SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid/high volume laboratories)

Part 1 of 16 *See related comments, page 41*	**Abbott Diagnostics** **Morné Herselmen** morne.herselman@abbott.com **1921 Hurd Drive, M.S. 8-24** **Irving, TX 75038** **800-323-9100** www.abbottdiagnostics.com	**Abbott Diagnostics** **Morné Herselmen** morne.herselman@abbott.com **1921 Hurd Drive, M.S. 8-24** **Irving, TX 75038** **800-323-9100** www.abbottdiagnostics.com
Name of instrument/First year sold in U.S.	Abbott Architect c8000/2003	Abbott Architect ci8200/2003
List price/Total No. sold in 2006	$225,000/724	$375,000/434
No. units in clinical use in U.S./Outside U.S.	330/1,770	215/1,123
Country where designed/Manufactured/Where reagents mftd.	U.S., Japan/U.S., Japan/U.S.	U.S., Japan/U.S., Japan/U.S.
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/self-contained multi-use cartridges, open reagent system
Sample handling system/Model type	3-dimensional robotic sample handler, carousel/floor standing	3-dimensional robotic sample handler/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	48 x 79 x 49/~26 sq ft	48 x 127 x 49/42 sq ft
No. of tests for which analyzer has FDA-cleared applications	102	125
Tests clinically released in last 12 months	salicylate, acetaminophen, PCP (semi-quant), propoxyphene (semi-quant), tobramycin	salicylate, acetaminophen, PCP (semi-quant), propoxyphene (semi-quant), ferritin, AUSAB, HBsAg, HBsAg confirmatory, tobramycin
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	lithium	lithium
Tests not available in U.S. but available in other countries	copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, CK-MB, bile acids, cholinesterase-dibucaine	copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, CK-MB, bile acids, cholinesterase-dibucaine, AFP, CA-19-9XR, anti-Tg, anti-TPO, B12, folate, HAVAB-G, core-M, anti-HBe, HBeAg, anti-HCV, HIV Ag/Ab combo
Research-use-only assays	—	—
Tests in development	tricyclics, barbs-serum, benzo-serum, enzymatic creatinine	tricyclics, barbs-serum, benzo-serum, enzymatic creatinine
User-defined methods implemented for what analytes	yes, varies	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/—	photometry, potentiometry, turbidimetric/chemiluminescence with flexible protocols
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	68	93
No. of different assays programmed, calibrated at once	220	320
No. of user-definable (open) channels/No. active simultaneously	220/220	220/220
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	65/50–1,700	90/chem 50–1,170, immunoassay 100–500
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/28 days/yes (2–8°C)	7 days/28 days/yes (2–8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/215/69,000+	varies/365/81,000-93,000
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	yes, immunoassay/1,200
Uses washable cuvettes/Replacement frequency	yes/minimum 1-yr guarantee	yes, chemistry/minimum 1-yr guarantee
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption per hour	yes/25 L	yes/30.5 L
Noise generated in decibels	normal operation ≤48 dB; peak: 70 dB for max 10 sec	normal operation: ≤48 dB; peak: 70 dB for max 10 sec
Dedicated pediatric sample cup/Dead volume	yes/50 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes, 2-D bar codes	yes, 2-D bar codes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes (for chemistry)
Autocalibration or autocalibration alert	in development	in development
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes, for chemistry only/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	8 hr/30 days/14 days/7–14 days	8 hr/30 days/14 days/7–14 days
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2.5 min, 200 specimens, 800 tests	2.5 min, 200 specimens, 800 tests
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	9.6 min, 160 specimens, 1,120 tests	9.6 min, 160 specimens, 1,120 tests
• Album., bili. direct & total, AST, ALT, ALP	9.6 min, 133 specimens, 800 tests	9.6 min, 133 specimens, 800 tests
Typical time delay from ordering stat test to aspir. of sample	<20 sec	<20 sec
How often QC required/Onboard SW capability to review QC	shortest interval: 8 hr; longest: 24 hr/yes	shortest interval: 8 hr; longest: 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes (addt'l cost, SW mftr: Abbott)	yes (addt'l cost, SW mftr: Abbott)
Interfaces up and running in active user sites with	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Triple G, CIS, others	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Triple G, CIS, others
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	—
How labs get LOINC codes for reagent kits	package insert	package insert
Interface avail. (or will be) to automated specimen handling system	yes	no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	>3 months/varies	>2 months/varies
Average time to complete maintenance by lab personnel	daily: <15 min; weekly: <35 min; monthly: 15 min	daily: 15 min; weekly: <45 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site, 5 days at vendor offices/yes	5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	flexible options available	flexible options available
Distinguishing features (provided by vendor)	unique 3-dimensional robotic sample handler provides exceptional sample management and ensures stat TAT remains constant regardless of routine workload; large reagent and sample capacity; liquid ready-to-use reagents; maximizes ease of use with patented ICT chip; easy-to-use, intuitive software with state-of-the-art online operation manuals and troubleshooting	integration of CC and IA without compromising stat TAT, results, or throughput because of the unique design of the robotic sample handler and patented SmartWash technology, which minimizes carryover to <0.1 ppm; large reagent capacity of 93 assays, with sample load up to 365; efficiency provided via multiple patented technologies

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Survey editor: Raymond D. Aller, MD

Chemistry analyzers (for mid/high volume laboratories)

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Name of instrument/First year sold in U.S.	Abbott Architect c16000/2007 planned	Abbott Architect ci16200/2007 planned
List price/Total No. sold in 2006	$325,000/—	$475,000/—
No. units in clinical use in U.S./Outside U.S.	0/25	0/20
Country where designed/Manufactured/Where reagents mftd.	U.S., Japan/U.S., Japan/U.S.	U.S., Japan/U.S., Japan/U.S.
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/Model type	3-dimensional robotic sample handler and carousel/floor-standing	3-dimensional robotic sample handler and carousel/floor-standing
Dimensions in inches (H x W x D)/Instrument footprint	48 x 79 x 49/26 sq ft	48 x 127 x 49/42 sq. ft
No. of tests for which analyzer has FDA-cleared applications	49	73
Tests clinically released in last 12 months	general chemistries and specific proteins	general chemistries and specific proteins, ferritin, AUSAB, HBsAg, HBsAg confirmatory
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	lithium	lithium
Tests not available in U.S. but available in other countries	D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, CK-MB, bile acids, cholinest-dibuc, A1 AGP, A1 anti-tryp, ASO, B2 microglob, ceruloplasmin, ferritin, IgE, LP(a), myoglob, p-amylase	D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, CK-MB, bile acids, cholinest-dibuc, A1 AGP, A1 anti-tryp, ASO, B2 microglob, ceruloplasmin, ferritin, IgE, LP(a), myoglob, p-amylase, AFP, CA 19-9XR, anti-Tg, anti-TPO, B12, folate, HAVAB-G, HAVAB-M, CORE, CORE-M, anti-HBe, HBeAg, anti-HCV, HIV Ag/Ab combo
Research-use-only assays	—	—
Tests in development	copper, enzymatic creatinine, phenytoin, phenobarb, carbamazapine, theophylline, HbA1c, amikacin, digoxin, gent, quinidine, tobra, valp acid, vanco, acetaminophen, amp/meth, barbs (S,U), benzo (S,U) cannab, cocaine, ecstasy, ethanol, methadone, opiates, PCP, propoxyphene, salicylate, tricyclics	copper, enzymatic creatinine, phenytoin, phenobarb, carbamazapine, theophylline, HbA1c, Amikacin, Digoxin, Gent, Quinidine, Tobra, Valp Acid, Vanco, acetaminophen, amp/meth, barbs (S,U), Benzo (S,U) Cannab, cocaine, ecstasy, ethanol, methadone, opiates, PCP, propoxyphene, salicylate, tricyclics
User-defined methods implemented for what analytes	yes, varies	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry (ISE), turbidimetric/—	photometry, potentiometry (ISE), turbidmetric/chemiluminescence with flexible protocols (ChemiFlex)
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	68	93
No. of different assays programmed, calibrated at once	220	320
No. of user-definable (open) channels/No. active simultaneously	220/220	220/220
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	65/50–1,700	93/50–1,700 chemistry; 100–500 immunoassay
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/28 days/yes (2–8°C)	7 days/28 days/yes (2–8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/215/69,000+	varies/365/81,000–93,000
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/330	yes/1,200 (IA)
Uses washable cuvettes/Replacement frequency	yes/minimum 1-yr guarantee	yes/minimum 1-yr guarantee
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	yes/54 L	yes/59 L
Noise generated in decibels	normal operation: ≤48 dB; peak: 70 dB for max 10 sec	normal operation: ≤48 dB peak; 70 dB for max 10 sec
Dedicated pediatric sample cup/Dead volume	yes/50 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes, 2-D bar codes	yes, 2-D bar codes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes (for chemistry)
Autocalibration or autocalibration alert	in development	in development
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	8 hr/30 days/14 days/7–13 days	8 hr/30 days/14 days/ 7–13 days
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2.5 min, 200 samples	2.5 min, 200 samples
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	9.6 min, 200 samples	9.6 min, 200 samples
• Album., bili. direct & total, AST, ALT, ALP	9.6 min, 300 samples	9.6 min, 300 samples
Typical time delay from ordering stat test to aspir. of sample	<20 sec	<20 sec
How often QC required/Onboard SW capability to review QC	shortest interval: 8 hr; longest: 24 hr/yes	shortest interval: 8 hr; longest: 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	optional add-on (addt'l—price varies; SW mftr: Abbott)	optional add-on (addt'l price varies; SW mftr: Abbott)
Interfaces up and running in active user sites with	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Citation, CHCS, Antek, Orchard, others	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Citation, CHCS, Antek, Orchard, others
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	—
How labs get LOINC codes for reagent kits	package insert	package insert
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 15 min; weekly: <35 min; monthly: 15 min	daily: 15 min; weekly: <45 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	yes/yes	yes/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site, 5 days at vendor office/yes	5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	flexible options available	flexible options available
Distinguishing features (provided by vendor)	<0.1 ppm carryover claim (SmartWash); workstation consolidation; true integration with immunoassay module; Integrated Chip Technology (ICT); FlexRate (extend linearities for enzymatic assays); in-line pressure monitoring that detects clots, bubbles, foam, and insufficient sample volume; reliability; low-sample volume requirements (2–35 µL); automatic repeat/dilution/reflex protocols; universal sample racks	high-speed integration of CC and IA without compromising stat TAT, results, or throughput because of the unique design of the robotic sample handler and patented SmartWash technology, which minimizes carryover to <0.1 ppm; large reagent capacity of 93 assays, with sample load up to 365; ChemiFlex and FlexRate technologies deliver assay extended linearities and enhance sensitivities

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SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid/high volume laboratories)

Part 3 of 16 *See related comments, page 41*	**Abbott Diagnostics** **Chris Barton** christina.barton@abbott.com **1921 Hurd Drive, M.S. 8-24** **Irving, TX 75038** **800-323-9100** www.abbottdiagnostics.com	**Awareness Technology Inc.** **Chris Schneider** info@awaretech.com **P.O. Box 1679** **Palm City, FL 34991** **772-283-6540** www.awaretech.com
Name of instrument/First year sold in U.S.	Abbott Aeroset/1998	ChemWell/1999
List price/Total No. sold in 2006	$345,000/8	$25,000/13
No. units in clinical use in U.S./Outside U.S.	232/683	15/1,000
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S.	U.S./U.S./open system
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/Model type	rack, carousel/floor standing	rack of 96 samples/benchtop
Dimensions in inches (H x W x D)/Instrument footprint	42.7 x 74.4 x 44.1/22.7 sq ft	19 x 36 x 22 in/7 sq ft
No. of tests for which analyzer has FDA-cleared applications	100	22
Tests clinically released in last 12 months	salicylate, acetaminophen, PCP (semi-quant), propoxyphene (semi-quant), tobramycin	none
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	lithium	18 EIA kits manuf. by BioCheck have been submitted
Tests not available in U.S. but available in other countries	copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, digitoxin, CK-MB, bile acids, cholinesterase-dibucaine	open system
Research-use-only assays	—	open system
Tests in development	tricyclics, barbs-serum, benzo-serum, enzymatic creatinine	none
User-defined methods implemented for what analytes	—	all colorimetric biochemistry & EIA that read between 340–700 nm
Methods supported/immunoassay methods	photometry, potentiometry turbidimetric/—	photometry/microwell assays
No. of direct ion selective electrode channels	3	0
No. of different measured assays onboard simultaneously	59	27
No. of different assays programmed, calibrated at once	100	unlimited
No. of user-definable (open) channels/No. active simultaneously	100/59	unlimited/27
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	59/50–1,700	27/reagent dependent
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/28 days/yes	reagent dependent/yes (15°C below ambient) optional
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	reagent dependent
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	60/231/50,000+	not limited/96/not limited
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/na	yes (optional)/96
Uses washable cuvettes/Replacement frequency	yes/minimum 1-yr guarantee	yes (optional)/weekly
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	no/no
Requires dedicated water system/Water consumption per hour	yes/45 L	no/<1 L
Noise generated in decibels	—	60
Dedicated pediatric sample cup/Dead volume	yes/50 µL	no
Primary tube sampling/Pierces caps on primary tubes	yes/no	no/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, by handheld scanner as tubes are loaded onto instrument (2 or 5 interl., UPC, Codabar, codes 39 & 128)/autodiscrimination depends on handheld scanner models
Reagent bar-code reading capability	yes	no
Bar code placement per CLSI standard Auto2A	yes	no
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/no
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/no
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	8 hr/30 days/14 days/7–14 days	user defined for all
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	10 min, 200+ specimens	na
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	10 min, 200+ specimens	na
• Album., bili. direct & total, AST, ALT, ALP	10 min, 200+ specimens	5.5 min, 28 specimens
Typical time delay from ordering stat test to aspir. of sample	<15 sec	15 sec
How often QC required/Onboard SW capability to review QC	shortest interval: 8 hr (ISE); longest: 24 hr/yes	reagent dependent/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	no/yes (addt'l cost)	onboard/yes (included in price)
Interfaces up and running in active user sites with	package insert	not known
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	package insert	supplied by reagent manufacturer
Interface avail. (or will be) to automated specimen handling system	in development	no
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	no/no/no	yes/yes/sometimes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	48 hr/yes
Mean time between failures/To repair failures	>2 months/varies	depends on user and varies/depends on problem and varies
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 30 min	daily: <5 min; weekly: about 15 min; monthly: about 30 min or less
Onboard maintenance records/Maint. training demo module	no/no	no/no
Training provided with purchase/Advanced oper. training avail.	5 days on site, 5 days at vendor offices/no	2 days on site, 3 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	flexible options available	$4,000
Distinguishing features (provided by vendor)	workstation consolidation; high throughput, large capacity, reliable, flexible system; extended assay linearity; open channel test capability; integrated chip technology for ISE (minimum 45,000 tests per ICT module); auto repeat and auto dilution capability; low sample volume (2–35 µL)	price; one instrument for EIA & biochemistry; completely open and user programmable; special discounts for biochemistry only; calculates indices; very flexible formatting of reports

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Chemistry analyzers (for mid/high volume laboratories)

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MID

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MID

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Brea, CA 92822-8000
800-526-3821 www.beckmancoulter.com

Name of instrument/First year sold in U.S.	Synchron CX9 Pro/2001	UniCel DxC 600/2004
List price/Total No. sold in 2006	$220,600/not available	$261,000/not available
No. units in clinical use in U.S./Outside U.S.	approximately 500/>600	>500/>100
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. & Ireland	U.S./U.S./U.S. & Ireland
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/Model type	sectors, centrifugable/floor standing	racks, centrifugable/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	69 x 74 x 30 in/15.4 sq ft	62 x 62 x 41 in/17.7 sq ft
No. of tests for which analyzer has FDA-cleared applications	>100	>100
Tests clinically released in last 12 months	none	none
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays		
Tests in development	none	none
User-defined methods implemented for what analytes	sirolimus, tacrolimus, tricyclics, semiquantitative drugs of abuse UIBC, cyclosporine, homocysteine	sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse UIBC, cyclosporine, homocysteine
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay	photometry, potentiometry, near-infrared bidentate turbidimetric/ particle enhanced turbidimetric, enzyme immunoassay, near infrared particle immunoassay
No. of direct ion selective electrode channels	5 (indirect)	5
No. of different measured assays onboard simultaneously	33	65
No. of different assays programmed, calibrated at once	59	100
No. of user-definable (open) channels/No. active simultaneously	102/33	100/65
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	33/25–2,500	65/about 3,500 modular; about 600 cartridge
Shortest/median onboard reag. stability/Refrigerated onboard	168 hr/30 days/yes (2–8°C)	168 hr/30 days/yes (2–8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	no
Walkaway capacity in minutes/Specimens/Tests-assays	100/63/2,079	83/132/5,280
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/na	na
Uses washable cuvettes/Replacement frequency	yes/permanent–2-yr warranty (80 stored on instrument)	yes/2-yr warranty, semi-permanent
Minimum sample volume aspirated precisely at one time	3 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	optional/no
Requires dedicated water system/Water consumption per hour	yes/7 L	yes/16 L
Noise generated in decibels	70	60
Dedicated pediatric sample cup/Dead volume	yes/40 µL	yes/40 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/yes
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hr/up to 90 days/up to 60 days/14 days	1 day/up to 90 days/up to 60 days/14 days
Automatic shutdown/Startup programmable	none required	none required
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	52 sec, 75 specimens	6:15 from standby, 96 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	52 sec, 75 specimens	6:15 from standby, 96 specimens
• Album., bili. direct & total, AST, ALT, ALP	10 min, 32 specimens	13:07 from standby, 57 specimens
Typical time delay from ordering stat test to aspir. of sample	45 sec	16 sec
How often QC required/Onboard SW capability to review QC	24 hr/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard & optional add-on (SW mftr: Beckman Coulter)/yes (addt'l cost)	onboard & optional add-on (SW mftr: Beckman Coulter)/yes (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	customer request	customer request
Interface avail. (or will be) to automated specimen handling system	yes (Power Processor)	yes (Beckman Coulter automation)
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/no/no	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day, rural: same or next day/yes	metro: same day, rural: same or next day/yes
Mean time between failures/To repair failures	—/—	na/na
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 15 min; monthly: 25 min	daily: none; weekly: 7 min (tech time); monthly: 11 min (tech time)
Onboard maintenance records/Maint. training demo module	no/no	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	—
Distinguishing features (provided by vendor)	serum indices; centrifugable sectors; clot detection; design optimized for automation; continuous random access for samples, controls, reagents, and results; no-maintenance glucose oxygen sensor; no-wait autoloader; polychromatic correction; thermal ring and semi-permanent glass cuvettes; pulsed xenon lamp; advanced workflow and results mgmt.; liquid, ready-to-use reagents, calibrators, controls; DL2000 Workflow and Results Manager	closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks, no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; DL2000: stat notification, review by exception, reflex testing, add-on test notification

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

Chemistry analyzers (for mid/high volume laboratories)

Part 5 of 16

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	MID	HIGH
	Beckman Coulter Inc. Katie Blount kjblount@beckman.com 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com
Name of instrument/First year sold in U.S.	Unicel DxC 600i/2006	Synchron LX20/1997
List price/Total No. sold in 2006	—/0	$278,000/not available
No. units in clinical use in U.S./Outside U.S.	6/2	>800/>300
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S., Ireland	U.S./U.S./U.S. & Ireland
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/Model type	racks, closed-tube/floor-standing	racks, centrifugable/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	62 x 126.5 x 48/42.16	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	>150	>100
Tests clinically released in last 12 months	—	na
Tests cleared but not clinically released	0	none
Tests not available in U.S. but submitted for 510(k) clearance	DHEA-S, TPO Ab, iPTH	none
Tests not available in U.S. but available in other countries	IL-6, TPO Ab, EPO, iPTH	none
Research-use-only assays	IL-6	none
Tests in development	EPO, ANA Screen, ds DNA Ab, β-2-glycoprotein 1 Ab, CMV IgG, CMV IgM, rubella IgM, Inhibin A, PIGF (pre-eclampsia), SVEGFRI (pre-eclampsia) BPH-A, [-2]proPSA, soluble transferrin receptor	sirolimus, tacrolimus, tricyclics, semiquantitative drugs of abuse homocysteine
User-defined methods implemented for what analytes	UIBC, cyclosporine, homocysteine	UIBC, cyclosporine, homocysteine
Methods supported/immunoassay methods	photometry, potentiometry (ISE), turbidimetric, enzyme immunoassay/chemiluminescence	photometry, potentiometry, near infrared/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay
No. of direct ion selective electrode channels	5	5 (indirect)
No. of different measured assays onboard simultaneously	89	41
No. of different assays programmed, calibrated at once	>150	100
No. of user-definable (open) channels/No. active simultaneously	100/65	100/41
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	89/about 300 cartridge (chem), 50 per pack (immuno)	41/10,650
Shortest/median onboard reag. stability/Refrigerated onboard	168 hr/28 days/yes (2–10°C)	168 hr/30 days/yes (2–8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	no	no
Walkaway capacity in minutes/Specimens/Tests-assays	180/96/5,280	83/132/5,280
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	yes/294 (immuno)	no/na
Uses washable cuvettes/Replacement frequency	yes/2-yr warranty (chem)	yes/semi-permanent—2-yr warranty (250 stored on instrument)
Minimum sample volume aspirated precisely at one time	5 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	optional/yes	yes/no
Requires dedicated water system/Water consumption per hour	yes/16 L	yes/16 L
Noise generated in decibels	—	65
Dedicated pediatric sample cup/Dead volume	yes/na	yes/40 µL (samples directly from pediatric bullet)
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/no	yes/yes
Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/90 days/up to 60 days/14 days	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	8:15 from standby, 96 specimens	38 sec, 90 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	8:15 from standby, 96 specimens	38 sec, 90 specimens
• Album., bili. direct & total, AST, ALT, ALP	15:07 from standby, 57 specimens	8 min, 90 specimens
Typical time delay from ordering stat test to aspir. of sample	2:16	16 sec
How often QC required/Onboard SW capability to review QC	24 hr/—	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	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard & optional add-on (sw mftr: Beckman Coulter)	onboard & optional add-on (Beckman Coulter DL2000)/yes (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	yes	no
How labs get LOINC codes for reagent kits	customer request	customer request
Interface avail. (or will be) to automated specimen handling system	no	yes (Power Processor, total lab automation)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day; rural: same day or next	metro: same day, rural: same or next day/yes
Mean time between failures/To repair failures	na/na	—/—
Average time to complete maintenance by lab personnel	daily: <15 min, weekly: 36 min; monthly: 11 min	daily: none; weekly: 5 min; monthly: 25 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/no	no/no
Training provided with purchase/Advanced oper. training avail.	10 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	na	—
Distinguishing features (provided by vendor)	closed-tube aliquot and closed-tube sampling reduce manual processes and improve safety; parallel processing of chemistry and immunoassay helps eliminate bottle necks; one of the broadest menus available on a single workstation; consolidation of chemistry and immunoassay without compromise	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 semi-permanent glass cuvettes; pulsed Xenon lamp; electronic stat notification; review by exception; reflex testing; add-on test, DL2000 Workflow and Results Manager

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

Chemistry analyzers (for mid/high volume laboratories)

Part 6 of 16

See related comments, page 41

	HIGH	HIGH
	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com	Beckman Coulter Inc. Kathleen Blount kjblount@beckman.com 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822 800-526-3821 www.beckmancoulter.com
Name of instrument/First year sold in U.S.	Synchron LX20 Pro/2001	Synchron LXi725/2002
List price/Total No. sold in 2006	$343,000/—	—/not available
No. units in clinical use in U.S./Outside U.S.	>800/>300	>400/>250
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. & Ireland	U.S./U.S./U.S.
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/Model type	racks, centrifugable/floor standing	racks, centrifugable/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	60 x 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	>100	>135
Tests clinically released in last 12 months	na	na
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays	none	none
Tests in development	sirolimus, tacrolimus, tricyclics, semiquantitative drugs of abuse	intact PTH, EPO, IL-6, dsDNA, TNF-α, soluble transferrin receptor, β-2-gylcoprotein 1 Ab
User-defined methods implemented for what analytes	UIBC, cyclosporine, homocysteine	UIBC, homocysteine, cyclosporine
Methods supported/immunoassay methods	photometry, potentiometry, near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay	photometry, potentiometry (ISE), near infrared-bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, chemiluminescence
No. of direct ion selective electrode channels	5 (indirect)	5 (indirect)
No. of different measured assays onboard simultaneously	41	65
No. of different assays programmed, calibrated at once	100	124
No. of user-definable (open) channels/No. active simultaneously	100/41	100/100
No. 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)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	no	no
Walkaway capacity in minutes/Specimens/Tests-assays	83/132/5,280	180/132/5,280
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/na	yes/294 (immuno)
Uses washable cuvettes/Replacement frequency	yes/semi-permanent—2-yr warranty (250 stored on instrument)	yes/2-yr (chemistry) warranty, semi-permanent
Minimum sample volume aspirated precisely at one time	3 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/yes
Requires dedicated water system/Water consumption per hour	yes/16 L	yes/16 L
Noise generated in decibels	65	na
Dedicated pediatric sample cup/Dead volume	yes/40 µL	—
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes (chemistry)/yes (chemistry)
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 (chemistry)/yes (chemistry)
Autocalibration or autocalibration alert	yes	yes (chemistry)
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/up to 90 days/up to 60 days/14 days	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, TCO2, glucose, urea, creatinine	38 sec, 90 specimens	38 sec, 90 specimens
• Album., bili. direct & total, AST, ALT, ALP	8 min, 90 specimens	8 min, 90 specimens
Typical time delay from ordering stat test to aspir. of sample	16 sec	36 sec
How often QC required/Onboard SW capability to review QC	24 hr/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard & optional add-on (Beckman Coulter DL2000)/ yes (addt'l cost)	onboard & optional add-on (Beckman Coulter)/ yes (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, all LISs	Cerner, Misys
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	customer request	customer request
Interface avail. (or will be) to automated specimen handling system	yes (Power Processor, total lab automation)	no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day, rural: same or next day/yes	metro: same day, rural: same or next day/yes
Mean time between failures/To repair failures	—/—	na/na
Average time to complete maintenance by lab personnel	daily: none; weekly: 5 min; monthly: 25 min	daily: 15 min; weekly: 33.5 min; monthly: 25 min
Onboard maintenance records/Maint. training demo module	no/no	no/no
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	10 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	na
Distinguishing features (provided by vendor)	serum indices; centrifugable racks; clot detection; no-wait autoloader/linear racks; multiple wavelength blanking; smart modules, fiber optics; advanced workflow & data management; thermal ring and semipermanent glass cuvettes; pulsed Xenon lamp; electronic stat notification; review by exception; reflex testing; add-on test; closed-tube sampling, near infrared detection (for high-sensitivity CRP), DL2000 Workflow and Results Manager	workstation consolidation without compromise through single point-of-sample entry for both chemistry and immunoassay testing; closed-tube sampling; one of fastest stats for chemistry samples; dual scheduling and parallel processing of chemistry and immunoassay samples for optimum throughput; menu equivalence to Synchron and Access product lines

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

Chemistry analyzers (for mid/high volume laboratories)

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See related comments, page 41

	HIGH	MID
	Beckman Coulter Inc. **Dan Siegenthaler** dmsiegenthaler@beckman.com **200 South Kraemer Blvd.** **P.O. Box 8000** **Brea, CA 92822** **800-526-3821** www.beckmancoulter.com	**Clinical Data** slsmktg@clda.com **2 Thurber Blvd.** **Smithfield, RI 02917** **800-345-2822** www.clda.com
Name of instrument/First year sold in U.S.	**UniCel DxC 800/2005**	**Envoy 500/2005**
List price/Total No. sold in 2006	**$340,000/not available**	**$96,750/—**
No. units in clinical use in U.S./Outside U.S.	**approximately 400/>200**	**40/—**
Country where designed/Manufactured/Where reagents mftd.	**U.S./U.S./U.S. & Ireland**	**Italy/Italy/U.S.**
Operational type/Reagent type	**continuous random access/open reagent system**	**random access/self-contained multi-use cartridges, packages, slides**
Sample handling system/Model type	**racks, centrifugable/floor standing**	**rotor/benchtop**
Dimensions in inches (H x W x D)/Instrument footprint	**62 x 70 x 41/19.9 sq ft**	**24 x 22 x 39/—**
No. of tests for which analyzer has FDA-cleared applications	**>100**	**28**
Tests clinically released in last 12 months	**na**	**—**
Tests cleared but not clinically released	**none**	**na**
Tests not available in U.S. but submitted for 510(k) clearance	**none**	**na**
Tests not available in U.S. but available in other countries	**none**	**na**
Research-use-only assays	**none**	**na**
Tests in development	**sirolimus, tacrolimus, tricyclics, semi-quantitative drugs of abuse**	**hsCRP, HbA1c, microalbumin, TIBC**
User-defined methods implemented for what analytes	**UIBC, cyclosporine, homocysteine**	**na**
Methods supported/immunoassay methods	**photometry, potentiometry (ISE), near-infrared bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay**	**photometry, potentiometry (ISE)/—**
No. of direct ion selective electrode channels	**5**	**4**
No. of different measured assays onboard simultaneously	**70**	**40**
No. of different assays programmed, calibrated at once	**100**	**40**
No. of user-definable (open) channels/No. active simultaneously	**100/70**	**40/40**
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	**70/approx. 3,500 (modular); 600 cartridge**	**40**
Shortest/median onboard reag. stability/Refrigerated onboard	**168 hr/30 days/yes (2–8°C)**	**40 hr/10 days/yes (12–15°C)**
Multiple reag. configurations supported	**yes**	**yes**
Reag. container placed directly on system for use	**yes**	**yes**
Instrument has same capabilities when 3rd-party reag. used	**no**	**no**
Walkaway capacity in minutes/Specimens/Tests-assays	**83/132/5,280**	**240/52/40**
System is liquid or dry	**liquid**	**liquid**
Uses disposable cuvettes/Max. No. stored	**no**	**no**
Uses washable cuvettes/Replacement frequency	**yes/2-yr warranty, semi-permanent**	**yes/never**
Minimum sample volume aspirated precisely at one time	**3 µL**	**1 µL**
Supplied with UPS (backup power)/Requires floor drain	**optional/no**	**yes/no**
Requires dedicated water system/Water consumption per hour	**yes/16 L**	**no/—**
Noise generated in decibels	**60**	**—**
Dedicated pediatric sample cup/Dead volume	**yes/40 µL (samples directly from bullet)**	**yes/50 µL**
Primary tube sampling/Pierces caps on primary tubes	**yes/yes**	**yes/no**
Sample bar-code reading capability/Autodiscrimination	**yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes**	**yes, as sample is being aspirated/—**
Reagent bar-code reading capability	**yes**	**yes**
Bar code placement per CLSI standard Auto2A	**yes**	**—**
Onboard test auto inventory (determines volume in container)	**yes**	**yes**
Measures no. tests remaining/Short sample detection/Clot detection	**yes/yes/yes**	**yes/yes/yes**
Automatic detection of adequate reag. for aspir. & analysis	**yes**	**yes**
Hemolysis/Turbidity detection-quantitation	**yes/yes**	**no/no**
Dilution of patient samples onboard/Automatic rerun capability	**yes/yes**	**yes/yes**
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	**yes/yes**	**yes/yes**
Autocalibration or autocalibration alert	**yes**	**no**
Calibrants stored onboard/Multipoint calibration supported	**no/yes**	**no/yes**
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	**1 day/up to 90 days/up to 60 days/14 days**	**4 hr/7 days/na/na**
Automatic shutdown/Startup programmable	**none required**	**yes/yes**
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	**2:23 (from standby), 91 specimens**	**2 min 20 sec, 240**
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	**2:22 (from standby), 91 specimens**	**7 min 30 sec, 47**
• Album., bili. direct & total, AST, ALT, ALP	**12:32 (from standby), 76 specimens**	**7 min, 28**
Typical time delay from ordering stat test to aspir. of sample	**16 sec**	**—**
How often QC required/Onboard SW capability to review QC	**24 hr/yes**	**daily/yes**
Onboard real-time QC/Support multiple QC lot Nos. per analyte	**yes/yes**	**yes/yes**
QC results transferred automatically to LIS	**yes**	**yes**
Data mgmt. capability/Instrument vendor supplies LIS interface	**onboard & optional add-on (Beckman Coulter)/yes (addt'l cost)**	**no/yes (addt'l cost)**
Interfaces up and running in active user sites with	**Cerner, Misys, Meditech, Citation, Medlab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps**	**Antek, Labdaq, Fletcher-Flora, Labpak**
Bidirectional interface capability	**yes (broadcast download & host query)**	**yes (broadcast download & host query)**
Test results transmitted to LIS as soon as chem. time complete	**yes**	**yes**
LIS interface operates simultaneously with running assays	**yes**	**yes**
Uses LOINC to transmit orders & results	**yes**	**—**
How labs get LOINC codes for reagent kits	**customer request**	**—**
Interface avail. (or will be) to automated specimen handling system	**yes, Beckman Coulter automation**	**—**
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	**yes/yes/yes**	**no/yes/yes**
On-site time of svc. engineer/Onboard error codes for troubleshooting	**metro: same day, rural: same or next day/yes**	**24 hr/yes**
Mean time between failures/To repair failures	**na/na**	**na/na**
Average time to complete maintenance by lab personnel	**daily: none; weekly: 10 min (tech time); monthly: 18 min (tech time)**	**daily: 5 min; weekly: 15 min; monthly: 30 min**
Onboard maintenance records/Maint. training demo module	**yes (includes audit trail of who replaced parts/yes**	**no/no**
Training provided with purchase/Advanced oper. training avail.	**5 days at vendor offices/yes**	**5 days on site**
Annual service contract cost (24 h/7 d)	**na**	**—**
Distinguishing features (provided by vendor)	**closed-tube sampling; serum indices/polychromatic correction; clot detection & correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; one of the fastest stat TAT; DL2000: stat notification, review by exception, reflex testing, add-on test notification**	**4 parameter dry ISE with CO_2; 570 tests per hour benchtop; onboard touchscreen LCD monitor**

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

Chemistry analyzers (for mid/high volume laboratories)

Part 8 of 16

See related comments, page 41

	MID	HIGH
	Dade Behring Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.dadebehring.com	Dade Behring Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.dadebehring.com
Name of instrument/First year sold in U.S.	Dimension RxL Max Integrated Chemistry System/2003	Dimension Vista Intelligent Lab System 1500/2006
List price/Total No. sold in 2006	—/—	—/—
No. units in clinical use in U.S./Outside U.S.	RxL: 2,500/—; RxL Max: >600/—	—/—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	U.S./U.S./U.S. and Germany
Operational type/Reagent type	batch, random access, continuous random access/self-contained multi-use cartridges-packages-slides	batch, random access, continuous random access/ self-contained multi-use cartridges-packages
Sample handling system/Model type	segmented sample wheel/floor standing	sample rack and aloquot plate system/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	44 x 62.5 x 30.5/13.2 sq ft	55 x 84 x 43/26 sq ft
No. of tests for which analyzer has FDA-cleared applications	>90	>100
Tests clinically released in last 12 months	CSA extended range, tacrolimus, ecstasy	>100
Tests cleared but not clinically released	CSA extended range	—
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	none	—
Research-use-only assays	none	—
Tests in development	MPA, sirolimus	120+
User-defined methods implemented for what analytes	propoxyphene, methaqualone, serum tricyclic antidepressant, serum barbiturate, serum benzodiazepine	propoxyphene, methaqualone, serum tricyclic antidepressant, serum barbiturate, serum benzodiazepine
Methods supported/immunoassay methods	photometry, potentiometry, Integrated Multisensor Technology (IMT)/heterogenous EIA using HM, EMIT latex particle turbidimetric, latex turbidimetric	photometry, potentiometry (ISE), advanced LOCI chemiluminescence technology, nephelometry, EMIT, PETINIA, PETIA, ACMIA, LOCI, turbidimetric
No. of direct ion selective electrode channels	3 (indirect) ECO2 photometric	
No. of different measured assays onboard simultaneously	47/91 with optional inventory management system	3 (indirect)
No. of different assays programmed, calibrated at once	190	up to 100 methods simultaneously
No. of user-definable (open) channels/No. active simultaneously	10/10	120+
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	44–88/max. 360	in development/up to 100 methods simultaneously 100/20-1,200 tests, flex
Shortest/median onboard reag. stability/Refrigerated onboard	72 hr/30 days/yes (2–8°C)	
Multiple reag. configurations supported	yes	—/30 days/yes
Reag. container placed directly on system for use	yes	no
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	can be hours	no
System is liquid or dry	liquid, reconstitutes onboard	>45 min/150/—
Uses disposable cuvettes/Max. No. stored	yes/12,000	liquid
Uses washable cuvettes/Replacement frequency	no/—	yes/>1,500 washed, disposable cuvettes and 1,000 LOCI vessels
Minimum sample volume aspirated precisely at one time	2 µL	yes/automatic
Supplied with UPS (backup power)/Requires floor drain	yes/no	2 µL
Requires dedicated water system/Water consumption per hour	yes/3.2 L (3.2 to 5.0 L with optional inventory management system)	yes/no
Noise generated in decibels	<70	no/20 L
Dedicated pediatric sample cup/Dead volume	no/20 µL	no (can use routine sample cup)/10-20 µL
Primary tube sampling/Pierces caps on primary tubes	yes, 5, 7, 10 mL/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/no	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/no
Autocalibration or autocalibration alert	yes (with 7.4 software)	yes
Calibrants stored onboard/Multipoint calibration supported	yes/30–90 days	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	every 2 hr-autocalibrate/—/60–90 days/30 days	automatic every 4 hr/30-90 days/30 days/30 days
Automatic shutdown/Startup programmable	no/no (2 min tech time, 5 min instrument time)	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	36 sec, 400 tests or 100 lytes	2 min, 166
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 min, 500 tests or 125 panels	4 min, 166
• Album., bili. direct & total, AST, ALT, ALP	4 min, 500 tests or 83 panels	<15 min, 200
Typical time delay from ordering stat test to aspir. of sample	24 sec	<2 min
How often QC required/Onboard SW capability to review QC	24 hr/yes	shortest: 24 hr; longest: user defined/yes, via EasyLink
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes
QC results transferred automatically to LIS	yes	yes, via EasyLink
Data mgmt. capability/Instrument vendor supplies LIS interface	optional add-on (EasyLink, Dade Behring)/yes (addt'l cost)	onboard (Dade Behring)/—
Interfaces up and running in active user sites with	all major LIS vendors	—
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	na
Interface avail. (or will be) to automated specimen handling system	yes	yes, Dade Behring StreamLab, SpecTrak
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	2–8 hr/yes	2–8 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 15 min	daily: none; weekly: none; monthly: 10–20 min
Onboard maintenance records/Maint. training demo module	no/no	in development/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site, 4 days at vendor offices/yes	5 days on site, 5 days at vendor office/yes (online training available)
Annual service contract cost (24 h/7 d)	multiple types	varies—multiple types
Distinguishing features (provided by vendor)	integrates heterogenous immunoassays onboard with other chemistries; allows single platform for more than 95 percent of most requested tests; eliminates sample splitting between general tests and immunoassays	first in a new class of intelligent lab systems where customer-driven design, ultra-integration of four best-in-class technologies; LOCI advanced chemiluminescence and automation onboard come together to set new standards of efficiency, simplicity, sensitivity, and convenience—all to provide a more efficient workflow for the laboratory

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

Chemistry analyzers (for mid/high volume laboratories)

Part 9 of 16

See related comments, page 41

	MID	MID
	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com
Name of instrument/First year sold in U.S.	AU400/1998; AU400e/2002	AU640/1999; AU640e/2002
List price/Total No. sold in 2006	$130,000/99	$185,000/49
No. units in clinical use in U.S./Outside U.S.	>670/>2,500	>300/>1,000
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S. & Ireland	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	random access, discrete, continuous random access/open reagent system	random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	rack & stat carousel/floor standing	rack & stat carousel/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	47.6 x 57.1 x 29.9/62.7 sq ft	50 x 74 x 32/68 sq ft
No. of tests for which analyzer has FDA-cleared applications	125	125
Tests clinically released in last 12 months	D-dimer	D-dimer
Tests cleared but not clinically released	—	none
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	none	none
Tests in development		
User-defined methods implemented for what analytes	fructosamine, oxycodone	fructosamine, oxycodone
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 76	up to 51
No. of different assays programmed, calibrated at once	99	99
No. of user-definable (open) channels/No. active simultaneously	95/72	95/47
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	76/100–1,333	48 x 2/100–1,333
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4–12˚C)	120 hr/30 days/yes (4–12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/up to 102/varies	varies/up to 172/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/na	no/na
Uses washable cuvettes/Replacement frequency	yes/permanent	yes/permanent
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes (no w/ optional water pump)	no (optional)/yes (no w/ optional water pump)
Requires dedicated water system/Water consumption per hour	yes/26 L per hr peak consumption	yes/40 L per hr peak consumption
Noise generated in decibels	65	65
Dedicated pediatric sample cup/Dead volume	no/na	no/na
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/30 days/14 days/14–20 days	1 day/30 days/14 days/14–20 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	<5 min, 200 specimens	<4 min, 200 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	<5 min, 80 specimens	<5 min, 160 specimens
• Album., bili. direct & total, AST, ALT, ALP	<9 min, 67 specimens	9 min, 133 specimens
Typical time delay from ordering stat test to aspir. of sample	<2 min	1 min
How often QC required/Onboard SW capability to review QC	per CLIA & laboratory's decision/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	average 2 calls per yr/<24 hr	average 2 calls per yr/<24 hr
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 12 min; monthly: 45 min	daily: 4 min; weekly: 27 min; monthly: 45 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	3–5 days on site, 5 days at vendor offices/yes	3–5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	inquire
Distinguishing features (provided by vendor)	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with family of chemistry immuno systems, the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems, the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation

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

SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid/high volume laboratories)

Part 10 of 16

See related comments, page 41

	HIGH	HIGH
	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com
Name of instrument/First year sold in U.S.	AU2700/2000	AU5421 with dual ISE/2001
List price/Total No. sold in 2006	$320,000/13	$465,000/5
No. units in clinical use in U.S./Outside U.S.	>60/>450	>100/300
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S. & Ireland	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	random access, discrete, continuous random access/open reagent system	random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	rack & stat carousel/floor standing	rack/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	50 x 79 x 45/92 sq ft	50 x 148 x 45/46.25 sq ft
No. of tests for which analyzer has FDA-cleared applications	125	125
Tests clinically released in last 12 months	D-dimer	D-dimer
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	none	none
Tests in development		
User-defined methods implemented for what analytes	fructosamine, oxycodone	fructosamine, oxycodone
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 51	99
No. of different assays programmed, calibrated at once	99	99
No. of user-definable (open) channels/No. active simultaneously	95/47	95/95
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	48 x 2/100–4,000	48 x 4/100–4,000
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4–12°C)	120 hr/30 days/yes (4–12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/up to 322/varies	varies/up to 300/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/na	no/na
Uses washable cuvettes/Replacement frequency	yes/permanent	yes/permanent
Minimum sample volume aspirated precisely at one time	1 µL	1 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes	no (optional)/yes
Requires dedicated water system/Water consumption per hour	yes/65 L per hr peak consumption	yes/120 L
Noise generated in decibels	<65	<65
Dedicated pediatric sample cup/Dead volume	no/na	no/na
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl.)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/30 days/14 days/14–20 days	1 day/30 days/14 days/14–20 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	<4 min, 267 specimens	—, max 600
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	<4 min, 267 specimens	—, max 600
• Album., bili. direct & total, AST, ALT, ALP	9 min, 267 specimens	—, max 533
Typical time delay from ordering stat test to aspir. of sample	1 min	—
How often QC required/Onboard SW capability to review QC	per CLIA & laboratory's decision/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	TBD/TBD	TBD/TBD
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 42 min; monthly: 15 min	daily: 30 min; weekly: 81 min; monthly: 40 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	3–5 days on site, 5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	inquire
Distinguishing features (provided by vendor)	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation

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

SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid/high volume laboratories)

Part 11 of 16 *See related comments, page 41*	Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com	Ortho-Clinical Diagnostics Greg Winther gwinther@ocdus.jnj.com 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com
Name of instrument/First year sold in U.S.	AU5431 with dual ISE/2001	VITROS 350/2005
List price/Total No. sold in 2006	$575,000/22	$110,000/—
No. units in clinical use in U.S./Outside U.S.	>100/300	—/—
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S. & Ireland	U.S./U.S./U.S.
Operational type/Reagent type	random access, discrete, continuous random access/open reagent system	batch, random access, discrete, continuous random access/self-contained single-use cartridges, packages, slides
Sample handling system/Model type	rack/floor standing	rack/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	50 x 200 x 45/62.5 sq ft	47 x 45.5 x 28/8.8 sq ft
No. of tests for which analyzer has FDA-cleared applications	125	70
Tests clinically released in last 12 months	—	none
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for 510(k) clearance	—	none
Tests not available in U.S. but available in other countries	—	none
Research-use-only assays	none	none
Tests in development	D-dimer	none
User-defined methods implemented for what analytes	fructosamine, ammonia, oxycodone	—
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	potentiometry, colorimetric, rate, immuno-rate
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 147	up to 60
No. of different assays programmed, calibrated at once	99	up to 60
No. of user-definable (open) channels/No. active simultaneously	95/95	na/na
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	48 x 6/100–4,000	up to 60/18, 50, 60
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4–12°C)	48 hr/14 days/no
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	na
Walkaway capacity in minutes/Specimens/Tests-assays	varies/up to 300/varies	varies/40/200
System is liquid or dry	liquid	dry
Uses disposable cuvettes/Max. No. stored	no/na	na
Uses washable cuvettes/Replacement frequency	yes/permanent	na
Minimum sample volume aspirated precisely at one time	1 µL	6 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes	available (not included)/no
Requires dedicated water system/Water consumption per hour	yes/180 L	no/na
Noise generated in decibels	—	61
Dedicated pediatric sample cup/Dead volume	no/na	no special sample cup required/35 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	not needed/not needed
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/no
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/no
Autocalibration or autocalibration alert	yes	no
Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/30 days/14 days/14–20 days	reagent lot changes
Automatic shutdown/Startup programmable	yes/yes	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	—, max 600	6 min, 240
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	—, max 600	6 min 24 sec, 287
• Album., bili. direct & total, AST, ALT, ALP	—, max 800	6 min 40 sec, 261
Typical time delay from ordering stat test to aspir. of sample	—	12 sec
How often QC required/Onboard SW capability to review QC	per CLIA & laboratory's decision/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	varies by location, usually 4–8 hr/yes
Mean time between failures/To repair failures	TBD/TBD	—/—
Average time to complete maintenance by lab personnel	daily: 30 min; weekly: 81 min; monthly: 40 min	daily: 2 min; weekly: 5 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	no/yes
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	3 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	varies
Distinguishing features (provided by vendor)	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400, AU400e, AU600, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation	cost-effective MicroSlide Technology delivers low cost per reportable result and high reagent efficiency without the costs, maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required just once each day and calibration intervals up to six months with minimal interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily

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

Chemistry analyzers (for mid/high volume laboratories)

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	HIGH	MID
	Ortho-Clinical Diagnostics Greg Winther gwinther@ocdus.jnj.com 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com	Randox Laboratories Ltd marketing@randox.com 4065 Oceanside Blvd., Ste. Q Oceanside, CA 92056 760-639-1506 www.randox.com
Name of instrument/First year sold in U.S.	VITROS 5,1 FS Chemistry System/2004	RX imola/2006
List price/Total No. sold in 2006	$225,000/—	—/—
No. units in clinical use in U.S./Outside U.S.	>500/—	—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	Japan/Japan/United Kingdom
Operational type/Reagent type	random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides; user-defined assay capability	random access/self-contained multi-use cartridges-packages-slides
Sample handling system/Model type	universal sample tray/floor standing	ring/benchtop
Dimensions in inches (H x W x D)/Instrument footprint	52.5 x 92.2 x 33.4/21.4 sq ft	23 x 38 x 28/3.1 x 2.3 sq ft
No. of tests for which analyzer has FDA-cleared applications	>100	62 diff analytes
Tests clinically released in last 12 months	haptoglobin, homocysteine, amphetamines, barbiturates, benzodiazepines, cocaine, methadone, opiates, phenyclidine, cannabinoids	— —
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	none	
Research-use-only assays	none	acetic acid, Apo E, Apo CIII, Apo CII, Apo AII, α-1-antitrypsin, α-1-acid glycoprotein, bile acids, butyryl cholinesterase, enzymatic chloride, glutamate dehydrogenase, glutathione reductase, haptoglobin, HBDH, leucine arylamidase, L-lactate, L-lactic acid, malic acid, total antioxidant status, β-hydroxybutyrate, glutathione peroxidase, glycerol, NEFA, superoxide dismutase, zinc
Tests in development	—	haptoglobin
User-defined methods implemented for what analytes	urine protein	acetaminophen, drugs of abuse, salicylate, cyclosporin, alcohol, glycerol-3-phosphate, oxidase, phospholipids, maltose, T4, T-uptake
Methods supported/immunoassay methods	photometry, potentiometry, immuno-rate, turbidimetric, colorimetric, spectrophotometeric/—	photometry, potentiometry (ISE), immunoturbidimetric, latex enhanced immunoturbidimetric
No. of direct ion selective electrode channels	3 (direct)	3
No. of different measured assays onboard simultaneously	up to 125	40
No. of different assays programmed, calibrated at once	up to 125	60
No. of user-definable (open) channels/No. active simultaneously	20/10	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	up to 125/up to 100	37/71–1,053
Shortest/median onboard reag. stability/Refrigerated onboard	48 hr/14 days/yes (temp: 10°C)	8 hr/28 days/yes (8–12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/160/8,940	443/72/2,880
System is liquid or dry	dry, liquid ready to use	liquid
Uses disposable cuvettes/Max. No. stored	yes/348	no/—
Uses washable cuvettes/Replacement frequency	no/disposable	yes/5 yr
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	available (not included)/no	no/yes
Requires dedicated water system/Water consumption per hour	no/na	yes/18 L
Noise generated in decibels	<60	—
Dedicated pediatric sample cup/Dead volume	no special sample cup required/35 µL	yes/20 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, UPC, Codabar, codes 39 &128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	—
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	system autodilutes	yes/yes
Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	reagent lot changes	daily/28 days/7 days/na
Automatic shutdown/Startup programmable	no/no (instrument maintained in ready mode)	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	5.5 min, 400	2 min (not including TC02—non ISE), 240
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.75 min, 625	11 min 55 sec, 560
• Album., bili. direct & total, AST, ALT, ALP	7.5 min, 360	12 min 15 sec, 400
Typical time delay from ordering stat test to aspir. of sample	~10 sec	30 sec
How often QC required/Onboard SW capability to review QC	once per 24 hr/yes	shortest interval: daily; longest: customer's discretion
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes/yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard (optional add-on)/no	onboard/no
Interfaces up and running in active user sites with	all major LIS vendors	no
Bidirectional interface capability	yes (broadcast download & host query)	yes (host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	LOINC database	—
Interface avail. (or will be) to automated specimen handling system	yes (enGen, plus any open point in space systems)	no
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	varies by location; usually 4–8 hr/yes	within 24 hr
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 9 min; weekly: 5 min; monthly: 31 min	daily 5 min; weekly: 15 min; monthly: —
Onboard maintenance records/Maint. training demo module	in development/yes	no/no
Training provided with purchase/Advanced oper. training avail.	yes/yes	3 days on site/yes
Annual service contract cost (24 h/7 d)	varies	—
Distinguishing features (provided by vendor)	cost-effective MicroSlide Technology delivers low cost per reportable result and high reagent efficiency without the costs, maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC required just once each day and calibration intervals up to lot change with min. interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides or disposable cuvette; eConnectivity interactive management system onboard	benchtop analyzer offering more methods than most other analyzers in its class; multi-speed mixers allowing optimum mixing for each assay; comprehensive QC software providing unrivaled confidence in results; direct ISE module prevents pseudohyponatremia

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Chemistry analyzers (for mid/high volume laboratories)

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MID

Roche Diagnostics
Todd Atkinson, Product Manager
9115 Hague Rd., P.O. Box 50457
Indianapolis, IN 46250
800-428-5074 www.roche.com

MID

Roche Diagnostics
Pete Van Overwalle peter.van_overwalle@roche.com
9115 Hague Rd.
Indianapolis, IN 46250
317-521-2000 us.labsystems.roche.com

Name of instrument/First year sold in U.S.	cobas Integra 800/2001 (Integra introduced 1995)	cobas c501 analyzer/2006
List price/Total No. sold in 2006	$265,000/—	—/>250
No. units in clinical use in U.S./Outside U.S.	>600/>2,000	>80/—
Country where designed/Manufactured/Where reagents mftd.	Switzerland/Switzerland/multiple countries	Japan/Japan/U.S. & Germany
Operational type/Reagent type	random access, discrete, continuous random access/ self-contained multi-use cartridges-packages-slides	continuous random access/ self-contained multi-use cartridges-packages-slides, open channels available
Sample handling system/Model type	sample racks: RD 5-position rack/floor standing	five-position rack/floor-standing
Dimensions in inches (H x W x D)/Instrument footprint	47.3 x 74.8 x 35.4/—	49.2 × 71.8 × 40/19.9 sq ft
No. of tests for which analyzer has FDA-cleared applications	139	88
Tests clinically released in last 12 months	—	fructosamine, LSD, methaqualone, mycophenolic acid, NAPA, procainamide, total protein urine/CSF, ceruloplasmin, B-2 microglobulin, soluble transferrin receptor, homocysteine
Tests cleared but not clinically released	—	HbA1c, hemolysate, amikacin, tobramycin, quinidine
Tests not available in U.S. but submitted for 510(k) clearance	none	lithium
Tests not available in U.S. but available in other countries	LDH (P→L), ALP (DGKC), AT3, CHE-D, GLDH, HBDH, lipoprotein(a), kappa/lambda light chains	alpha I microglobulin, %CDT, HBDH, AT3, ACP, kappa, lambda, GLDH
Research-use-only assays	—	none
Tests in development	sirolimus, tacrolimus, EDDP, oxycodone	trig GB, amikacin, lidocaine, lithium, quinidine, alpha 1 microglobulin, cyclosporine
User-defined methods implemented for what analytes	yes, varies	n/a
Methods supported/immunoassay methods	photometry, potentiometry, fluorescence polarization/ turbidimetric	photometry, potentiometry (ion selective electrode)/micro-particle
No. of direct ion selective electrode channels	4	3
No. of different measured assays onboard simultaneously	72	up to 63
No. of different assays programmed, calibrated at once	72	>100
No. of user-definable (open) channels/No. active simultaneously	0/na	varies/up to 63
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	72/50–800	up to 60 (plus 3 ISE)/varies (100–800)
Shortest/median onboard reag. stability/Refrigerated onboard	336 hr/84 days/yes (8°C)	21 days/>60/yes (5–12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	no	yes
Walkaway capacity in minutes/Specimens/Tests-assays	450/180/4,000	varies/250/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	yes/3,600	no
Uses washable cuvettes/Replacement frequency	no/na	yes/monthly
Minimum sample volume aspirated precisely at one time	2 µL	1.5 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	no (direct connection, type I NCCLS)/5–7 L	yes/40 max, 20 mean
Noise generated in decibels	58.5	<65
Dedicated pediatric sample cup/Dead volume	yes/approx. 50–70 µL	yes/50µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes (on sample transport, shortly before sample is aspirated, 2 of 5 interl., Codabar, code 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	5 hr/once per lot/140 days/60 days	24 hr/once per lot/varies/once per lot
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	8.6 min, 118 specimens	5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	8.6 min, 99 specimens	7 min, 150 specimens
• Album., bili. direct & total, AST, ALT, ALP	9.8, 118 specimens	10 min, 100 specimens
Typical time delay from ordering stat test to aspir. of sample	1 min	<1 min
How often QC required/Onboard SW capability to review QC	typically once per 24 hr/yes	typically once per 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/yes (addt'l cost)	onboard/no (included)
Interfaces up and running in active user sites with	Cerner, CHCS, Citation, Compton, CompuLab, DynaMedix, EDS, Fletcher Flora, McKesson (ALG, PathLabs, StarLabs), HMS, Intellilabs, Isys, LabDaq, Labforce, Labfusion, LabSoft, LCI, Meditech, Northern Soft, Orsys, Seacoast, Siemens, Soft Computer, Misys	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (both supported)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	—	Web site
Interface avail. (or will be) to automated specimen handling system	no	yes, Roche Diagnostics MPA system
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	8 hr or next business day/yes	≤8 hr
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: <1 min; weekly: <5 min; monthly: none	daily: 20 min; weekly: 25 min; montly: 40 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes (onscreen help with diagrams & maintenance wizard)	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	1 day on site, 5 days at vendor offices/yes	days on site varies, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	varies	varies
Distinguishing features (provided by vendor)	comprehensive test menu including hemoglobin A1c; reagent cassette requires no operator prep. or special handling (can go straight from refrigerator to system with no warmup time); 97 percent of reagents are liquid, ready to use; system automatically reconstitutes if necessary; system forecasts daily reagent requirements based on history; operator maintenance automatically scheduled by system, based on actual use, not by calendar schedule; 800 has clot detection, bubble detection, and can accommodate universal five-position Roche rack for modular systems and Elecsys IA analyzers	flexible/modular system; can be upgraded on-site; ready-to-use bar-coded reagents; connectivity to Roche preanalytics; requires small sample volumes <2–10 µL

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SURVEY OF INSTRUMENTS

Chemistry analyzers (for mid/high volume laboratories)

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HIGH

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Roche Diagnostics
Adam Sterle, Product Manager
9115 Hague Rd.
Indianapolis, IN 46250
800-428-5074 ext. 3099
us.labsystems.roche.com

Name of instrument/First year sold in U.S.	Integrated Modular Analytics/1998
List price/Total No. sold in 2006	varies
No. units in clinical use in U.S./Outside U.S.	>800/>5,000
Country where designed/Manufactured/Where reagents mftd.	multiple countries/multiple countries/multiple countries
Operational type/Reagent type	continuous random access/self-contained multiuse cartridges-packages-slides
Sample handling system/Model type	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	>140
Tests clinically released in last 12 months	—
Tests cleared but not clinically released	—
Tests not available in U.S. but submitted for 510(k) clearance	—
Tests not available in U.S. but available in other countries	Lp(a), kappa, lambda, P/NP, TG
Research-use-only assays	none
Tests in development	PAPP-A, vitamin D3, P1NP, anti-CMV IgG, anti-CMV IgM, anti-TSH receptor, homocysteine, mycophenolic acid, tacrolimus, protease inhibitors, hepatitis A, hepatitis B, HIV combi, rubella IgG & IgM, toxo IgG & IgM, IL-6, sCD40 ligand, CA 72-4 (gastric), cyfra 21-1/NSE (lung), NSE
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	47–>100
No. of different assays programmed, calibrated at once	47–>100
No. of user-definable (open) channels/No. active simultaneously	varies
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	47–100/100–3,000
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	yes
Instrument has same capabilities when 3rd-party reag. used	limited
Walkaway capacity in minutes/Specimens/Tests-assays	varies/300/varies
System is liquid or dry	liquid
Uses disposable cuvettes/Max. No. stored	no/na
Uses washable cuvettes/Replacement frequency	yes/monthly
Minimum sample volume aspirated precisely at one time	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes
Requires dedicated water system/Water consumption per hour	yes/varies (50 L/hr/mod)
Noise generated in decibels	<62
Dedicated pediatric sample cup/Dead volume	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes
Bar code placement per CLSI standard Auto2A	yes
Onboard test auto inventory (determines volume in container)	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes
Hemolysis/Turbidity detection-quantitation	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes
Autocalibration or autocalibration alert	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hr/varies/bottle change/lot change
Automatic shutdown/Startup programmable	yes/yes
Stat time to completion of all analytes, throughput per hr. for:	
• Sodium, potassium, chloride, TCO2	3.5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 min, 160–600 specimens
• Album., bili. direct & total, AST, ALT, ALP	10.5 min, 133–1,200 specimens
Typical time delay from ordering stat test to aspir. of sample	<1 min
How often QC required/Onboard SW capability to review QC	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes
QC results transferred automatically to LIS	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no
Interfaces up and running in active user sites with	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes
LIS interface operates simultaneously with running assays	yes
Uses LOINC to transmit orders & results	no
How labs get LOINC codes for reagent kits	database
Interface avail. (or will be) to automated specimen handling system	yes (Roche Pre-Analytical Modular)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	8 hr/yes
Mean time between failures/To repair failures	260 days/3.5 hr
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	varies
Distinguishing features (provided by vendor)	Roche Hitachi chemistry and automation proven reliability and more than 20 years of experience; capable of consolidating 95 percent of test menu on one high-throughput Integrated Modular System; system can be connected directly to preanalytical automation with 12 modules per configuration; flexible, expandable to lab's changing needs; up to four modules per system

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Chemistry analyzers (for mid/high volume laboratories)

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	MID	MID
	Roche Diagnostics **Pete Van Overwalle** peter.van_overwalle@roche.com **9115 Hague Rd.** **Indianapolis, IN 46250** **317-521-2000** us.labsystems.roche.com	**Siemens Medical Solutions Diagnostics** **Pamela Curtin** pamela.curtin@siemens.com **511 Benedict Ave.** **Tarrytown, NY 10591** **914-524-3824** www.siemens.com
Name of instrument/First year sold in U.S.	cobas c501/e601/2006	ADVIA 1200/2005
List price/Total No. sold in 2006	na/>250	$189,000/—
No. units in clinical use in U.S./Outside U.S.	>80/na	na/na
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S., Germany	Japan/Japan/Ireland
Operational type/Reagent type	continuous random access/self-contained multi-use cartridges/packages/slide	random access/open reagent system
Sample handling system/Model type	five-position rack/floor standing	carousel/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	4.1 ft x variable x 3.3 ft (base = 9.9 ft)/32.67 sq ft	33.5 x 48 x 44 in/1.04 square meters
No. of tests for which analyzer has FDA-cleared applications	127	79
Tests clinically released in last 12 months	fructosamine, LSD, methaqualone, mycophenolic acid, NAPA, procainamide, total protein urine/CSF, ceruloplasmin, B-2 microglobulin, soluable transferrin receptor, homocysteine	none
Tests cleared but not clinically released	HbA1c, hemolysate, amikacin, tobramycin, quinidine	none
Tests not available in U.S. but submitted for 510(k) clearance	lithium	none
Tests not available in U.S. but available in other countries	alpha1 microglobulin, %cDT, HBDH, AT3, ACP, kappa, lambda, GLDH	none
Research-use-only assays	none	none
Tests in development	P1NP, vitamin D3 OH-25, thyroglobulin, anti-TSH receptor, tPSA (screening), free PSA, CA 72-4, NSE, cyfra 21-1, anti-CMV IgG, anti-CMV IgM, toxoplasma IgG, toxoplasma IgM, rubella IgG, rubella IgM, HIV combi, anti-HAV, anti-HAV IgM, anti-HBs, HbsAg, HbsAg conf., anti-Hbc, anti-HBc IgM, anti-HBe, HBeAg, oxycodone, cyclosporine, mycophenolic acid, sirolimus, tacrolimus, alpha-1 microglobulin	gentamicin, ASO ecstasy
User-defined methods implemented for what analytes	na	open system architecture, CK-MB, myoglobin, fructosamine, β-2 microglobulin, D-dimer, caffeine, TCA, Lp(a)
Methods supported/immunoassay methods	photometry, potentiometry (ion selective electrode)/micro-particle, ECL	photometry, potentiometry, turbidimetric/—
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	88	40 colorimetric, 3 ISE
No. of different assays programmed, calibrated at once	>100	100
No. of user-definable (open) channels/No. active simultaneously	varies/88	100/43
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	up to 85 (plus 3 ISE)/varies (100–800)	43/700
Shortest/median onboard reag. stability/Refrigerated onboard	21 days/>60 days/yes (5–20°)	7 days/45 days/yes
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/250/varies	20,000 photometrics
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no	no/231
Uses washable cuvettes/Replacement frequency	yes/once per month	yes/4 mos
Minimum sample volume aspirated precisely at one time	1.5 µL	1 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	yes/40 L per hour (e501), 20 L per hour (e601)	yes/20 L
Noise generated in decibels	≤65 dB	<60 decibels
Dedicated pediatric sample cup/Dead volume	yes/50 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes/—
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hr/once per lot/varies/once per lot	daily/45 days/30 days/14 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	5 min, 300–600 specimens	2.5 min
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	7 min, 150 specimens	10 min
• Album., bili. direct & total, AST, ALT, ALP	10 min, 100 specimens	10 min
Typical time delay from ordering stat test to aspir. of sample	<1 min	10 sec
How often QC required/Onboard SW capability to review QC	typically once per 24 hr	per laboratory protocol/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	yes/na
Interfaces up and running in active user sites with	all major LIS vendors	Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens, others
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	yes	yes
How labs get LOINC codes for reagent kits	Web site	yes
Interface avail. (or will be) to automated specimen handling system	yes, Roche MPA system	na
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	≤8 hr/yes	varies by location, generally <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	yes (includes audit trail of who replaced parts)/yes	no/yes
Training provided with purchase/Advanced oper. training avail.	varies on site, 5 days at vendor offices/yes	yes/no
Annual service contract cost (24 h/7 d)	varies	na
Distinguishing features (provided by vendor)	flexible modular system—can be upgraded on-site; second-generation integrated platform; ready-to-use bar-coded reagents; automation connectivity; small sample size	clot detection; serum indices; 1,200 tests per hour; auto reruns, dilutions, repeats, reflex testing; open system for third-party assays; part of family of chemistry systems (ADVIA 2400 & ADVIA 1650) and uses same reagents; short sample detection; liquid level sensing, refrigerated compartment for calibrators/QC; integration to Centralink

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Chemistry analyzers (for mid/high volume laboratories)

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	MID	HIGH
	Siemens Medical Solutions Diagnostics **Pamela Curtin** pamela.curtin@siemens.com 511 Benedict Ave. Tarrytown, NY 10591 914-524-3824 www.siemens.com	Siemens Medical Solutions Diagnostics **Pamela Curtin** pamela.curtin@siemens.com 511 Benedict Ave. Tarrytown, NY 10591 914-524-3824 www.siemens.com
Name of instrument/First year sold in U.S.	ADVIA 1800/2006	ADVIA 2400/2003
List price/Total No. sold in 2006	$299,000/—	$305,000/—
No. units in clinical use in U.S./Outside U.S.	—/—	—/—
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/Ireland	Japan/Japan/Ireland
Operational type/Reagent type	random access/open reagent system	random access/open reagent system
Sample handling system/Model type	carousel rack handler option, automation option/floor standing	carousel, rack handler option, automation option/floor standing
Dimensions in inches (H x W x D)/Instrument footprint	45 × 58 × 34/14 sq ft	1,157 × 1,711 × 934 mm/—
No. of tests for which analyzer has FDA-cleared applications	80	80
Tests clinically released in last 12 months	none	—
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	neonatal bilirubin, tricyclics, serum benzo, serum barb	none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays	none	none
Tests in development	ecstasy	—
User-defined methods implemented for what analytes	open system architecture, CK-MB, myoglobin, fructosamine, caffeine, TCA, Lp(a), β-2-mincroglobulin, D-dimer	open system architecture, CK-MB, myoglobin, fructosamine, caffeine, TCA, Lp(a), β-2-microglobulin, D-dimer
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetrics	photometry, potentiometry turbidimetric/—
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	52 colorimetric, 3 ISE	46 colormetric, 3 ISE
No. of different assays programmed, calibrated at once	100	100
No. of user-definable (open) channels/No. active simultaneously	100/52 (plus 3 ISE)	100/49
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	52/850	49/850
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/45 days/yes	7 days/45 days/yes
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	32,000 photometrics	32,000 photometric
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/221	no/340
Uses washable cuvettes/Replacement frequency	yes/every 4 months	yes/every 4 months
Minimum sample volume aspirated precisely at one time	2 µL of diluted specimen	2 µL of diluted specimen
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes (or sink)
Requires dedicated water system/Water consumption per hour	yes/25 L	yes/40 L
Noise generated in decibels	<45 decibels	<50 decibels
Dedicated pediatric sample cup/Dead volume	yes/<50 µL	yes/~50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 inter., Codabar, codes 39 & 128)/—	yes/—
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	daily/45 days/30 days/14 days	daily/45 days/30 days/14 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	45 sec, —	2.5 min
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	10 min, —	10 min
• Album., bili. direct & total, AST, ALT, ALP	10 min, —	10 min
Typical time delay from ordering stat test to aspir. of sample	10 sec	10 sec
How often QC required/Onboard SW capability to review QC	per laboratory protocol	per laboratory protocol/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes/na	yes/na
Interfaces up and running in active user sites with	Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Computer Service & Support Q, Fletcher Flora, HDS, PSA consultants, Siemens, others	Dawning, Paradox LIS, PerSé, Data Innovations, Misys, Soft, Cerner, Citation
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	yes	yes
How labs get LOINC codes for reagent kits	via e-mail & software	via software
Interface avail. (or will be) to automated specimen handling system	yes (all systems)	yes (with ADVIA WorkCell as of October 2003)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	—/yes	varies by location, generally <4 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	automated daily maintenance	automated daily maintenance
Onboard maintenance records/Maint. training demo module	yes/yes	no/yes
Training provided with purchase/Advanced oper. training avail.	yes/yes	yes/yes
Annual service contract cost (24 h/7 d)	na	na
Distinguishing features (provided by vendor)	comprehensive menu; >80 assays, including chemistry; special chemistry, TDMs, TAUs, special proteins; long life ISEs; 90,000 tests; unlimited open channels; third-party applications available; three-second cycle time; 1,800 tests per hour; automation ready; multiple reagent pack sizes available; clot detect; liquid level sense; auto reruns, dilutions, and repeats	system provides workstation consolidation with a comprehensive menu including routine chemistry, TDMs, TAUs, special chemistry, and special proteins; offers unlimited open channels and unrivaled walkaway capability (>450 specimens) when combined with the universal rack handler; offers microvolume sample and reagent technology, multiple reagent wedge sizes, two-second cycle time; fast throughput; sample saver technology allows automatic repeats, dilutions, and reflex testing without operator intervention of having to return to the original specimen

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