-cleared applications	22	>100
ests clinically released in last 12 months	none	C3, C4, haptoglobin
ests cleared but not clinically released	none	none
ests not available in U.S. but submitted for 510(k) clearance	18 EIA kits manuf. by BroCheck have been submitted	none
ests not available in U.S. but available in other countries	open system	none
esearch-use-only assays ests in development	open system none	none homocysteine, D-dimer, sirolimus, tacrolimus, lp(a), tricyclics,
ser-defined methods implemented for what analytes	all colorimetric biochemistry & EIA that read between 340–700 nm	semiquantitative DATs UIBC, cyclosporine
lethods supported/Immunoassay methods	photometry/microwell assays	photometry, potentiometry, turbidimetric/bidentate turbidimetric, dire
o. of direct ion selective electrode channels	0	turbidimetric, particle enhanced turbidimetric, enzyme immunoassay 5 (indirect)
o. of different measured assays onboard simultaneously o. of different assays programmed, calibrated at once	27 unlimited	33 59
o. of user-definable (open) channels/No. active simultaneously	unlimited/27	102/33
lo. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	27/reagent dependent	33/25–2,500
hortest/median onboard reag. stability/Refrigerated onboard	reagent dependent/yes (15°C below ambient)	168 hr/30 days/yes (2–8°C)
lultiple reag. configurations supported eag. container placed directly on system for use	yes reagent dependent	yes yes
nstrument has same capabilities when 3rd-party reag. used Jalkaway capacity in minutes/Specimens/Tests-assays	yes not limited/96/not limited	yes 400/63/2,079
ystem is liquid or dry	liquid	liquid
ses disposable cuvettes/Max. No. stored ses washable cuvettes/Replacement frequency	yes (optional)/96 yes (optional)/weekly	no/n/a yes/permanent–2-yr warranty (80 stored on instrument)
linimum sample volume aspirated precisely at one time upplied with UPS (backup power)/Requires floor drain	2 μL no/no	3 μL yes/yes
equires dedicated water system/Water consumption per hour	no/<1 L	yes/7 L
loise generated in decibels ledicated pediatric sample cup/Dead volume	60 no	70 yes/40 μL
rimary tube sampling/Pierces caps on primary tubes ample bar-code reading capability	no/no yes, by handheld scanner as tubes are loaded onto instrument (2 or 5	yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5
ample bar-code reading capability	interl., UPC, Codabar, codes 39 & 128)/autodiscrimination depends on	interl., Codabar, codes 39 & 128)/autodiscrimination
eagent bar-code reading capability	handheld scanner models no	yes
ar code placement per NCCLS standard Auto2A	no	yes
inboard test auto inventory (determines volume in container) leasures no. tests remaining/Short sample detection/Clot detection	yes yes/yes/no	yes yes/yes/yes
utomatic detection of adequate reag. for aspir. & analysis emolysis/Turbidity detection-quantitation	yes no/no	yes
ilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes yes/yes
ample volume can be reduced/Increased to rerun out-of-linear- range high/low results	yes/no	yes/yes
utocalibration or autocalibration alert	yes	yes
alibrants stored onboard/Multipoint calibration supported ypical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	yes/yes user defined for all	no/yes 24 hr/up to 90 days/up to 60 days/14 days
utomatic shutdown/Startup programmable	yes/yes	none required
tat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2	n/a	52 sec, 75 specimens
Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP	n/a 5.5 min, 28 specimens	52 sec, 75 specimens 10 min, 32 specimens
ypical time delay from ordering stat test to aspir. of sample	15 sec	45 sec
low often QC required/Onboard SW capability to review QC inboard real-time QC/Support multiple QC lot Nos. per analyte	reagent dependent/yes yes/yes	24 hr/yes yes/yes
C results transferred automatically to LIS	yes	yes
ata mgmt. capability/Instrument vendor supplies LIS interface nterfaces up and running in active user sites with	onboard/yes (included in price) not known	onboard & optional add-on (SW mftr: Beckman Coulter DL2000)/yes (addt'l cost)
		Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesso
idirectional interface capability	yes (broadcast download)	Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query)
est results transmitted to LIS as soon as chem. time complete IS interface operates simultaneously with running assays	yes yes	yes yes
ses LOINC to transmit orders & results	no	no
ow labs get LOINC codes for reagent kits	supplied by reagent manufacturer	Web site, customer request
nterface avail. (or will be) to automated specimen handling system	NO Voca/voca/competimes	yes (Power Processor)
lodem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/sometimes	yes/no/no
n-site time of svc. engineer/Onboard error codes for troubleshooting lean time between failures/To repair failures	48 hr/yes depends on user and varies/depends on problem and varies	metro: same day, rural: same or next day/yes
verage time to complete maintenance by lab personnel inboard maintenance records/Maint. training demo module	daily: <5 min; weekly: about 15 min; monthly: about 30 min or less	daily: 5 min; weekly: 15 min; monthly: 25 min no/no
	no/no 2 days on site, 3 days at vendor offices/yes \$4,000	5 days at vendor offices/yes —
raining provided with purchase/Advanced oper. training avail. Innual service contract cost (24 h/7 d)		
raining provided with purchase/Advanced oper. training avail. nnual service contract cost (24 h/7 d) istinguishing features	price; one instrument for EIA & biochemistry; completely open and	serum indices; centrifugable sectors: clot detection: design ontimiz
nnual service contract cost (24 h/7 d)	price; one instrument for EIA & biochemistry; completely open and user programmable; special discounts for biochemistry-only;	serum indices; centrifugable sectors; clot detection; design optimiz for automation; continuous random access for samples, controls, reagents, and results; no-maintenance glucose gyggen sensor; no-
nnual service contract cost (24 h/7 d)	price; one instrument for EIA & biochemistry; completely open and	for automation; continuous random access for samples, controls, reagents, and results; no-maintenance glucose oxygen sensor; no-wait autoloader; polychromatic correction; thermal ring and semi-
nnual service contract cost (24 h/7 d)	price; one instrument for EIA & biochemistry; completely open and user programmable; special discounts for biochemistry-only;	for automation; continuous random access for samples, controls, reagents, and results; no-maintenance glucose oxygen sensor; no-

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Chemistry analyzers (for mid-volume laboratories)

art 4 of 13	Clinical Data	Olympus America Inc.
nt 4 01 13	slsmktg@clda.com	Susan M. Watanabe, PhD susan.watanabe@olympus.com
	2 Thurber Blvd.	Two Corporate Center Dr.
	Smithfield, RI 02917	Melville, NY 11747
ee related comments, page 62	800-345-2822 www.clda.com	800-223-0125 www.olympus.com
ame of instrument/First year sold in U.S.	Vitalab Selectra XL/2004	AU400/1998; AU400e/2002
st price o. units in clinical use in U.S./Outside U.S.	\$98,750 0/—	\$130,000 500/1,700
puntry where designed/Manufactured/Where reagents mftd.	Netherlands/Netherlands/U.S.	Japan/Japan/U.S. & Ireland
perational type/Reagent type	random access/multi-use bottles	random access, discrete, continuous random access/open
ample handling system/Model type	rotor/floor standing	reagent system rack & stat carousel/floor standing
imensions in inches (H x W x D)/Instrument footprint	45 x 46 x 30/12 sq ft	47.6 x 57.1 x 29.9/62.7 sq ft
o of toots for which analyzer has EDA algored applications	21	122
o. of tests for which analyzer has FDA-cleared applications ests clinically released in last 12 months	31 ALT, alk phos., albumin, amylase, GOT, direct & total bilirubin,	122 ceruloplasmin, urinary/CSF protein, cholinesterase, HbA1c
	calcium, CO ₂ , chloride, cholesterol, CPK, creatinine, digoxin,	,, ,, ,, ,, ,, ,, ,, ,, ,, ,
	direct HDL & LDL, GGT, glucose, total iron, LDH, magnesium, phe-	
	nobarbital, phenytoin, phosphorus, potassium, total protein, sodium theophylline, triglycerides, BUN, uric acid	
ests cleared but not clinically released	—	-
ests not available in U.S. but submitted for 510(k) clearance	_	-
ests not available in U.S. but available in other countries esearch-use-only assays	_	none
ests in development	hsCRP	lactate
ser-defined methods implemented for what analytes	n/a	fructosamine, ammonia
ethods supported/immunoassay methods	photometry, potentiometry (ISE)/immunoturbidimetric	photometry, potentiometry, calculated tests/homogeneous
	p	p
o. of direct ion selective electrode channels	4	3 un to 76
o. of different measured assays onboard simultaneously o. of different assays programmed, calibrated at once	40 40	up to 76 99
o. of user-definable (open) channels/No. active simultaneously	5/40	95/—
o. of different analytes for which system accommodates	70/700	76/100–1,333
reag. containers onboard at once/Tests per container set nortest/median onboard reag. stability/Refrigerated onboard	72 hr/7 days/yes (12°C below ambient)	120 hr/30 days/yes (4-12°C)
ultiple reag. configurations supported	—	yes
eag. container placed directly on system for use	yes	yes
strument has same capabilities when 3rd-party reag. used alkaway capacity in minutes/Specimens/Tests-assays	yes 240/80/2,400	yes varies/up to 102/varies
stem is liquid or dry	liquid	liquid
ses disposable cuvettes/Max. No. stored	no .	no/n/a
ses washable cuvettes/Replacement frequency inimum sample volume aspirated precisely at one time	yes/every 10,000 reactions 1 µL	yes/permanent 2 µL
upplied with UPS (backup power)/Requires floor drain	yes/no	no (optional)/yes (no w/ optional water pump)
equires dedicated water system/Water consumption per hour	no/0.8 L	yes/26 L per hr peak consumption
oise generated in decibels edicated pediatric sample cup/Dead volume	— yes/20 μL	65 no/n/a
rimary tube sampling/Pierces caps on primary tubes	yes/no Ves/no	yes/no
ample bar-code reading capability	yes, as sample is being aspirated (2 of 5 interl., UPC, Codabar,	yes, on sample transport, shortly before sample is aspirated (2 of
eagent bar-code reading capability	codes 39 & 128) no	5 interl., Codabar, codes 39 & 128)/autodiscrimination
ar code placement per NCCLS standard Auto2A	yes	yes yes
		<u> </u>
nboard test auto inventory (determines volume in container) easures no. tests remaining/Short sample detection/Clot detection	yes yes/yes	yes yes/yes/yes
utomatic detection of adequate reag. for aspir. & analysis	yes	yes
emolysis/Turbidity detection-quantitation	<u>_/_</u>	yes/yes
ilution of patient samples onboard/Automatic rerun capability ample volume can be reduced/Increased to rerun out-of-linear-	yes/yes yes/no	yes/yes yes/yes
range high/low results	,csc	,,
utocalibration or autocalibration alert	yes	yes
alibrants stored onboard/Multipoint calibration supported pical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	no/yes 4 hr/1–14 days/—/—	yes/yes 1 day/30 days/14 days/14–20 days
utomatic shutdown/Startup programmable	yes/yes	yes/yes
at time to completion of all analytics throughout and		
at time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2	8 min. —	<5 min. 200 specimens
 Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine 	8 min, — 10 min, —	<5 min, 200 specimens <5 min, 80 specimens
 Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP 	10 min, — 10 min, —	<5 min, 80 specimens <9 min, 67 specimens
 Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP pical time delay from ordering stat test to aspir. of sample 	10 min, — 10 min, — 6 min	<5 min, 80 specimens <9 min, 67 specimens <2 min
 Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP 	10 min, — 10 min, —	<5 min, 80 specimens <9 min, 67 specimens
 Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP pical time delay from ordering stat test to aspir. of sample ow often QC required/Onboard SW capability to review QC 	10 min, — 10 min, — 6 min shortest interval: 4 hr; longest: once a day/yes	<5 min, 80 specimens <9 min, 67 specimens <2 min per CLIA & laboratory's decision/yes
Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP //pical time delay from ordering stat test to aspir. of sample ow often QC required/Onboard SW capability to review QC nboard real-time QC/Support multiple QC lot Nos. per analyte C results transferred automatically to LIS	10 min, — 10 min, — 6 min shortest interval: 4 hr; longest: once a day/yes no/yes yes	<5 min, 80 specimens <9 min, 67 specimens <2 min per CLIA & laboratory's decision/yes yes/yes yes
 Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP pical time delay from ordering stat test to aspir. of sample ow often QC required/Onboard SW capability to review QC nboard real-time QC/Support multiple QC lot Nos. per analyte 	10 min, — 10 min, — 6 min shortest interval: 4 hr; longest: once a day/yes no/yes	<5 min, 80 specimens <9 min, 67 specimens <2 min per CLIA & laboratory's decision/yes yes/yes
Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Alpum. Approximately to aspir. of sample of sampl	10 min, — 10 min, — 6 min shortest interval: 4 hr; longest: once a day/yes no/yes yes	<5 min, 80 specimens <9 min, 67 specimens <2 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens,
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Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album, bili. direct & total, AST, ALT, ALP Album, bili. direct & total, AST, ALT ALP Album, bili. direct & total, AST, AST, AST, AST, AST, AST, AST, AST	10 min, — 10 min, — 6 min shortest interval: 4 hr; longest: once a day/yes no/yes yes optional add on/yes — yes yes yes —	<5 min, 80 specimens <9 min, 67 specimens <2 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation yes (broadcast download & host query) yes
Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP //pical time delay from ordering stat test to aspir. of sample ow often QC required/Onboard SW capability to review QC nboard real-time QC/Support multiple QC lot Nos. per analyte C results transferred automatically to LIS ata mgmt. capability/Instrument vendor supplies LIS interface terfaces up and running in active user sites with directional interface capability est results transmitted to LIS as soon as chem. time complete S interface operates simultaneously with running assays	10 min, — 10 min, — 6 min shortest interval: 4 hr; longest: once a day/yes no/yes yes optional add on/yes — yes yes	<5 min, 80 specimens <9 min, 67 specimens <2 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation yes (broadcast download & host query) yes yes
Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album, bili. direct & total, AST, ALT, ALP Album, bili. direct & total, AST, ALT ALP Album, bili. direct & total, AST, AST, AST, AST, AST, AST, AST, AST	10 min, — 10 min, — 6 min shortest interval: 4 hr; longest: once a day/yes no/yes yes optional add on/yes — yes yes yes —	<5 min, 80 specimens <9 min, 67 specimens <2 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation yes (broadcast download & host query) yes yes
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Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP pical time delay from ordering stat test to aspir. of sample ow often QC required/Onboard SW capability to review QC piboard real-time QC/Support multiple QC lot Nos. per analyte C results transferred automatically to LIS ata mgmt. capability/Instrument vendor supplies LIS interface terfaces up and running in active user sites with directional interface capability est results transmitted to LIS as soon as chem. time complete S interface operates simultaneously with running assays ses LOINC to transmit orders & results ow labs get LOINC codes for reagent kits terface avail. (or will be) to automated specimen handling system odem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component n-site time of svc. engineer/Onboard error codes for troubleshooting ean time between failures/To repair failures verage time to complete maintenance by lab personnel nboard maintenance records/Maint. training demo module raining provided with purchase/Advanced oper. training avail.	10 min, — 10 min, — 6 min shortest interval: 4 hr; longest: once a day/yes no/yes yes optional add on/yes — yes yes yes — — no/yes/yes within 24 hr/yes 6 mo/4 hr	<5 min, 80 specimens <9 min, 67 specimens <2 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation yes (broadcast download & host query) yes yes no — yes yes/yes/yes <24 hr/yes average 2 calls per yr/<24 hr
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Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP pical time delay from ordering stat test to aspir. of sample ow often QC required/Onboard SW capability to review QC mboard real-time QC/Support multiple QC lot Nos. per analyte C results transferred automatically to LIS ata mgmt. capability/Instrument vendor supplies LIS interface terfaces up and running in active user sites with directional interface capability est results transmitted to LIS as soon as chem. time complete S interface operates simultaneously with running assays ses LOINC to transmit orders & results ow labs get LOINC codes for reagent kits terface avail. (or will be) to automated specimen handling system odem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component n-site time of svc. engineer/Onboard error codes for troubleshooting ean time between failures/To repair failures verage time to complete maintenance by lab personnel mboard maintenance records/Maint. training demo module raining provided with purchase/Advanced oper. training avail. nnual service contract cost (24 h/7 d)	10 min, — 10 min, — 6 min shortest interval: 4 hr; longest: once a day/yes no/yes yes optional add on/yes — yes yes yes — — no/yes/yes within 24 hr/yes 6 mo/4 hr daily: 10 min; weekly: 20 min; monthly: 60 min no/yes 3 days on site/yes n/a	<5 min, 80 specimens <9 min, 67 specimens <2 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation yes (broadcast download & host query) yes yes yes yes yes/yes/yes <24 hr/yes average 2 calls per yr/<24 hr daily: 3 min; weekly: 7 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 3-5 days on site, 5 days at vendor offices/yes inquire
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Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP pical time delay from ordering stat test to aspir. of sample ow often QC required/Onboard SW capability to review QC mboard real-time QC/Support multiple QC lot Nos. per analyte C results transferred automatically to LIS ata mgmt. capability/Instrument vendor supplies LIS interface terfaces up and running in active user sites with directional interface capability est results transmitted to LIS as soon as chem. time complete S interface operates simultaneously with running assays ses LOINC to transmit orders & results ow labs get LOINC codes for reagent kits terface avail. (or will be) to automated specimen handling system odem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component n-site time of svc. engineer/Onboard error codes for troubleshooting ean time between failures/To repair failures verage time to complete maintenance by lab personnel mboard maintenance records/Maint. training demo module raining provided with purchase/Advanced oper. training avail. nnual service contract cost (24 h/7 d)	10 min, — 10 min, — 6 min shortest interval: 4 hr; longest: once a day/yes no/yes yes optional add on/yes — yes yes yes — — no/yes/yes within 24 hr/yes 6 mo/4 hr daily: 10 min; weekly: 20 min; monthly: 60 min no/yes 3 days on site/yes n/a 4 parameter dry ISE with CO ₂ ; reusable reaction cuvette rotor;	<5 min, 80 specimens <9 min, 67 specimens <2 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation yes (broadcast download & host query) yes yes yes yes yes/yes/yes <24 hr/yes average 2 calls per yr/<24 hr daily: 3 min; weekly: 7 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 3–5 days on site, 5 days at vendor offices/yes inquire 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
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70 / CAP TODAY

Chemistry analyzers (for mid-volume laboratories)

Part 5 of 13	Roche Diagnostics Todd Atkinson, Product Manager	Roche Diagnostics Lisa Davis, Product Manager
2	9115 Hague Rd., P.O. Box 50457 Indianapolis, IN 46250	9115 Hague Rd. Indianapolis, IN 46250
See related comments, page 62 Name of instrument/First year sold in U.S.	800-428-5074 www.roche.com Cobas Integra 800/2001 (Integra introduced 1995)	800-428-5074 ext. 3531 us.labsystems.roche.com
List price	\$265,000	Integrated Modular Analytics/2002 varies
No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd.	>500/>2,000 Switzerland/Switzerland/multiple countries	>50/>200 multiple countries/multiple countries
Operational type/Reagent type	random access, discrete, continuous random access/self-	continuous random access/self-contained, multi-use cartridges-pack-
Sample handling system/Model type	contained multi-use cartridges-packages-slides sample racks: RD 5-position rack/floor standing	ages-slides 5-position rack/floor-standing
Dimensions in inches (H x W x D)/Instrument footprint	47.3 x 74.8 x 35.4/—	varies with configuration/varies with configuration
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months	137 —	>140 amikacin, quinidine, SHBG, C-peptide
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance	none	n/a n/a
Tests not available in U.S. but available in other countries	LDH (P→L), ALP (DGKC)	TG, anti-TG, urine cortisol, kappa, lambda, apoA, apoB, Lp(a), osteocalcin, P1NP
Research-use-only assays Tests in development	— IgE, lipoprotein (a), kappa/lambda light chains, IMA	n/a anti-HBc, anti-HBc IgM, anti-HBe, HBe-Aq, rubella IgG, rubella IgM,
	3-,	toxo IgG, toxo IgM, CA 19-9, CA 72-4, Lp PLA ₂ , vancomycin, lidocaine, cyclosporin
User-defined methods implemented for what analytes	yes, varies	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry, fluorescence polarization/ turbidimetric	photometry, potentiometry (ion selective electrode)/ electrochemiluminescence
No. of direct ion selective electrode channels	4	3
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	72 72	72->140 72->140
No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates	0/n/a 72/50–800	varies 72->140/100-3,000
reag. containers onboard at once/Tests per container set		,
Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported	336 hr/84 days/yes (8°C) yes	72 hr/90 days/yes (2–12°C) yes
Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used	yes no	yes limited
Walkaway capacity in minutes/Specimens/Tests-assays	450/180/4,000	6 hr/300/varies
System is liquid or dry Uses disposable cuvettes/Max. No. stored	liquid yes/3,600	liquid yes, 1,000 tests
Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time	no/n/a	yes/monthly
Supplied with UPS (backup power)/Requires floor drain	2 μL yes/yes	2 μL yes/yes
Requires dedicated water system/Water consumption per hour Noise generated in decibels	no (direct connection, type I NCCLS)/5-7 L 58.5	yes/50 L <62
Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes	yes/approx. 50–70 μL	yes/50 µL
Sample bar-code reading capability	yes/no yes (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5
Reagent bar-code reading capability	yes	interl., Codabar, codes 39 & 128)/autodiscrimination 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
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes yes/yes yes/yes	yes yes/yes yes/yes
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results	yes yes/yes	yes yes/yes
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Chemistry analyzers (for high-volume laboratories)

Part 6 of 13	Abbott Diagnostics Brian Michalski brian.michalski@abbott.com	Bayer HealthCare, Diagnostics Division Denise Pastore denise.pastore.b@bayer.com
	100 Abbott Park Road	511 Benedict Ave.
	Abbott Park, IL 60064 800-323-9100	Tarrytown, NY 10591 914-333-6162
See related comments, page 62	www.abbott.com	labnews.com
Name of instrument/First year sold in U.S.	Abbott Aeroset/1998	ADVIA 1650/1999
List price No. units in clinical use in U.S./Outside U.S.	\$345,000 330/600+	\$279,000 180/805
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 Tests clinically released in last 12 months	62 digoxin, valproic acid, CRP, RF, HbA1c, direct LDL, phenytoin	74 TIBC, C3, C4, haptoglobin
Tests cleared but not clinically released	microalbumin	salicylate, ethanol, acetaminophen
Tests not available in U.S. but submitted for 510(k) clearance		none
Tests not available in U.S. but available in other countries	A-1-AGP, ASP, β2-microglobulin, digitoxin, ferritin, IgE, myoglobin, hsCRP, alpha amylase pancreatic, alpha HBDH, cholinesterase,	_
Describe use only second	CK-MB	7000
Research-use-only assays Tests in development	ultra HDL, ammonia, ceruloplasmin, iron (UIBC), A-1 antitrypsin	none lithium
User-defined methods implemented for what analytes	ammonia, lithium	alcohol, C3, C4, salicylate, CK-MB, myoglobin, fructosamine, β2-microglobulin, DAUs
Methods supported/Immunoassay methods No. of direct ion selective electrode channels	photometry, potentiometry/—	photometry, potentiometry, turbidimetrics/—
No. of different measured assays onboard simultaneously	5 59	49
No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously	100 100/59	100 62/62
No. of different analytes for which system accommodates	59/400	49/840
reag. containers onboard at once/Tests per container set 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 Instrument has same capabilities when 3rd-party reag. used	yes yes	yes yes
Walkaway capacity in minutes/Specimens/Tests-assays	60/231/50,000+	90-470/200/32,000
System is liquid or dry Uses disposable cuvettes/Max. No. stored	liquid no/n/a	liquid 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 Supplied with UPS (backup power)/Requires floor drain	2 μL no/no	2 μL 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 Sample bar-code reading capability	yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5	yes/no yes (2 of 5 interl., Codabar [NW7], codes 39 & 128)/autodiscrimination
	interl., Codabar, codes 39 & 128)/autodiscrimination	yes (2 01 3 lilleri., oodabai [NW7], codes 35 & 120//aditodiscrimination
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A	yes yes	yes yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/no	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation	yes yes/yes	yes yes/yes
Dilution of patient samples onboard/Automatic rerun capability	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	yes	yes
Calibrants Stored onboard/Multiboint Calibration Sunnorted	· · · · · · · · · · · · · · · · · · ·	
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	yes/yes 8 hr/28 days/28 days/28 days	yes/yes daily/30 days/30 days/daily
		• •
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Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/	8 hr/28 days/28 days/28 days yes/yes 10 min, 200+ specimens 10 min, 200+ specimens 10 min, 200+ specimens <15 sec shortest interval: 8 hr (ISE); longest: 24 hr/yes yes/yes yes no/yes (addt'l cost) all major vendors yes (broadcast download & host query) yes yes no —	daily/30 days/30 days/daily yes/yes 10 min, 150 samples, 600 tests 10 min, 150 samples, 1,050 tests 10 min, 200 samples, 1,200 tests 3 sec per CLIA and laboratory's decision/yes yes/yes yes onboard/no Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens yes (broadcast download & host query) yes yes yes yes e-mail, software
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting	8 hr/28 days/28 days/28 days yes/yes 10 min, 200+ specimens 10 min, 200+ specimens 10 min, 200+ specimens <15 sec shortest interval: 8 hr (ISE); longest: 24 hr/yes yes/yes yes no/yes (addt'l cost) all major vendors yes (broadcast download & host query) yes yes no — in development	daily/30 days/30 days/daily yes/yes 10 min, 150 samples, 600 tests 10 min, 150 samples, 1,050 tests 10 min, 200 samples, 1,200 tests 3 sec per CLIA and laboratory's decision/yes yes/yes yes onboard/no Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens yes (broadcast download & host query) yes yes yes yes yes yes yes yes e-mail, software yes (all systems) yes/yes/yes 4-8 hr/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures	8 hr/28 days/28 days/28 days yes/yes 10 min, 200+ specimens 10 min, 200+ specimens 10 min, 200+ specimens <15 sec shortest interval: 8 hr (ISE); longest: 24 hr/yes yes/yes yes no/yes (addt'l cost) all major vendors yes (broadcast download & host query) yes yes no — in development no/no/no <24 hr/yes >2 mo/varies	daily/30 days/30 days/daily yes/yes 10 min, 150 samples, 600 tests 10 min, 200 samples, 1,050 tests 10 min, 200 samples, 1,200 tests 3 sec per CLIA and laboratory's decision/yes yes/yes yes onboard/no Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens yes (broadcast download & host query) yes yes yes e-mail, software yes (all systems) yes/yes/yes 4–8 hr/yes —/4-8 hr
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Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album, bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	8 hr/28 days/28 days/28 days yes/yes 10 min, 200+ specimens 10 min, 200+ specimens 10 min, 200+ specimens 10 min, 200+ specimens 110 min, 200+ specim	daily/30 days/30 days/daily yes/yes 10 min, 150 samples, 600 tests 10 min, 150 samples, 1,050 tests 10 min, 200 samples, 1,200 tests 3 sec per CLIA and laboratory's decision/yes yes/yes yes onboard/no Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens yes (broadcast download & host query) yes yes e-mail, software yes (all systems) yes/yes/yes 4-8 hr/yes —/4-8 hr daily: 10 min; weekly: 45 min; monthly: 1 hr yes/yes ongoing on site, 5 days at vendor offices/— \$23,000 system will aspirate every three seconds and retain aliquot onboard; original sample is available to leave system; all testing performed with aliquot of sample remaining on ADVIA 1650; all reruns/repeats/ dilutions automatically performed without operator intervention;

Chemistry analyzers (for high-volume laboratories)

Part 7 of 13	Bayer HealthCare, Diagnostics Division Denise Pastore denise.pastore.b@bayer.com	Beckman Coulter Inc. 200 South Kraemer Blvd.
	511 Benedict Ave.	P.O. Box 8000
	Tarrytown, NY 10591 914-333-6162	Brea, CA 92822-8000 800-526-3821
See related comments, page 62	labnews.com	www.beckmancoulter.com
lame of instrument/First year sold in U.S.	ADVIA 2400/2003	Synchron LX20/1997
List price No. units in clinical use in U.S./Outside U.S.	\$305,000 10/9	\$278,000 900/400
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/ireland	U.S./U.S. & Irela nd
Operational type/Reagent type	random access/self-contained single-use cartridges-packages-slides; open reagent system	continuous random access/open reagent system
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	carousel, rack handler option, automation optionl/floor standing 1,157 x 1,711 x 934 mm/—	racks, centrifugable/floor standing LX20 60 x 70 x 41/19.9 sq ft; LX4201 60 x 140 x 41/39.8 sq ft
No. of tests for which analyzer has FDA-cleared applications	69	>100
Tests clinically released in last 12 months	valproic acid, TIBC, C3, C4, RH, TDMs, pre-albumin, ASO, AAT	C3, C4, haptoglobin
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance	none none	none none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays Tests in development	none salicylate, ethanol, lithium, acetaminophen	none homocysteine, D-dimer, sirolimus, tacrolimus, Lp(a), tricyclic.,
User-defined methods implemented for what analytes	_	semiquantitative DATs, lithium, HbA1c online, IMA UIBC, cyclosporine, homocysteine
Methods supported/Immunoassay methods	photometry, potentiometry (ISE)/homogeneous turbidimetric	photometry, potentiometry, near infrared/bidentate turbidimetric, direct
		turbidimetric, particle enhanced turbidimetric, enzyme immunoassay
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously	3 46 colormetric, 3 ISE	5 (indirect) 41
No. of different assays programmed, calibrated at once	100	100
No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates	100/49 —/500	100/41 41/10,650
reag. containers onboard at once/Tests per container set		·
Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported	24 hr/14 day/yes (6–12°C) no	168 hr/30 days/yes (2–8°C) yes
Reag. container placed directly on system for use	yes	yes
nstrument has same capabilities when 3rd-party reag. used Nalkaway capacity in minutes/Specimens/Tests-assays	yes 3.8 hr max./234/32,000 photometric, +90,000 ISE	no 83/132/5,280
System is liquid or dry	liquid	liquid
lses disposable cuvettes/Max. No. stored Ises washable cuvettes/Replacement frequency	no/340 yes/every 4 months	no/n/a yes/semipermanent—2-yr warranty (250 stored on instrument)
Minimum sample volume aspirated precisely at one time	2 μL of diluted specimen	3 μL
Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour	yes/yes (or sink) yes/40 L	yes/no yes/16 L
loise generated in decibels	<50	65
Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes	yes/~50 µL yes/no	yes/40 µL (samples directly from pediatric bullet) yes/no
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5	yes, on sample transport, shortly before sample is aspirated (2 of 5
Reagent bar-code reading capability	interl., Codabar, codes 39 & 128) yes	interl., Codabar, codes 39 & 128)/autodiscrimination yes
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection	yes yes/yes	yes yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes yes yes
Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes/yes yes/yes	yes/yes yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-	yes/—	yes/yes
range high/low results Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	once per day/once per month/once per month/once per month yes/yes	24 hr/up to 90 days/up to 60 days/14 days none required
Stat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine	11 min, 200 samples 11 min, 200 samples	38 sec, 90 specimens 38 sec, 90 specimens
Album., bili. direct & total, AST, ALT, ALP	11 min, 300 samples	8 min, 90 specimens
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC	30 sec shortest interval: 8 hr; longest: 24 hr/yes	16 sec 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/included in system price (TDC Technodata or Bayer CentraLink)	onboard & optional add-on (Beckman Coulter DL2000)/yes (addt'l cost)
	CentraLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner,	cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesso
interfaces up and running in active user sites with	CentraLink)	cost)
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete	CentraLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation yes (broadcast download & host query) yes	cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesso Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes
Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays	CentraLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation yes (broadcast download & host query) yes yes yes	cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesso Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query)
nterfaces up and running in active user sites with Bidirectional interface capability Fest results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	CentraLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation yes (broadcast download & host query) yes yes	cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesso Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes
Interfaces up and running in active user sites with Bidirectional interface capability Fest results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	CentraLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation yes (broadcast download & host query) yes yes yes	cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKessol Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no
Interfaces up and running in active user sites with Bidirectional interface capability Fest results transmitted to LIS as soon as chem. time complete Fils interface operates simultaneously with running assays Filses LOINC to transmit orders & results Flow labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system	CentraLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation yes (broadcast download & host query) yes yes yes yes via software	cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesso Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no Web site, customer request
Interfaces up and running in active user sites with Bidirectional interface capability Fest results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Wodem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting	CentraLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation yes (broadcast download & host query) yes yes yes yia software yes (with ADVIA WorkCell as of October 2003)	cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesso Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no Web site, customer request yes (Power Processor, total lab automation) yes/yes/yes metro: same day, rural: same or next day/yes
Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel	CentraLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation yes (broadcast download & host query) yes yes yes yes via software yes (with ADVIA WorkCell as of October 2003) yes/yes/yes varies by location, generally <4 hr/yes daily: <5 min; weekly: 10 min; monthly: 20 min	cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesso Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no Web site, customer request yes (Power Processor, total lab automation) yes/yes/yes metro: same day, rural: same or next day/yes —/— daily: none; weekly: 5 min; monthly: 25 min
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Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	CentraLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation yes (broadcast download & host query) yes yes yes via software yes (with ADVIA WorkCell as of October 2003) yes/yes/yes varies by location, generally <4 hr/yes daily: <5 min; weekly: 10 min; monthly: 20 min yes/yes varies according to need on site; 5 days at vendor offices/yes \$23,500 system provides true workstation consolidation with more than 80 available chemistry and special chemistry methods and applications; also offers user-defined methods that equate to cost-effective consolidation; offers unrivaled walkaway capability with an onboard	cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKessol Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no Web site, customer request yes (Power Processor, total lab automation) yes/yes/yes metro: same day, rural: same or next day/yes —/— daily: none; weekly: 5 min; monthly: 25 min no/no 5 days at vendor offices/yes — 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
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Interfaces up and running in active user sites with Bidirectional interface capability Fest results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays LIS interface operates simultaneously with running assays LIS interface operates simultaneously with running assays LIS interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Verage time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	CentraLink) Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation yes (broadcast download & host query) yes yes yes yes via software yes (with ADVIA WorkCell as of October 2003) yes/yes/yes varies by location, generally <4 hr/yes daily: <5 min; weekly: 10 min; monthly: 20 min yes/yes varies according to need on site; 5 days at vendor offices/yes \$23,500 system provides true workstation consolidation with more than 80 available chemistry and special chemistry methods and applications; also offers user-defined methods that equate to cost-effective consolidation; offers unrivaled walkaway capability with an onboard capacity of >450 specimens with the Universal Rack Handler option;	cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesso Labquest, CCA, VA-Mumps, all LISs yes (broadcast download & host query) yes yes no Web site, customer request yes (Power Processor, total lab automation) yes/yes/yes metro: same day, rural: same or next day/yes —/— daily: none; weekly: 5 min; monthly: 25 min no/no 5 days at vendor offices/yes — 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-

Chemistry analyzers (for high-volume laboratories)

Part 8 of 13	Beckman Coulter Inc. 200 South Kraemer Blvd.	Beckman Coulter Inc. Craig Hoechstetter
	P.O. Box 8000	200 South Kraemer Blvd.
	Brea, CA 92822-8000 800-526-3821	P.O. Box 8000 Brea, CA 92822
See related comments, page 62	www.beckmancoulter.com	800-526-3821 www.beckmancoulter.com
lame of instrument/First year sold in U.S.	Synchron LX20 Pro/2001	Synchron LXi725/2002
ist price	\$343,000	_
No. units in clinical use in U.S./Outside U.S.	500/200	200/100
Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	U.S./U.S./U.S. & Ireland continuous random access/open reagent system	U.S./U.S./U.S. continuous random access/open reagent system
Sample handling system/Model type	racks, centrifugable/floor standing	racks, centrifugable/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	60 x 70 x 41/19.9 sq ft	60 x 134.5 x 48/44.8 sq ft
No. of tests for which analyzer has FDA-cleared applications Fests clinically released in last 12 months	>100 C3, C4, haptoglobin	>135 C3, C4, haptoglobin, Triage BNP, GI monitor (CA 19.9 antigen), BR
Fests cleared but not clinically released	none	monitor (CA 15.3 antigen)
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 Fests in development	none homocysteine, D-dimer, sirolimus, tacrolimus, Lp(a), tricyclic.,	none DHEAS, intact PTH, intrinsic factor, EPO, HbA1c online, IL6, IMA,
	semiquantitative DATs, lithium, HbA1c online, IMA	lithium, dsDNA, D-dimer, TNF- $lpha$
Jser-defined methods implemented for what analytes	UIBC, cyclosporine, homocysteine	UIBC, homocysteine
Methods supported/Immunoassay methods	photometry, potentiometry, near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme	photometry, potentiometry (ISE), near infrared-bidentate turbidimetri direct turbidimetric, particle enhanced turbidimetric/enzyme
	immunoassay, near infrared particle immunoassay	immunoassay, chemiluminescence
No. of direct ion selective electrode channels	5 (indirect)	5 (indirect)
lo. of different measured assays onboard simultaneously lo. of different assays programmed, calibrated at once	41 100	65 124
o. of user-definable (open) channels/No. active simultaneously	100/41	100/100
lo. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	41/10,650	65/11,850
Shortest/median onboard reag. stability/Refrigerated onboard	168 hr/30 days/yes (2–8°C)	168 hr/28 days/yes (2-10°C)
Aultiple reag. configurations supported leag. container placed directly on system for use	yes yes	yes yes
nstrument has same capabilities when 3rd-party reag. used	no	no
Valkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry	83/132/5,280 liquid	180/132/5,280 liquid
system is inquid or dry Ises disposable cuvettes/Max. No. stored	no/n/a	yes/294 (immuno)
Ises washable cuvettes/Replacement frequency	yes/semipermanent—2-yr warranty (250 stored on instrument)	yes/2 yr (chemistry)
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain	3 µL yes/no	3 μL yes/yes
lequires dedicated water system/Water consumption per hour	yes/16 L	yes/16 L
loise generated in decibels Dedicated pediatric sample cup/Dead volume	65 yes/40 μL	n/a —
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar code placement per NCCLS standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection	yes yes/yes	yes yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
lemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes/yes yes/yes	yes (chemistry)/yes (chemistry) yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-	yes/yes	yes (chemistry but not immuno)/yes (chemistry but not immuno)
range high/low results Autocalibration or autocalibration alert	Van	you (chamistry but not immuno)
Calibrants stored onboard/Multipoint calibration supported	yes no/yes	yes (chemistry but not immuno) 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
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, TC02, glucose, urea, creatinine	38 sec, 90 specimens	38 sec, 90 specimens
Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	8 min, 90 specimens 16 sec	8 min, 90 specimens 36 sec
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC	24 hr/yes	shortest: 24 hr; longest: n/a/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	yes/yes yes	yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard & optional add-on (Beckman Coulter DL2000)/	onboard & optional add-on (Beckman Coulter DL2000)/
	yes (addt'l cost)	yes (addt'l cost)
nterfaces up and running in active user sites with	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs	Cerner, Misys
	Labquest, Oon, an intilips, all Lios	
Ridirectional interface canability		ves (hroadcast download & host guent)
Bidirectional interface capability Fest results transmitted to LIS as soon as chem. time complete	yes (broadcast download & host query) yes	yes (broadcast download & host query) yes
Fest results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays	yes (broadcast download & host query) yes yes	yes yes
Fest results transmitted to LIS as soon as chem. time complete	yes (broadcast download & host query) yes	yes
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	yes (broadcast download & host query) yes yes no	yes yes yes
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/	yes (broadcast download & host query) yes yes no Web site, customer request	yes yes yes customer request
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Jses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Wodem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes (broadcast download & host query) yes yes no Web site, customer request yes (Power Processor, total lab automation) yes/yes/yes	yes yes yes yes customer request no yes/yes/yes
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Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Jses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Fraining provided with purchase/Advanced oper. training avail.	yes (broadcast download & host query) yes yes no Web site, customer request yes (Power Processor, total lab automation) yes/yes/yes metro: same day, rural: same or next day/yes —/— daily: none; weekly: 5 min; monthly: 25 min no/no 5 days at vendor offices/yes — serum indices; centrifugable racks; clot detection; no-wait	yes yes yes customer request no yes/yes/yes metro: same day, rural: same or next day/yes n/a/n/a daily: 15 min; weekly: 33.5 min; monthly: 25 min no/no 10 days at vendor offices/yes
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes (broadcast download & host query) yes yes no Web site, customer request yes (Power Processor, total lab automation) yes/yes/yes metro: same day, rural: same or next day/yes —/— daily: none; weekly: 5 min; monthly: 25 min no/no 5 days at vendor offices/yes — serum indices; centrifugable racks; clot detection; no-wait autoloader/linear racks; multiple wavelength blanking; smart modules, fiber optics; advanced workflow & data management;	yes yes yes customer request no yes/yes/yes metro: same day, rural: same or next day/yes n/a/n/a daily: 15 min; weekly: 33.5 min; monthly: 25 min no/no 10 days at vendor offices/yes n/a workstation consolidation without compromise through single point of sample entry for both chemistry and immunoassay testing; closed tube sampling; one of fastest stats for chemistry samples; dual
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes (broadcast download & host query) yes yes no Web site, customer request yes (Power Processor, total lab automation) yes/yes/yes metro: same day, rural: same or next day/yes —/— daily: none; weekly: 5 min; monthly: 25 min no/no 5 days at vendor offices/yes — 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;	yes yes yes customer request no yes/yes/yes metro: same day, rural: same or next day/yes n/a/n/a daily: 15 min; weekly: 33.5 min; monthly: 25 min no/no 10 days at vendor offices/yes n/a workstation consolidation without compromise through single point of sample entry for both chemistry and immunoassay testing; closed tube sampling; one of fastest stats for chemistry samples; dual scheduling and parallel processing of chemistry and immunoassay
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes (broadcast download & host query) yes yes no Web site, customer request yes (Power Processor, total lab automation) yes/yes/yes metro: same day, rural: same or next day/yes —/— daily: none; weekly: 5 min; monthly: 25 min no/no 5 days at vendor offices/yes — serum indices; centrifugable racks; clot detection; no-wait autoloader/linear racks; multiple wavelength blanking; smart modules, fiber optics; advanced workflow & data management;	yes yes yes customer request no yes/yes/yes metro: same day, rural: same or next day/yes n/a/n/a daily: 15 min; weekly: 33.5 min; monthly: 25 min no/no 10 days at vendor offices/yes n/a workstation consolidation without compromise through single point of sample entry for both chemistry and immunoassay testing; closed tube sampling; one of fastest stats for chemistry samples; dual

Chemistry analyzers (for high-volume laboratories)

Part 9 of 13	Dade Behring Inc.	Olympus America Inc.
rait 9 Ui 13	P.O. Box 6101	Susan M. Watanabe, PhD susan.watanabe@olympus.com
	Newark, DE 19714-6101	Two Corporate Center Dr.
	800-242-3233 www.dadebehring.com	Melville, NY 11747 800-223-0125
See related comments, page 62		www.olympus.com
Name of instrument/First year sold in U.S.	Dimension RxL Integrated Chemistry System w/ Heterogeneous Module	AU640/1999; AU640e/2002
·	(HM)/1997; Dimension RxL Max Integrated Chemistry System/2003	·
List price No. units in clinical use in U.S./Outside U.S.		\$185,000 300/>1,000
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	batch, random access, continuous random access/self-contained multiuse 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	>90	122
Fests clinically released in last 12 months Fests cleared but not clinically released	none	ceruloplasmin, urinary/CSF protein, cholinesterase, HbA1c none
Tests not available in U.S. but submitted for 510(k) clearance	none	-
Tests not available in U.S. but available in other countries Research-use-only assays	none	—
Tests in development	none NT-proBNP, microalbumin, quinidine, triiodothyronine, tacrolimus	none lactate
User-defined methods implemented for what analytes	none	fructosamine, ammonia
	none	·
Methods supported/Immunoassay methods	photometry, potentiometry, Integrated Multisensor Technology (IMT)/heterogeneous EIA using HM, EMIT latex particle turbidimet-	photometry, potentiometry, calculated tests/homogeneous
	ric, latex turbidimetric	
No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously	4 (indirect) 48/92 with optional inventory management system	3 up to 51
No. of different assays programmed, calibrated at once	190	99
No. of user-definable (open) channels/No. active simultaneously	10/10 44–88/may 240	95/— 48 × 2/100–1 333
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	44-88/max. 240	48 x 2/100–1,333
Shortest/median onboard reag. stability/Refrigerated onboard	72 hr/30 days/yes (2-8°C)	120 hr/30 days/yes (4–12°C)
Multiple reag. configurations supported Reag. container placed directly on system for use	yes yes	yes yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry	can be hours liquid, reconstitutes onboard	varies/up to 172/varies liquid
Uses disposable cuvettes/Max. No. stored	yes/12,000	no/n/a
Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time	no/— 2 μL	yes/permanent 2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no (optional)/yes (no w/ optional water pump)
Requires dedicated water system/Water consumption per hour Noise generated in decibels	yes/3.2 L <70	yes/40 L per hr peak consumption 65
Dedicated pediatric sample cup/Dead volume	yes/20 μL	no/n/a
Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	yes, 5, 7, 10 mL/no	yes/no yes on sample transport, shortly before sample is aspirated (2 of
oampie vai-coue reaumy 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 sinterl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A	yes	yes
bai code piacement per Noolo Standard Autoza	yes	yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection	yes yes/yes	yes yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes/yes yes/yes	yes/yes yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-	yes/yes	yes/yes
range high/low results Autocalibration or autocalibration alert	yes	ves
Calibrants stored onboard/Multipoint calibration supported	yes/30–90 days	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
	no/no (2 min tech time 5 min instrument time)	
Automatic shutdown/Startup programmable	no/no (2 min tech time, 5 min instrument time)	yes/yes
Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for:		
Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	no/no (2 min tech time, 5 min instrument time) 50 sec, 288 tests 4.5 min, 500 tests	<4 min, 200 specimens <5 min, 160 specimens
Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP	50 sec, 288 tests 4.5 min, 500 tests 10–11 min, 500 tests	<4 min, 200 specimens <5 min, 160 specimens 9 min, 133 specimens
Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	50 sec, 288 tests 4.5 min, 500 tests	<4 min, 200 specimens <5 min, 160 specimens
Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte	50 sec, 288 tests 4.5 min, 500 tests 10–11 min, 500 tests 24 sec 24 hr/yes no/yes	<4 min, 200 specimens <5 min, 160 specimens 9 min, 133 specimens 1 min per CLIA & laboratory's decision/yes yes/yes
Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte	50 sec, 288 tests 4.5 min, 500 tests 10–11 min, 500 tests 24 sec 24 hr/yes	<4 min, 200 specimens <5 min, 160 specimens 9 min, 133 specimens 1 min per CLIA & laboratory's decision/yes
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Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface	50 sec, 288 tests 4.5 min, 500 tests 10–11 min, 500 tests 24 sec 24 hr/yes no/yes yes optional add-on (DBNet, Dade Behring)/yes (addt'l cost)	<4 min, 200 specimens <5 min, 160 specimens 9 min, 133 specimens 1 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens,
Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	50 sec, 288 tests 4.5 min, 500 tests 10–11 min, 500 tests 24 sec 24 hr/yes no/yes yes optional add-on (DBNet, Dade Behring)/yes (addt'l cost)	<4 min, 200 specimens <5 min, 160 specimens 9 min, 133 specimens 1 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware,
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Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	50 sec, 288 tests 4.5 min, 500 tests 10–11 min, 500 tests 24 sec 24 hr/yes no/yes yes optional add-on (DBNet, Dade Behring)/yes (addt'l cost) All major LIS vendors yes (broadcast download & host query)	<4 min, 200 specimens <5 min, 160 specimens 9 min, 133 specimens 1 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation yes (broadcast download & host query)
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Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures	50 sec, 288 tests 4.5 min, 500 tests 10–11 min, 500 tests 24 sec 24 hr/yes no/yes yes optional add-on (DBNet, Dade Behring)/yes (addt'l cost) All major LIS vendors yes (broadcast download & host query) yes yes no — yes yes/yes/yes 2–8 hr/yes —/—	<4 min, 200 specimens <5 min, 160 specimens 9 min, 133 specimens 1 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation yes (broadcast download & host query) yes yes no yes yes yes no yes/yes/yes <24 hr/yes average 2 calls per yr/<24 hr
Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module	50 sec, 288 tests 4.5 min, 500 tests 10–11 min, 500 tests 24 sec 24 hr/yes no/yes yes optional add-on (DBNet, Dade Behring)/yes (addt'l cost) All major LIS vendors yes (broadcast download & host query) yes yes no — yes yes/yes/yes 2–8 hr/yes —/— daily: 5 min; weekly: 10 min; monthly: 15 min yes/no	<4 min, 200 specimens <5 min, 160 specimens 9 min, 133 specimens 1 min per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation yes (broadcast download & host query) yes yes yes yes/yes/yes <24 hr/yes average 2 calls per yr/<24 hr daily: 3 min; weekly: 27 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes
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Chemistry analyzers (for high-volume laboratories)

Part 10 of 13	Olympus America Inc. Susan M. Watanabe, PhD susan.watanabe@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125	Olympus America Inc. Hiro Sekiya hiro.sekiya@olympus.com Two Corporate Center Dr. Melville, NY 11747 800-223-0125
See related comments, page 62	www.olympus.com	www.olympus.com
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	AU2700/2000 \$320,000 45/360 Japan/Japan/U.S. & Ireland random access, discrete, continuous random access/open reagent	AU5421 with dual ISE/2001 \$465,000 100/130 Japan/Japan/U.S. & Ireland random access, discrete, continuous random access/open reagent
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	system rack & stat carousel/floor standing 50 x 79 x 45/92 sq ft	system rack/floor standing 50 x 148 x 45/46.25 sq ft
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months Tests cleared but not clinically released	122 ceruloplasmin, urinary/CSF protein, cholinesterase, HbA1c none	122 ceruloplasmin, urinary/CSF protein, cholinesterase, HbA1c none
Tests not available in U.S. but submitted for 510(k) clearance	_	_
Tests not available in U.S. but available in other countries Research-use-only assays Tests in development	none lactate	none lactate
User-defined methods implemented for what analytes	fructosamine, ammonia	fructosamine, ammonia
Methods supported/immunoassay methods No. of direct ion selective electrode channels No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	photometry, potentiometry, calculated tests/homogeneous 3 up to 51 99 95/— 48 x 2/100–4,000 120 hr/30 days/yes (4–12°C) yes yes yes varies/up to 322/varies liquid no/n/a yes/permanent 1 µL no (optional)/yes yes/65 L per hr peak consumption <65 no/n/a yes/no yes, on sample transport, shortly before sample is aspirated (2 of	photometry, potentiometry, calculated tests/homogeneous 3 99 99 95/— 48 x 4/100–4,000 120 hr/30 days/yes (4–12°C) yes yes yes yes varies/up to 300/varies liquid no/n/a yes/permanent 1 µL no (optional)/yes yes/120 L <65 no/n/a yes/no yes, on sample transport, shortly before sample is aspirated (2 of
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A	5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes	5 interl.)/autodiscrimination yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes	yes yes/yes/yes yes yes/yes yes/yes yes/yes yes/yes 1 day/30 days/14 days/14-20 days yes/yes
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Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation yes (broadcast download & host query) yes yes	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation yes (broadcast download & host query) yes yes
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 3–5 days on site, 5 days at vendor offices/yes inquire	yes/yes/yes <24 hr/yes TBD/TBD daily: 5 min; weekly: 30 min; monthly: 45 min yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes inquire
Distinguishing features	Olympus 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 one of the best walkaways 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 one of the best walkaways in industry today

Chemistry analyzers (for high-volume laboratories)

Dart 11 of 12	Olympus America Inc	Ortho Clinical Diagnostics
Part 11 of 13	Olympus America Inc. Hiro Sekiya hiro.sekiya@olympus.com	Ortho-Clinical Diagnostics Donna Woodall
	Two Corporate Center Dr.	1001 U.S. Highway 202
	Melville, NY 11747	Raritan, NJ 08869
See related comments, page 62	800-223-0125 www.olympus.com	800-828-6316 www.orthoclinical.com
Name of instrument/First year sold in U.S. List price	AU5431 with dual ISE/2001 \$575,000	VITROS 950, VITROS 950AT/1995 950: \$196,000; 950 AT: \$250,000
No. units in clinical use in U.S./Outside U.S.	100/220	>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
	·	J J J J
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	rack/floor standing 50 x 200 x 45/62.5 sq ft	sample trays/floor standing 55 x 68 x 38/26 sq ft
<u> </u>	00 X 200 X 40/02/0 04 It	
No. of tests for which analyzer has FDA-cleared applications Tests clinically released in last 12 months	122 ceruloplasmin, urinary/CSF protein, cholinesterase, HbA1c	69 none
rosts difficulty roleased in last 12 months	tordiopidsinin, drindry/tool protein, cholinesterdse, hiberto	Hono
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	_	_
Research-use-only assays	none	_
Tests in development User-defined methods implemented for what analytes	lactate fructosamine, ammonia	
<u> </u>	<u> </u>	
Methods supported/Immunoassay methods No. of direct ion selective electrode channels	photometry, potentiometry, calculated tests/homogeneous	potentiometry, colorimetric–rate/—
No. of different measured assays onboard simultaneously	up to 147	3 75
No. of different assays programmed, calibrated at once	99	75
No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates	95/— 48 x 6/100–4,000	n/a/n/a 75/60
reag. containers onboard at once/Tests per container set	,	
Shortest/median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported	120 hr/30 days/yes (4–12°C) yes	7 days/14 days/n/a yes
Reag. container placed directly on system for use	yes yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	n/a
Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry	varies/up to 300/varies liquid	—/40/900 per hr dry
Uses disposable cuvettes/Max. No. stored	no/n/a	no/n/a
Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time	yes/permanent 1 μL	no/n/a 6 μL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes	ο μΕ no (optional)/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
	5 interi., coudbar, coues 59 & 120//autouiscrimination	5 mileri., Gouabar, codes 59 & 120//autodiscrimination
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2A	yes	yes
bai code piacement per NCCLS standard AutoZA	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag, for aspir. & analysis	yes/yes yes	yes/yes/yes yes
Hemolysis/Turbidity detection-quantitation	yes/yes	not needed/not needed
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-	yes/yes yes/yes	no/no no/no
range high/low results	yes/yes	110/110
Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported	yes yes/yes	n/a no/yes
Cambrants stored onboard/munipoint Cambranon supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/30 days/14 days/14–20 days	6 mo/6 mo/6 mo/n/a
Automatic shutdown/Startup programmable	yes/yes	no/no
Stat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TC02	—, max 600	~6 min, 600 specimens
Sodium, potassium, chloride, TCO2, glucose, urea, creatinine		
• Alhum hili direct X, total ASI ALL ALP	—, max 600 —, max 800	~6 min, ~700 specimens
Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	—, max 600 —, max 800 —	
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC	—, max 800 —, per CLIA & laboratory's decision/yes	~6 min, ~700 specimens ~7 min, ~700 specimens 8 sec 24 hr/yes
Typical time delay from ordering stat test to aspir. of sample	—, max 800 —	~6 min, ~700 specimens ~7 min, ~700 specimens 8 sec
Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	—, max 800 — per CLIA & laboratory's decision/yes yes/yes yes	~6 min, ~700 specimens ~7 min, ~700 specimens 8 sec 24 hr/yes yes/yes yes
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Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	—, max 800 — per CLIA & laboratory's decision/yes yes/yes yes onboard/no (optional) all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens,	~6 min, ~700 specimens ~7 min, ~700 specimens 8 sec 24 hr/yes yes/yes yes onboard/no (optional)
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Chemistry analyzers (for high-volume laboratories)

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Part 12 of 13	Ortho-Clinical Diagnostics Donna Woodall	Ortho-Clinical Diagnostics Melissa Heard
	1001 U.S. Highway 202	1001 U.S. Highway 202
	Raritan, NJ 08869 800-828-6316	Raritan, NJ 08869 908-218-8480
See related comments, page 62	www.orthoclinical.com	www.orthoclinical.com
Name of instrument/First year sold in U.S.	VITROS 250, VITROS 250AT/1993	VITROS 5,1 FS Chemistry System/2004
List price	250 \$115,000; 250 AT \$130,000	\$305,000
No. units in clinical use in U.S./Outside U.S.	>3,000/—	0/0
Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	U.S./—/— batch, random access, discrete, continuous random access/self-	U.S./U.S./— random access, discrete, continuous random access/
, , , , ,	contained single-use cartridges-packages-slides	self-contained single-use cartridges-packages-slides;
Sample handling system/Model type	rack/floor standing	open reagent system (post-launch) universal sample tray/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	47 x 45.5 x 28/8.8 sq ft	92.2 x 33.4 x 52.5/21.4 sq ft
No. of tests for which analyzer has FDA-cleared applications	69	70
Tests clinically released in last 12 months	none	none
Tests cleared but not clinically released	_	dHDL
Tools not qualished in H.C. but submitted for F40(k) alcohome		
Tests not available in U.S. but submitted for 510(k) clearance	_	none
Tests not available in U.S. but available in other countries	_	none
Research-use-only assays Tests in development	_	none —
•		
User-defined methods implemented for what analytes		_
Methods supported/immunoassay methods	potentiometry, colorimetric-rate/—	photometry, potentiometry (ion selective electrode), immuno-rate,
		turbidimetric, colorimetric/—
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	60 60	125 400
No. of user-definable (open) channels/No. active simultaneously	n/a/n/a	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	60/60	125/up to 100
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/14 days/n/a	48 hrs/14 days/yes (temp: 10°C)
Multiple reag. configurations supported Reag. container placed directly on system for use	yes yes	yes yes
Instrument has same capabilities when 3rd-party reag. used	n/a	yes
Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry	—/40/200 per hr dry	varies/160/8,940 dry or liquid
Uses disposable cuvettes/Max. No. stored	n/a/n/a	yes/348
Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time	n/a/n/a 6 μL	no/— 2 μL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/no	no (optional)/no
Requires dedicated water system/Water consumption per hour Noise generated in decibels	no/n/a —	no/n/a —
Dedicated pediatric sample cup/Dead volume	 yes/30 μL	
Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	yes/no yes, on sample transport, shortly before sample is aspirated (2 of	yes/no yes, on sample transport, shortly before sample is aspirated (2 of
pro and court county capability	5 interl., Codabar, codes 39 & 128)/autodiscrimination	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 Automatic detection of adequate reag. for aspir. & analysis	yes/yes/yes	yes/yes
Hemolysis/Turbidity detection-quantitation	yes not needed/not needed	yes yes/yes
Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-	yes/no no/no	yes/yes
range high/low results	III/III	-/-
Autocalibration or autocalibration alert	no no/yes	no no/yes
Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	no/yes 6 mo/6 mo/n/a	no/yes 6 mo/6 mo/—
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TCO2	7 min, 237 specimens	
 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP 	7 min, 277 specimens 7 min, 250 specimens	
Typical time delay from ordering stat test to aspir. of sample	12 sec	~10 sec
How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte	24 hr/yes yes/yes	once per 24 hr/yes yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional add-on)/no
Interfaces up and running in active user sites with	all common interfaces	_
	un continuon interiaces	
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete	yes (broadcast download)	yes (broadcast download & host query)
LIS interface operates simultaneously with running assays	yes yes	yes yes
Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	Ξ	no
Interface avail. (or will be) to automated specimen handling system	yes (Lab-InterLink, Labotix, Coulter IDS, AutoLab)	yes (enGen, any open point in space systems)
Modem servicing available/Can diagnose own malfunctions/	—/yes/yes	yes/yes/yes
Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting	<4 hr/yes	<4 hr/yes
Mean time between failures/To repair failures	—/— [*]	TBD/TBD
Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module	daily: 2 min; weekly: 5 min; monthly: 15 min —/yes	daily: 9 min; weekly: 5 min; monthly: 31 min planned post-launch/yes
Training provided with purchase/Advanced oper. training avail.	3 days on site, 5 days at vendor offices/—	varies on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)		varies
Distinguishing features	minimal interference from hemolysis, lipemia, bilirubin; smart	minimal interference from hemolysis, lipemia, bilirubin; smart
	metering; continuous process verification; minimal infectious waste; no plumbing, water, or drains; high reportable result	metering; continuous process verification; minimal infectious waste; no plumbing, water drains, or fixed probes; high reportable
	efficiency	result efficiency; e-connectivity interactive system management;
		V-DOCS; Microsensor Technology
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Chemistry analyzers (for high-volume laboratories)

Chemistry analyzers	
Part 13 of 13	Roche Diagnostics
	Ed Gilligan, Product Manager 9115 Hague Rd.
	Indianapolis, IN 46250 800-428-5074 ext. 4195
See related comments, page 62	us.labsystems.roche.com
Name of instrument/First year sold in U.S.	Modular/1998
List price No. units in clinical use in U.S./Outside U.S.	varies >400/>3,000
Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	multiple countries/multiple countries/multiple countries continuous random access/self-contained multiuse cartridges-
Sample handling system/Model type	packages-slides 5-position rack/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	varies per configuration/varies
No. of tests for which analyzer has FDA-cleared applications	>100
Tests clinically released in last 12 months	amikacin; quinidine
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	apo A, apo B, Lpa, kappa, lambda
Research-use-only assays	none
Tests in development	lidocaine, cyclosporin, vancomycin
User-defined methods implemented for what analytes	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry/HbA1c
No. of direct ion selective electrode channels	3
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	47->100 47->100
No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates	varies 47–100/100–3,000
reag. containers onboard at once/Tests per container set Shortest/median onboard reag. stability/Refrigerated onboard	72 hr/28 days/yes (2–12°C)
Multiple reag. configurations supported	yes
Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used	yes no
Walkaway capacity in minutes/Specimens/Tests-assays System is liquid or dry	varies/300/varies liquid
Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency	no/n/a yes/monthly
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain	2 µL yes/yes
Requires dedicated water system/Water consumption per hour	yes/varies (50 L/hr/mod)
Noise generated in decibels Dedicated pediatric sample cup/Dead volume	<62 yes/50 μL
Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability	yes/no yes, on sample transport, shortly before sample is aspirated (2
, ,	of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Rar code placement per NCCLS standard Auto2A	yes ves
Bar code placement per NCCLS standard Auto2A	yes
Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection	yes yes yes/yes/no
Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation	yes
Bar code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability	yes yes yes/yes/no yes yes/yes yes/yes yes/yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes yes yes/yes/no yes yes/yes yes/yes yes/yes yes/yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported	yes yes yes/yes/no yes yes/yes yes/yes yes/yes yes/yes yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert	yes yes yes/yes/no yes yes/yes yes/yes yes/yes yes/yes yes/yes
Dinboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for:	yes yes yes/yes/no yes yes/yes yes/yes yes/yes yes y
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes yes/yes/no yes yes/yes yes/yes yes/yes yes y
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP	yes yes yes/yes/no yes yes/yes yes/yes yes/yes yes yes/yes 24 hr/varies/bottle change/lot change yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag, for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC	yes yes yes/yes/no yes yes/yes yes/yes yes/yes yes yes/yes yes yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min 24 hr/yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	yes yes yes/yes/no yes yes/yes yes/yes yes/yes yes yes/yes yes yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes yes yes/yes/no yes yes/yes yes/yes yes/yes yes yes/yes yes yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min 24 hr/yes yes/yes
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Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag, for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with	yes yes/yes/no yes yes/yes yes/yes yes/yes yes/yes yes yes/yes 24 hr/varies/bottle change/lot change yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min 24 hr/yes yes/yes yes onboard/no all major LIS vendors
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete	yes yes/yes/no yes yes/yes yes/yes yes/yes yes/yes yes yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min 24 hr/yes yes/yes onboard/no all major LIS vendors yes (broadcast download & host query) no
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes yes/yes/no yes yes/yes yes/yes yes/yes yes/yes yes yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min 24 hr/yes yes/yes yes onboard/no all major LIS vendors yes (broadcast download & host query) no yes no
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag, for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays	yes yes/yes/no yes yes/yes yes/yes yes/yes yes/yes yes yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min 24 hr/yes yes/yes onboard/no all major LIS vendors yes (broadcast download & host query) no yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes yes/yes/no yes yes/yes yes/yes yes/yes yes/yes yes yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min 24 hr/yes yes/yes yes onboard/no all major LIS vendors yes (broadcast download & host query) no yes no
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/	yes yes/yes/no yes yes/yes yes/yes yes/yes yes/yes yes yes/yes 24 hr/varies/bottle change/lot change yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min 24 hr/yes yes/yes yes onboard/no all major LIS vendors yes (broadcast download & host query) no yes no database
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting	yes yes/yes/no yes yes/yes yes/yes yes/yes yes/yes yes yes/yes 24 hr/varies/bottle change/lot change yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min 24 hr/yes yes/yes yes onboard/no all major LIS vendors yes (broadcast download & host query) no yes no database yes (Roche Pre-Analytical Modular) yes/yes/yes 8 hr/yes
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable Stat time to completion of all analytes, throughput per hr. for: Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel	yes yes/yes/no yes yes/yes yes/yes yes/yes yes/yes yes yes/yes 24 hr/varies/bottle change/lot change yes/yes 3.5 min, 300–600 specimens 5.5 min, 160–600 specimens 10.5 min, 133–1,200 specimens <1 min 24 hr/yes yes/yes yes onboard/no all major LIS vendors yes (broadcast download & host query) no yes no database yes (Roche Pre-Analytical Modular) yes/yes/yes 8 hr/yes 260 days/3.5 hr daily: 5 min; weekly: 10 min; monthly: 15 min
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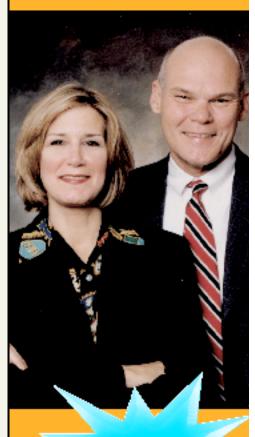


September 19-22, 2004

With CAP '04 being only six weeks before the 2004 presidential election, we've selected two political prosto give us the latest inside news:

Mary Matalin - Former Assistant to President Bush and Counselor to Vice President Cheney

James Carville - Former
Senior Political Advisor
to President Clinton and
Co-Host of CNN's Crossfire



v/v/v/.cap2004.org or 800-758-5590 to register

