Chemistry analyzers for mid- and high-volume laboratories

Part 1 of 16	MID Abbott Diagnostics Mark Jackman mark.jackman@abbott.com 1921 Hurd Drive, MS 8-24 Irving, TX 75038 972-518-6775 www.abbottdiagnostics.com	MID Abbott Diagnostics Mark Jackman mark.jackman@abbott.com 1921 Hurd Drive, MS 8-24 Irving, TX 75038 972-518-6775 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 2007	$225,000/388	$375,000/157
No. units in clinical use in U.S./Outside U.S.	386/2,126	251/1,245
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 × W × D)/Instrument footprint in sq ft	48 × 79 × 49/~26	48 × 127 × 49/42
No. of tests for which analyzer has FDA-cleared applications	98	138
Tests clinically released in last 12 months	general chemistries, specific proteins, DAUs, TDMs, lithium	general chemistries, specific proteins, DAUs, TDMs, lithium
Tests cleared but not clinically released	tricyclics, barbs-serum, benzo-serum, enzymatic creatinine, NextGen creatinine, NextGen calcium	tricyclics, barbs-serum, benzo-serum, enzymatic creatinine, NextGen creatinine, NextGen calcium
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	CK-MB, myoglobin, ALT activated, AST activated, p-amylase, bile acids, cholinesterase, cholinesterase/dibucaine, copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, enzymatic creatinine	CK-MB, myoglobin, ALT activated, AST activated, p-amylase, bile acids, cholinesterase, cholinesterase/dibucaine, copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, enzymatic creatinine
Research-use-only assays	—	—
Tests in development	NextGen LD, NextGen direct bili	NextGen LD, NextGen direct bili
User-defined methods implemented for what analytes	yes, varies	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/—	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° to 8°C)	7 days/28 days/yes (2° to 8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	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; peak: 70 for max 10 sec	normal operation: ≤48; peak: 70 for max 10 sec
Dedicated pediatric sample cup/Dead volume	yes/50 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes, 2-D bar codes	yes, 2-D bar codes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	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 aspiration of sample	<20 sec	<20 sec
How often QC required/Onboard SW capability to review QC	shortest interval: 8 hr; longest: 24 hr/yes	shortest interval: 8 hr; longest: 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes (addt'l cost, SW mftr: Abbott)	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)	3-dimensional robotic sample handler provides 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 ICT chip; easy-to-use, intuitive software with online operation manuals and troubleshooting	integration of CC and IA without compromising stat TAT, results, or throughput because of the design of the robotic sample handler and SmartWash technology, which minimizes carryover to <0.1 ppm; large reagent capacity of 93 assays, with sample load up to 365; efficiency provided via multiple patented technologies

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Survey Editor: Raymond Aller, MD

Chemistry analyzers for mid- and high-volume laboratories

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	HIGH	HIGH
	Abbott Diagnostics Mark Jackman mark.jackman@abbott.com 1921 Hurd Drive, MS 8-24 Irving, TX 75038 972-518-6775 www.abbottdiagnostics.com	Abbott Diagnostics Mark Jackman mark.jackman@abbott.com 1921 Hurd Drive, MS 8-24 Irving, TX 75038 972-518-6775 www.abbottdiagnostics.com
Name of instrument/First year sold in U.S.	Abbott Architect c16000/2007	Abbott Architect ci16200/2007
List price/Total No. sold in 2007	$325,000/98	$475,000/3
No. units in clinical use in U.S./Outside U.S.	3/135	3/133
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 × W × D)/Instrument footprint in sq ft	48 × 79 × 49/26	48 × 127 × 49/42
No. of tests for which analyzer has FDA-cleared applications	98	138
Tests clinically released in last 12 months	general chemistries, specific proteins, DAUs, TDMs, lithium	general chemistries, specific proteins, DAUs, TDMs
Tests cleared but not clinically released	tricyclics, barbs-serum, benzo-serum, enzymatic creatinine, NextGen creatinine, NextGen calcium	tricyclics, barbs-serum, benzo-serum, enzymatic creatinine, NextGen creatinine, NextGen calcium
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	CK-MB, myoglobin, ALT activated, AST activated, p-amylase, bile acids, cholinesterase, cholinesterase/dibucaine, copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, enzymatic creatinine	CK-MB, myoglobin, ALT activated, AST activated, p-amylase, bile acids, cholinesterase, cholinesterase/dibucaine, copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, enzymatic creatinine
Research-use-only assays	—	—
Tests in development	NextGen LD, NextGen direct bili	NextGen LD, NextGen direct bili
User-defined methods implemented for what analytes	yes, varies	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry (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° to 8°C)	7 days/28 days/yes (2° to 8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	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; peak: 70 for max 10 sec	normal operation: ≤48 peak; 70 for max 10 sec
Dedicated pediatric sample cup/Dead volume	yes/50 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes, 2-D bar codes	yes, 2-D bar codes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	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 specimens, 800 Tests	2.5 min, 200 specimens, 800 Tests
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	9.6 min, 190 specimens, 1,330 Tests	9.6 min, 190 specimens, 1,330 Tests
• Album., bili. direct & total, AST, ALT, ALP	9.6 min, 200 specimens, 1,200 Tests	9.6 min, 200 specimens, 1,200 Tests
Typical time delay from ordering stat test to aspiration of sample	<20 sec	<20 sec
How often QC required/Onboard SW capability to review QC	shortest interval: 8 hr; longest: 24 hr/yes	shortest interval: 8 hr; longest: 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	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 design of the robotic sample handler and SmartWash technology, which minimizes carryover to <0.1 ppm; large reagent capacity of 93 assays, with sample load up to 365; ChemiFlex and FlexRate technologies deliver assay extended linearities and enhance sensitivities

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Chemistry analyzers for mid- and high-volume laboratories

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	HIGH	MID
	Abbott Diagnostics Mark Jackman mark.jackman@abbott.com 1921 Hurd Drive, MS 8-24 Irving, TX 75038 972-518-6775 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 2007	$345,000/2	$25,000/450
No. units in clinical use in U.S./Outside U.S.	223/401	20/1,900
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 × W × D)/Instrument footprint in sq ft	42.7 × 74.4 × 44.1/22.7	19 × 36 × 22/7
No. of tests for which analyzer has FDA-cleared applications	98	22
Tests clinically released in last 12 months	general chemistries, specific proteins, DAUs, TDMs, Lithium	none
Tests cleared but not clinically released	tricyclics, barbs-serum, benzo-serum, enzymatic creatinine, NextGen creatinine, NextGen calcium	none
Tests not available in U.S. but submitted for 510(k) clearance	—	18 EIA kits manuf. by BioCheck have been submitted
Tests not available in U.S. but available in other countries	CK-MB, myoglobin, ALT activated, AST activated, p-amylase, bile acids, cholinesterase, cholinesterase/dibucaine, copper, D-dimer, fructosamine, HBDH, kappa & lambda light chains, enzymatic creatinine	open system
Research-use-only assays	—	open system
Tests in development	NextGen LD, NextGen direct bili	none
User-defined methods implemented for what analytes	yes, varies	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/—	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 aspiration & 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, 800 tests	—
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	10 min, 200 specimens, 1,400 tests	—
• Album., bili. direct & total, AST, ALT, ALP	10 min, 266 specimens, 1,600 tests	5.5 min, 28 specimens
Typical time delay from ordering stat test to aspiration 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 autodilution capability; low sample volume (2–35 µL)	price; one instrument for EIA & biochemistry; open and user programmable; discounts for biochemistry only; calculates indices; flexible formatting of reports

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Chemistry analyzers for mid- and high-volume laboratories

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MID

Beckman Coulter Inc.
Dan Siegenthaler dmsiegenthaler@beckman.com
200 South Kraemer Blvd., P.O. Box 8000
Brea, CA 92822-8000
714-961-3594 www.beckmancoulter.com

MID

Beckman Coulter Inc.
Mark Watanabe mswatanabe@beckman.com
200 South Kraemer Blvd., P.O. Box 8000
Brea, CA 92822-8000
(714) 961-3779 www.beckmancoulter.com

Name of instrument/First year sold in U.S.	UniCel DxC 600/2004	Unicel DxC 600i/2006
List price/Total No. sold in 2007	$261,000/not available	$400,000/0
No. units in clinical use in U.S./Outside U.S.	>1300 />2500	>350 />700
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. & Ireland	U.S./U.S./U.S., Ireland, France
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/Model type	racks, centrifugable/floor standing	racks, closed-tube/floor-standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	62 × 62 × 41/17.7	62 × 126.5 × 48/42.16
No. of tests for which analyzer has FDA-cleared applications	>100	>150
Tests clinically released in last 12 months	none	—
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for 510(k) clearance	none	soluble transferrin receptor
Tests not available in U.S. but available in other countries	none	—
Research-use-only assays	—	IL-6
Tests in development	none	CMV IgG, CMV IgM, rubella IgM, PIGF (pre-eclampsia), SVEGFRI (pre-eclampsia) BPH-A, p2PSA, ultrasensitive estradiol, ultrasensitive testosterone
User-defined methods implemented for what analytes	sirolimus, tacrolimus, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cyclosporine	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, sirolimus, tacrolimus
Methods supported/immunoassay methods	photometry, potentiometry, near-infrared bidentate turbidimetric/ particle enhanced turbidimetric, enzyme immunoassay, near infrared particle immunoassay	photometry, potentiometry (ISE), turbidimetric, enzyme immunoassay/ chemiluminescence
No. of direct ion selective electrode channels	5	5
No. of different measured assays onboard simultaneously	65	89
No. of different assays programmed, calibrated at once	100	>150
No. of user-definable (open) channels/No. active simultaneously	100/65	100/65
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	65/about 3,500 modular; about 600 cartridges	89/about 300 cartridges (chem), 50 per pack (immuno)
Shortest/median onboard reag. stability/Refrigerated onboard	168 hr/30 days/yes (2° to 8°C)	168 hr/28 days/yes (2° to 10°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	no	no
Walkaway capacity in minutes/Specimens/Tests-assays	83/132/5,280	180/96/5,280
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	—	yes/294 (immuno)
Uses washable cuvettes/Replacement frequency	yes/2-yr warranty, semi-permanent	yes/2-yr warranty (chem)
Minimum sample volume aspirated precisely at one time	3 µL	5 µL
Supplied with UPS (backup power)/Requires floor drain	optional/no	optional/yes
Requires dedicated water system/Water consumption per hour	yes/16 L	yes/16 L
Noise generated in decibels	60	—
Dedicated pediatric sample cup/Dead volume	yes/40 µL	yes/—
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/no
Autocalibration or autocalibration alert	yes	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/up to 90 days/up to 60 days/14 days	1 day/90 days/up to 60 days/14 days
Automatic shutdown/Startup programmable	none required	none required
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	6:15 min. from standby, 96 specimens	8:15 min. from standby, 96 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	6:15 min. from standby, 96 specimens	8:15 min. from standby, 96 specimens
• Album., bili. direct & total, AST, ALT, ALP	13:07 min. from standby, 57 specimens	15:07 min. from standby, 57 specimens
Typical time delay from ordering stat test to aspiration of sample	16 sec	2:16
How often QC required/Onboard SW capability to review QC	24 hr/yes	24 hr/—
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes/yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard & optional add-on (SW mftr: Beckman Coulter)/yes (addt'l cost)	onboard & optional add-on (sw mftr: Beckman Coulter)
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	yes	yes
How labs get LOINC codes for reagent kits	customer request	customer request
Interface avail. (or will be) to automated specimen handling system	yes (Beckman Coulter automation)	no
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day, rural: same or next day/yes	metro: same day; rural: same day or next
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: none; weekly: 7 min (tech time); monthly: 11 min (tech time)	daily: <15 min, weekly: 36 min; monthly: 11 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/no
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	10 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	—
Distinguishing features (provided by vendor)	closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks, no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; REMISOL Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification	closed-tube aliquot and closed-tube sampling reduce manual processes and improve safety; parallel processing of chemistry and immunoassay helps eliminate bottlenecks; broad menu; consolidation of chemistry and immunoassay without compromise

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Chemistry analyzers for mid- and high-volume laboratories

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	HIGH	HIGH
	Beckman Coulter Inc. Dan Siegenthaler dmsiegenthaler@beckman.com 200 South Kraemer Blvd., P.O. Box 8000 Brea, CA 92822 714-961-3594 www.beckmancoulter.com	Beckman Coulter Inc. Mark Watanabe mswatanabe@beckman.com 200 South Kraemer Blvd. Brea, CA 92822-8000 (714) 961-3779 www.beckmancoulter.com
Name of instrument/First year sold in U.S.	UniCel DxC 800/2005	UniCel DxC 880i Synchron Access Clinical System/2008
List price/Total No. sold in 2007	$340,000/not available	$650,000/—
No. units in clinical use in U.S./Outside U.S.	>475 />900	3/15
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. & Ireland	U.S./U.S./U.S., Ireland and France
Operational type/Reagent type	continuous random access/open reagent system	continuous random access/open reagent system for chemistry; self-contained single use cartridges for immunoassay
Sample handling system/Model type	racks, centrifugable/floor standing	rack closed tube/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	62 × 70 × 41/19.9	68 × 161 × 48/53.66
No. of tests for which analyzer has FDA-cleared applications	>100	>150
Tests clinically released in last 12 months	—	—
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for 510(k) clearance	none	soluble transferrin receptor
Tests not available in U.S. but available in other countries	none	HIV 1/2, HBsAg, HBsAg confirm., HBsAb, HCV Ab, HAV Ab, HAV IgM, HBcAb, Rubella IgM, HBc IgM, IL-6
Research-use-only assays	none	IL-6
Tests in development	—	CMV IgG & IgM, BPH-A, p2PSA, PAPP-A, SHBG, HBeAb, HBeAg, HIV combo, ANA, PIGF, sVEGF RI (preeclampsia), ultrasensitive estradiol, ultrasensitive testosterone
User-defined methods implemented for what analytes	sirolimus, tacrolimus, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cyclosporine	ecstasy, serum tox barb/benz/tricyclics, amikacin, amylase G7, cyclosporine, quinidine
Methods supported/immunoassay methods	photometry, potentiometry (ISE), near-infrared bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near infrared particle immunoassay	photometry, potentiometry (ISE), turbidimetric/enzyme immunoassay, near infrared particle immunoassay, chemiluminescence, magnetic particle/chemiluminescence; magnetic particle
No. of direct ion selective electrode channels	5	5
No. of different measured assays onboard simultaneously	70	120
No. of different assays programmed, calibrated at once	100	120
No. of user-definable (open) channels/No. active simultaneously	100/70	100/100
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	70/approx. 3,500 (modular); 600 cartridges	120/100 tests/kit (immunoassay); 300 test/container (general chem)
Shortest/median onboard reag. stability/Refrigerated onboard	168 hr/30 days/yes (2° to 8°C)	316 hours/28 days/yes (2° to 10°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	no	no
Walkaway capacity in minutes/Specimens/Tests-assays	83/132/5,280	assay mix dependent/112/assay dependent
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no	no/—
Uses washable cuvettes/Replacement frequency	yes/2-yr warranty, semi-permanent	yes/2-year warranty, semi-permanent
Minimum sample volume aspirated precisely at one time	3 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	optional/no	yes/yes
Requires dedicated water system/Water consumption per hour	yes/16 L	yes/up to 16 L
Noise generated in decibels	60	64
Dedicated pediatric sample cup/Dead volume	yes/40 µL (samples directly from bullet)	yes/20 µL (chemistry)
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	—
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/no
Autocalibration or autocalibration alert	yes	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/up to 90 days/up to 60 days/14 days	every 24 hours/up to 90 days/up to 60 days/up to 90 days
Automatic shutdown/Startup programmable	none required	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2:23 min. (from standby), 91 specimens	<1 min, 90 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	2:22 min. (from standby), 91 specimens	<1 min, 90 specimens
• Album., bili. direct & total, AST, ALT, ALP	12:32 min. (from standby), 76 specimens	approx. 6.5 min, 90 specimens
Typical time delay from ordering stat test to aspiration of sample	16 sec	<1 min
How often QC required/Onboard SW capability to review QC	24 hr/yes	24 hours/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard & optional add-on (Beckman Coulter)/yes (addt'l cost)	onboard & optional add-on (Beckman Coulter)/yes (additional cost)
Interfaces up and running in active user sites with	Cerner, Misys, Meditech, Citation, Medlab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps	Cerner, Misys, Meditech, Citation, Medlab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	yes	yes
How labs get LOINC codes for reagent kits	customer request	customer request
Interface avail. (or will be) to automated specimen handling system	yes, Beckman Coulter automation	yes (If cleaved, DxI and DxC systems can interface w/Beckman Coulter automation)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day; rural: same or next day/yes	metro: same day; rural: same or next day/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: none; weekly: 10 min (tech time); monthly: 18 min (tech time)	daily: <10 min; weekly: <10 min; monthly: <18 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts/yes	yes (includes audit trail of who replaced parts/no
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	—
Distinguishing features (provided by vendor)	closed-tube sampling; serum indices/polychromatic correction; clot detection & correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; one of the fastest stat TAT; REMISOL Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification	parallel processing of immunoassay and chemistry tests on a single workstation; closed-tube aliquot and sampling eliminate manual processes; test menu integrates immunoassay and chemistry product lines; immunossay: high-throughput immunoassay analyzer; uses chemiluminescent assay technology and reagent packs to deliver consistent results; allows operators to load consumables on the fly; chemistry: closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat TAT; REMISOL Data Manager: stat notification, review by exception, reflex testing, add-on test notification

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Chemistry analyzers for mid- and high-volume laboratories

Part 6 of 16	MID Carolina Liquid Chemistries Lori Nicholson MT, ASCP, MBA lnicholson@carolinachemistries.com 391 Technology Way Winston-Salem NC 27101 877-722-8910 www.carolinachemistries.com	MID Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com
Name of instrument/First year sold in U.S.	BioLis 24i/2008	AU400/1998; AU400e/2002
List price/Total No. sold in 2007	45,000/—	$130,000/79
No. units in clinical use in U.S./Outside U.S.	5/>3,000	809/2,824
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S.	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	batch, random access, discrete, continuous random access/open reagent system	random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	cup, bar-coded tubes, stat/benchtop	rack & stat carousel/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	20 × 31 × 25/5	47.6 × 57.1 × 29.9/62.7
No. of tests for which analyzer has FDA-cleared applications	100	125
Tests clinically released in last 12 months	direct (no-pretreatment) HbA1c and cystatin C	D-dimer
Tests cleared but not clinically released	LpPLA2	—
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	—	none
Tests in development	vitamin D	—
User-defined methods implemented for what analytes	—	fructosamine, oxycodone, homocysteine
Methods supported/immunoassay methods	photometry, potentiometry/—	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	39	up to 76
No. of different assays programmed, calibrated at once	39	99
No. of user-definable (open) channels/No. active simultaneously	39/39	95/72
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	39/300 (3 × 100)	76/100–1,333
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/14 days/yes	120 hr/30 days/yes (4° to 12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	4 hours/40/39	varies/up to 102/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	yes/6 months	yes/permanent
Minimum sample volume aspirated precisely at one time	3 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	no (optional)/yes (no w/ optional water pump)
Requires dedicated water system/Water consumption per hour	no/3.5 L	yes/26 L per hr peak consumption
Noise generated in decibels	—	65
Dedicated pediatric sample cup/Dead volume	yes/30 µL	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved)/—	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/no	yes/yes
Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hours/14 days/14 days/14 days	1 day/30 days/14 days/14–20 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	12 min, 160 specimens	<5 min, 200 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	1 hour, 60 specimens	<5 min, 80 specimens
• Album., bili. direct & total, AST, ALT, ALP	14 min, 240 specimens	<9 min, 67 specimens
Typical time delay from ordering stat test to aspiration of sample	5 min	<2 min
How often QC required/Onboard SW capability to review QC	2 levels per operational shift; shortest interval: 8 hours; longest: 24 hours/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes, onboard/yes (additional cost)	onboard/no (optional)
Interfaces up and running in active user sites with	all common LISs	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC
Bidirectional interface capability	yes (broadcast download, host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	—	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	no	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	no/no/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	within 24 hours/yes	<24 hr/yes
Mean time between failures/To repair failures	—/—	average 2 calls per yr/<24 hr
Average time to complete maintenance by lab personnel	weekly: 20 min; monthly: visual inspections, <5 min	daily: 5 min; weekly: 12 min; monthly: 45 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/no	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site/yes	3–5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	$5,500	inquire
Distinguishing features (provided by vendor)	small size and large menu; most analyzers with this menu are floor models; 39 onboard chemistries as opposed to 24 with most analyzers of its size; can run general chemistries and special chemistries from CMPs to D-dimer, cystatin C, insulin and more	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with family of chemistry immuno systems—the AU400, AU400e, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation

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Chemistry analyzers for mid- and high-volume laboratories

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	MID Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com	HIGH Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com
Name of instrument/First year sold in U.S.	AU680/2008	AU2700/2000
List price/Total No. sold in 2007	$203,000/13	$320,000/22
No. units in clinical use in U.S./Outside U.S.	13/20	110/690
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S. & Ireland	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	random access, discrete, continuous random access/open reagent system	random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	rack & stat carousel/floor standing	rack & stat carousel/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	42.5 × 76.8 × 50/94.5	50 × 79 × 45/92
No. of tests for which analyzer has FDA-cleared applications	125	125
Tests clinically released in last 12 months	D-dimer, HbA1c APT	D-dimer
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	—	o
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	none	none
Tests in development		
User-defined methods implemented for what analytes	fructosamine, oxycodone, homocysteine	fructosamine, oxycodone, homocysteine
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 63	up to 51
No. of different assays programmed, calibrated at once	120	99
No. of user-definable (open) channels/No. active simultaneously	116/60	95/48
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	63/100–1,500	48/100–4,000
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4° to 12°C)	120 hr/30 days/yes (4° to 12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/up to 172/varies	varies/up to 322/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	yes/permanent	yes/permanent
Minimum sample volume aspirated precisely at one time	1.6 µL	1 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes (no w/ optional water pump)	no (optional)/yes
Requires dedicated water system/Water consumption per hour	yes/40 L per hr peak consumption	yes/65 L per hr peak consumption
Noise generated in decibels	60	<65
Dedicated pediatric sample cup/Dead volume	no/—	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/30 days/14 days/14–20 days	1 day/30 days/14 days/14–20 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	<4 min, 200 specimens	<4 min, 267 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	<5 min, 160 specimens	<4 min, 267 specimens
• Album., bili. direct & total, AST, ALT, ALP	9 min, 133 specimens	9 min, 267 specimens
Typical time delay from ordering stat test to aspiration of sample	1 min	1 min
How often QC required/Onboard SW capability to review QC	per CLIA & laboratory's decision/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	average 2 calls per year/<24 hr	<4 calls per year/<24 hr
Average time to complete maintenance by lab personnel	daily: 4 min; weekly: 27 min; monthly: 45 min	daily: 5 min; weekly: 42 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	3–5 days on site, 5 days at vendor offices/yes	3–5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	inquire
Distinguishing features (provided by vendor)	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400, AU400e, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods; designed as a stand-alone or with direct-track sampling capability; fully automated HbA1c option available; newly reduced sampling volume; laboratory definable enhanced options for reflex, repeat, pre-dilution, auto-calibration, auto-QC, and multi-lot advanced calibration	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400, AU400e, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation

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Chemistry analyzers for mid- and high-volume laboratories

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	HIGH Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com	HIGH Olympus America Inc. 3500 Corporate Parkway Center Valley, PA 18034 484-896-5000 www.olympusamerica.com
Name of instrument/First year sold in U.S.	AU5421 with dual ISE/2001	AU5431 with dual ISE/2001
List price/Total No. sold in 2007	$465,000/3	$575,000/15
No. units in clinical use in U.S./Outside U.S.	>100/300	>100/300
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S. & Ireland	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	random access, discrete, continuous random access/open reagent system	random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	rack/floor standing	rack/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	50 × 148 × 45/46.25	50 × 200 × 45/62.5
No. of tests for which analyzer has FDA-cleared applications	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, homocysteine	fructosamine, ammonia, oxycodone, homocysteine
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	99	up to 99
No. of different assays programmed, calibrated at once	99	99
No. of user-definable (open) channels/No. active simultaneously	95/95	95/95
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	48 × 2/100–4,000	48 × 3/100–4,000
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4° to 12°C)	120 hr/30 days/yes (4° to 12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/up to 300/varies	varies/up to 300/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/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/120 L	yes/180 L
Noise generated in decibels	<65	—
Dedicated pediatric sample cup/Dead volume	no/—	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.)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/30 days/14 days/14–20 days	1 day/30 days/14 days/14–20 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	—, max 600 specimens	—, max 600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	—, max 600 specimens	—, max 600 specimens
• Album., bili. direct & total, AST, ALT, ALP	—, max 533 specimens	—, max 800 specimens
Typical time delay from ordering stat test to aspiration of sample	—	—
How often QC required/Onboard SW capability to review QC	per CLIA & laboratory's decision/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technol., ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innov.), CPSI, Meditech, Misys, Citation, SCC
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	<9 calls per year/<24 hr	<9 calls per year/<24 hr
Average time to complete maintenance by lab personnel	daily: 30 min; weekly: 81 min; monthly: 40 min	daily: 30 min; weekly: 81 min; monthly: 40 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	inquire
Distinguishing features (provided by vendor)	Olympus SUPPORTVISION, an Internet-based, real-time monitoring system for proactive services; standardization with its family of chemistry immuno systems—the AU400, AU400e, 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, AU640, AU640e, AU2700, and AU5400; broad test menu of 125 methods delivers standardized results for improved patient management and streamlined operation

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Chemistry analyzers for mid- and high-volume laboratories

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	MID	HIGH
	Ortho-Clinical Diagnostics Greg Winther gwinther@ocdus.jnj.com 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.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.	VITROS 350/2005	VITROS 5,1 FS Chemistry System/2004
List price/Total No. sold in 2007	$110,000/—	$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.	U.S./U.S./U.S.
Operational type/Reagent type	batch, random access, discrete, continuous random access/self-contained single-use cartridges, packages, slides	random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides; user-defined assay capability
Sample handling system/Model type	rack/floor standing	universal sample tray/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	47 × 45.5 × 28/8.8	52.5 × 92.2 × 33.4/21.4
No. of tests for which analyzer has FDA-cleared applications	70	>100
Tests clinically released in last 12 months	none	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	none	—
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays	none	none
Tests in development	none	—
User-defined methods implemented for what analytes	—	urine protein
Methods supported/immunoassay methods	potentiometry, colorimetric, rate, immuno-rate	photometry, potentiometry, immuno-rate, turbidimetric, colorimetric, spectrophotometeric/—
No. of direct ion selective electrode channels	3	3 (direct)
No. of different measured assays onboard simultaneously	up to 60	up to 125
No. of different assays programmed, calibrated at once	up to 60	up to 125
No. of user-definable (open) channels/No. active simultaneously	na/na	20/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	up to 60/18, 50, 60	up to 125/up to 100
Shortest/median onboard reag. stability/Refrigerated onboard	48 hr/14 days/no	48 hr/14 days/yes (temp: 10°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	—	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/40/200	varies/160/8,940
System is liquid or dry	dry	dry, liquid ready to use
Uses disposable cuvettes/Max. No. stored	—	yes/348
Uses washable cuvettes/Replacement frequency	—	no/disposable
Minimum sample volume aspirated precisely at one time	6 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	available (not included)/no	available (not included)/no
Requires dedicated water system/Water consumption per hour	no/—	no/—
Noise generated in decibels	61	<60
Dedicated pediatric sample cup/Dead volume	no special sample cup required/35 µL	no special sample cup required/35 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	not needed/not needed	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/no	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/no	system autodilutes
Autocalibration or autocalibration alert	no	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	reagent lot changes	reagent lot changes
Automatic shutdown/Startup programmable	no/no	no/no (instrument maintained in ready mode)
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	6 min, 240 specimens	5.5 min, 400 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	6 min 24 sec, 287 specimens	5.75 min, 625 specimens
• Album., bili. direct & total, AST, ALT, ALP	6 min 40 sec, 261 specimens	7.5 min, 360 specimens
Typical time delay from ordering stat test to aspiration of sample	12 sec	~10 sec
How often QC required/Onboard SW capability to review QC	24 hr/yes	once per 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard (optional add-on)/no
Interfaces up and running in active user sites with	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	yes (broadcast download)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	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	yes (enGen, plus any open point in space systems)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	no/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	varies by location, usually 4–8 hr/yes	varies by location; usually 4–8 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 2 min; weekly: 5 min; monthly: 15 min	daily: 9 min; weekly: 5 min; monthly: 31 min
Onboard maintenance records/Maint. training demo module	no/yes	in development/yes
Training provided with purchase/Advanced oper. training avail.	3 days on site, 5 days at vendor offices/yes	yes/yes
Annual service contract cost (24 h/7 d)	varies	varies
Distinguishing features (provided by vendor)	MicroSlide technology delivers low cost per reportable result and high reagent efficiency without the maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required once each day and calibration intervals up to six months with minimal interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily	MicroSlide technology delivers low cost per reportable result and high reagent efficiency without the maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC required once each day and calibration intervals up to lot change with min. interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides or disposable cuvette; eConnectivity interactive management system onboard

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Chemistry analyzers for mid- and high-volume laboratories

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MID

Randox Laboratories Ltd
marketing@randox.com
4065 Oceanside Blvd., Ste. Q
Oceanside, CA 92056
760-639-1506 www.randox.com

MID

Roche Diagnostics
Sheila Brewer sheila.brewer@roche.com
9115 Hague Rd., P.O. Box 50457
Indianapolis, IN 46250
800-428-5074 www.roche.com

Name of instrument/First year sold in U.S.	RX imola/2006	cobas Integra 800/2001 (cobas Integra introduced 1995)
List price/Total No. sold in 2007	—/—	$265,000/—
No. units in clinical use in U.S./Outside U.S.	—	>600/>2,000
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/United Kingdom	Switzerland/Switzerland/multiple countries random access, discrete, continuous random access/self-contained multi-use cartridges-packages-slides
Operational type/Reagent type	random access/self-contained multi-use cartridges-packages-slides	sample racks: RD 5-position rack/floor standing
Sample handling system/Model type	ring/benchtop	47.3 × 74.8 × 35.4/—
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	23 × 38 × 28/3.1 × 2.3 sq ft	139
No. of tests for which analyzer has FDA-cleared applications	62 different analytes	—
Tests clinically released in last 12 months	—	—
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	—	LDH (P›L), ALP (DGKC), AT3, CHE-D, GLDH, HBDH, lipoprotein(a), kappa/lambda light chains
Research-use-only assays	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	sirolimus, tacrolimus, EDDP, oxycodone
Tests in development	haptoglobin, cystatin C, amphetamines, barbiturates, benzodiazepines, cocaine, MDMA, methadone, opiates, THC, EDDP, oxycodone, PCP, propoxyphene, caeruloplasmin, D-dimer, salicylate, paracetomol, cotinine	yes, varies
User-defined methods implemented for what analytes	acetaminophen, drugs of abuse, salicylate, cyclosporin, alcohol, glycerol-3-phosphate, oxidase, phospholipids, maltose, T4, T-uptake	photometry, potentiometry, fluorescence polarization/
Methods supported/immunoassay methods	photometry, potentiometry (ISE), immunoturbidimetric, latex enhanced immunoturbidimetric	turbidimetric
No. of direct ion selective electrode channels	3	4
No. of different measured assays onboard simultaneously	40	72
No. of different assays programmed, calibrated at once	60	72
No. of user-definable (open) channels/No. active simultaneously	10/10	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	37/71–1,053	72/50–800
Shortest/median onboard reag. stability/Refrigerated onboard	8 hr/28 days/yes (8° to 12°C)	336 hr/84 days/yes (8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	443/72/2,880	450/180/4,000
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	yes/3,600
Uses washable cuvettes/Replacement frequency	yes/5 yr	no/—
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	no/yes	yes/yes
Requires dedicated water system/Water consumption per hour	yes/18 L	no (direct connection, type I NCCLS)/5–7 L
Noise generated in decibels	—	58.5
Dedicated pediatric sample cup/Dead volume	yes/40 µL	yes/approx. 50–70 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl, UPC, Codabar, codes 39 &128)/yes	yes (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	—	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	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/28 days/7 days/na	5 hr/once per lot/140 days/60 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2 min (not including TCO2—non ISE), 240 specimens	8.6 min, 118 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	11 min 55 sec, 560 specimens	8.6 min, 99 specimens
• Album., bili. direct & total, AST, ALT, ALP	12 min 15 sec, 400 specimens	9.8, 118 specimens
Typical time delay from ordering stat test to aspiration of sample	30 sec	1 min
How often QC required/Onboard SW capability to review QC	shortest interval: daily; longest: customer's discretion	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	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	no	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
Bidirectional interface capability	yes (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	no	no
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	no/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	within 24 hr	8 hr or next business day/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily 5 min; weekly: 15 min; monthly: —	daily: <1 min; weekly: <5 min; monthly: none
Onboard maintenance records/Maint. training demo module	no/no	yes (includes audit trail of who replaced parts)/yes (onscreen help with diagrams & maintenance wizard)
Training provided with purchase/Advanced oper. training avail.	3 days on site/yes	1 day on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	varies
Distinguishing features (provided by vendor)	benchtop analyzer offers many methods for its class; multi-speed mixers allowing optimum mixing for each assay; comprehensive QC software provides confidence in results; direct ISE module prevents pseudohyponatremia	comprehensive test menu includ. HbA1c; reagent cassette requires no operator prep. or special handling (from refrigerator to system with no warmup time); 97% of reagents are liquid, ready to use; system auto. reconstitutes if necessary; system forecasts daily reagent requirements based on history; operator maintenance auto. scheduled by system, based on actual use; clot and bubble detection, and accommodates universal 5-position Roche rack for modular systems and Elecsys IA analyzers

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Chemistry analyzers for mid- and high-volume laboratories

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	MID	HIGH
	Roche Diagnostics Jeremy Lynn jeremy.lynn@roche.com 9115 Hague Rd. Indianapolis, IN 46250 317-521-2000 us.labsystems.roche.com	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.	cobas c501 analyzer/2006	Integrated Modular Analytics/1998
List price/Total No. sold in 2007	—/>250	varies
No. units in clinical use in U.S./Outside U.S.	>80/—	>800/>5,000
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S. & Germany	multiple countries/multiple countries/multiple countries
Operational type/Reagent type	continuous random access/self-contained multi-use cartridges-packages-slides, open channels available	continuous random access/self-contained multiuse cartridges-packages-slides
Sample handling system/Model type	five-position rack/floor-standing	5-position rack/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	49.2 × 71.8 × 40/19.9	varies per configuration/varies
No. of tests for which analyzer has FDA-cleared applications	88	>140
Tests clinically released in last 12 months	lithium, TinaQuant HbA1c	toxo IgG
Tests cleared but not clinically released	HbA1c, hemolysate	—
Tests not available in U.S. but submitted for 510(k) clearance	—	anti-TSH receptor, rubella IgG & IgM, toxo IgM
Tests not available in U.S. but available in other countries	alpha-1 microglobulin, %CDT, HBDH, AT3, ACP, kappa, lambda, GLDH	Lp(a), kappa, lambda, P/NP, TG
Research-use-only assays	none	none
Tests in development	trig GB, cyclosporine	PAPP-A, P1NP, anti-CMV IgG, anti-CMV IgM, homocysteine, mycophenolic acid, tacrolimus, hepatitis A, hepatitis B, HIV combi, IL-6, sCD40 ligand, CA 72-4, cyfra 21-1/NSE, NSE
User-defined methods implemented for what analytes	—	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry (ion selective electrode)/micro-particle	photometry, potentiometry/HbA1c
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 63	47–>100
No. of different assays programmed, calibrated at once	>100	47–>100
No. of user-definable (open) channels/No. active simultaneously	10/10	varies
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	up to 60 (plus 3 ISE)/varies (100–800)	47–100/100–3,000
Shortest/median onboard reag. stability/Refrigerated onboard	21 days/>60/yes (5° to 12°C)	72 hr/28 days/yes (2° to 12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	limited
Walkaway capacity in minutes/Specimens/Tests-assays	varies/250/varies	varies/300/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no	no/—
Uses washable cuvettes/Replacement frequency	yes/monthly	yes/monthly
Minimum sample volume aspirated precisely at one time	1.5 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	yes/40 max, 20 mean	yes/varies (50 L/hr/mod)
Noise generated in decibels	<65	<62
Dedicated pediatric sample cup/Dead volume	yes/50µL	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, code 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hr/once per lot/varies/once per lot	24 hr/varies/bottle change/lot change
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	3.5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	7 min, 150 specimens	5.5 min, 160–600 specimens
• Album., bili. direct & total, AST, ALT, ALP	10 min, 100 specimens	10.5 min, 133–1,200 specimens
Typical time delay from ordering stat test to aspiration of sample	<1 min	<1 min
How often QC required/Onboard SW capability to review QC	typically once per 24 hr/yes	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 (included)	onboard/no
Interfaces up and running in active user sites with	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	yes (both supported)	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	Web site	database
Interface avail. (or will be) to automated specimen handling system	yes, Roche Diagnostics MPA system	yes (Roche Pre-Analytical Modular)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	≤8 hr	8 hr/yes
Mean time between failures/To repair failures	—/—	260 days/3.5 hr
Average time to complete maintenance by lab personnel	daily: 20 min; weekly: 25 min; montly: 40 min	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	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	days on site varies, 5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	varies	varies
Distinguishing features (provided by vendor)	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	Roche Hitachi chemistry and automation reliability and more than 20 years of experience; capable of consolidating 95 percent of test menu on one high-throughput Integrated Modular System; system can be connected directly to preanalytical automation with 12 modules per configuration; flexible, expandable to lab's changing needs; up to four modules per system

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Chemistry analyzers for mid- and high-volume laboratories

Part 12 of 16

MID

Roche Diagnostics
Jeremy Lynn jeremy.lynn@roche.com
9115 Hague Rd.
Indianapolis, IN 46250
317-521-2000 us.labsystems.roche.com

MID

Siemens Healthcare Diagnostics Inc.
Pamela Curtin pamela.curtin@siemens.com
1717 Deerfield Rd., Deerfield, IL 60015
800-242-3233
www.siemens.com/diagnostics

Name of instrument/First year sold in U.S.	cobas c501/e601/2006	ADVIA 1200/2005
List price/Total No. sold in 2007	—/>250	$189,000/—
No. units in clinical use in U.S./Outside U.S.	>80/—	—/—
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 × W × D)/Instrument footprint in sq ft	4.1 ft × variable × 3.3 ft (base = 9.9 ft)/32.67	33.5 × 48 × 44/1.04 square meters
No. of tests for which analyzer has FDA-cleared applications	127	79
Tests clinically released in last 12 months	lithium, TinaQuant HbA1c, toxo IgG	none
Tests cleared but not clinically released	HbA1c, hemolysate	none
Tests not available in U.S. but submitted for 510(k) clearance	anti-TSH receptor, tPSA (screening), free PSA, toxoplasma IgM, rubella IgG, rubella IgM, anti-HBs, HbsAg, HbsAg conf.	none
Tests not available in U.S. but available in other countries	alpha-1 microglobulin, %cDT, HBDH, AT3, ACP, kappa, lambda, GLDH	none
Research-use-only assays	none	none
Tests in development	P1NP, thyroglobulin, CA 72-4, NSE, cyfra 21-1, anti-CMV IgG, anti-CMV IgM, HIV combi, anti-HAV, anti-HAV IgM, anti-Hbc, anti-HBc IgM, anti-HBe, HBeAg, oxycodone, cyclosporine, mycophenolic acid, sirolimus, tacrolimus	gentamicin, ASO ecstasy
User-defined methods implemented for what analytes	—	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	10/10	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° to 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	<60
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 aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	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:	5 min, 300–600 specimens	
• Sodium, potassium, chloride, TCO2	7 min, 150 specimens	2.5 min
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	10 min, 100 specimens	10 min
• Album., bili. direct & total, AST, ALT, ALP	<1 min	10 min
Typical time delay from ordering stat test to aspiration of sample	typically once per 24 hr	10 sec
How often QC required/Onboard SW capability to review QC	yes/yes	per laboratory protocol/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes	yes/yes
QC results transferred automatically to LIS	onboard/no	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	all major LIS vendors	yes/—
Interfaces up and running in active user sites with	yes (broadcast download & host query)	Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Comp Service & Suppt Q, Fletcher Flora, HDS, PSA Consultants, Siemens, others
Bidirectional interface capability	yes	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	Website	yes
How labs get LOINC codes for reagent kits	yes, Roche MPA system	yes
Interface avail. (or will be) to automated specimen handling system	yes/yes/yes	—
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	≤8 hr/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	TBD/TBD	varies by location, generally <4 hr/yes
Mean time between failures/To repair failures	—/—/—	—/—
Average time to complete maintenance by lab personnel	yes (includes audit trail of who replaced parts)/yes	—
Onboard maintenance records/Maint. training demo module	varies on site, 5 days at vendor offices/yes	no/yes
Training provided with purchase/Advanced oper. training avail.	varies	yes/no
Annual service contract cost (24 h/7 d)	flexible modular system—can be upgraded on-site; second-generation	na
Distinguishing features (provided by vendor)	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- and high-volume laboratories

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	MID	HIGH
	Siemens Healthcare Diagnostics Inc. Pamela Curtin pamela.curtin@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Inc. Pamela Curtin pamela.curtin@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics
Name of instrument/First year sold in U.S.	ADVIA 1800/2006	ADVIA 2400/2003
List price/Total No. sold in 2007	$299,000/—	$305,000/—
No. units in clinical use in U.S./Outside U.S.	—/—	—/—
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/Ireland	Japan/Japan/Ireland
Operational type/Reagent type	random access/open reagent system	random access/open reagent system
Sample handling system/Model type	carousel rack handler option, automation option/floor standing	carousel, rack handler option, automation option/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	45 × 58 × 34/14	1,157 × 1,711 × 934 mm/—
No. of tests for which analyzer has FDA-cleared applications	80	80
Tests clinically released in last 12 months	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	<50
Dedicated pediatric sample cup/Dead volume	yes/<50 µL	yes/~50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 inter., Codabar, codes 39 & 128)/—	yes/—
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	daily/45 days/30 days/14 days	daily/45 days/30 days/14 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	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 aspiration of sample	10 sec	10 sec
How often QC required/Onboard SW capability to review QC	per laboratory protocol	per laboratory protocol/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes/—	yes/—
Interfaces up and running in active user sites with	Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Computer Service & Support Q, Fletcher Flora, HDS, PSA consultants, Siemens, others	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	—
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 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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Chemistry analyzers for mid- and high-volume laboratories

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MID

Siemens Healthcare Diagnostics Inc.
1717 Deerfield Rd.
Deerfield, IL 60015
800-242-3233
www.siemens.com/diagnostics

HIGH

Siemens Healthcare Diagnostics Inc.
Colleen Grier
1717 Deerfield Rd., Deerfield, IL 60015
800-242-3233
www.siemens.com/diagnostics

	MID	HIGH
Name of instrument/First year sold in U.S.	Dimension RxL Max/Max Suite Integrated Chemistry System/2003/Dimension RxL Integrated Chemistry System/1997	Dimension Vista Intelligent Lab System 1500/2006
List price/Total No. sold in 2007	—/—	—/—
No. units in clinical use in U.S./Outside U.S.	—	—/—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	U.S./U.S./U.S. and Germany
Operational type/Reagent type	batch, random access, continuous random access/self-contained multi-use flex containers	batch, random access, continuous random access/self-contained multi-use cartridges-packages
Sample handling system/Model type	segmented sample wheel/floor standing	sample rack and aloquot plate system/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	44 × 62.5 × 30.5/13.2	55 × 84 × 43/26 sq ft
No. of tests for which analyzer has FDA-cleared applications	>90	>100
Tests clinically released in last 12 months	enzymatic creatinine, iron (plasma), revised CSA, monoclonal NT-proBNP	>100
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	—
Tests in development	MPA, sirolimus, myeloperoxidase, liquid lipase, oxycodone, buprenorphine, meperidine, tramadol	CEA, AFP, CA-125, CA15-3, CA19-9, fertility panel, plasma proteins, cardiac, infectious disease
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	ACMIA, EMIT, PETINIA, photometry, potentiometry/heterogeneous, magnetic particle	photometry, potentiometry (ISE), advanced LOCI chemiluminescence technology, nephelometry, EMIT, PETINIA, PETIA, ACMIA, turbidimetric
No. of direct ion selective electrode channels	3 (indirect) ECO2 photometric	3 (indirect)
No. of different measured assays onboard simultaneously	47/91 with optional inventory management system	up to 100 methods simultaneously
No. of different assays programmed, calibrated at once	190	120+
No. of user-definable (open) channels/No. active simultaneously	10/10	10/up to 100 methods simultaneously
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	44–88/max. 360	100/20-1,200 tests, flex
Shortest/median onboard reag. stability/Refrigerated onboard	48 hours/30 days/yes (2° to 8°C)	—/30 days/yes
Multiple reag. configurations supported	yes	no
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	no
Walkaway capacity in minutes/Specimens/Tests-assays	can be hours/60/>2,000 or >5,000 (with RMS)	>45 min/150/>100
System is liquid or dry	liquid, reconstitutes onboard	liquid
Uses disposable cuvettes/Max. No. stored	yes/12,000	yes/>1,500 washed, disposable cuvettes and 1,000 LOCI vessels
Uses washable cuvettes/Replacement frequency	no/—	yes/automatic
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption per hour	yes/3.2 L (3.2 to 5.0 L with optional inventory management system)	no/20 L
Noise generated in decibels	<70	<70
Dedicated pediatric sample cup/Dead volume	yes/10-20 µL	no (can use routine sample cup)/10-20 µL
Primary tube sampling/Pierces caps on primary tubes	yes, 5, 7, 10 mL/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/no	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/no	yes/no
Autocalibration or autocalibration alert	yes (with 7.4 software)	yes
Calibrants stored onboard/Multipoint calibration supported	yes (Na, K, Cl)/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	every 2 hr-autocalibrate/—/60–90 days/30 days	automatic every 4 hr/30-90 days/30 days/30 days
Automatic shutdown/Startup programmable	—/—	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	36 sec (Na, K, Cl)/2 min w/ECO2, 300 ISE or 500 photometric tests/hr, 100 panels	4 min, 166
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 min, 300 ISE or 500 photometric tests/hr, 100 panels	<15 min, 200
• Album., bili. direct & total, AST, ALT, ALP	9 min, 500 tests/hr or 83 panels	<2 min
Typical time delay from ordering stat test to aspiration of sample	24 sec	shortest: 24 hr; longest: user defined/yes, via EasyLink
How often QC required/Onboard SW capability to review QC	24 hr/yes	2 min, 166
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/yes	yes/yes
QC results transferred automatically to LIS	yes	yes, via EasyLink
Data mgmt. capability/Instrument vendor supplies LIS interface	optional add-on (EasyLink, Siemens)/yes (addt'l cost)	onboard/—
Interfaces up and running in active user sites with	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes, Siemens StreamLab, SpecTrak
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	2–8 hr/yes	2–8 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 15 min	daily: 10 min; weekly: none; monthly: 10–20 min
Onboard maintenance records/Maint. training demo module	no/no	in development/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site, 4 days at vendor offices/yes	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	intelligent lab systems with customer-driven design, ultra-integration of technologies; LOCI advanced chemiluminescence and automation onboard for efficiency, simplicity, sensitivity, and convenience—all to provide a more efficient workflow for the laboratory

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Chemistry analyzers for mid- and high-volume laboratories

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	MID Siemens Healthcare Diagnostics Inc. 1717 Deerfield Road Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics	MID Siemens Healthcare Diagnostics Inc. 1717 Deerfield Road Deerfield, IL 60015 800-242-3233 www.siemens.com/diagnostics
Name of instrument/First year sold in U.S.	Dimension EXL Integrated Chemistry System (upgradeable w/LOCI Module)/2007	Dimension EXL with LM Integrated Chemistry System/—
List price/Total No. sold in 2007	—/—	—/—
No. units in clinical use in U.S./Outside U.S.	—/—	—/—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	U.S./U.S./U.S.
Operational type/Reagent type	batch, random access, continuous random access/self-contained multi-use cartridges/packages/slides	batch, random access, continuous random access/self-contained multi-use cartridges/packages/slides
Sample handling system/Model type	segmented sample wheel/floor-standing	segmented sample wheel/floor-standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	49 × 82 × 34 (without monitor)/19.4 (with printer shelf down)	49 × 82 × 44 (without monitor)/25.1 (with printer shelf down)
No. of tests for which analyzer has FDA-cleared applications	>90	
Tests clinically released in last 12 months	enzymatic creatinine, iron (plasma), revised CSA, monoclonal NT-proBNP	enzymatic creatinine, iron (plasma), revised CSA, monoclonal NT-proBNP
Tests cleared but not clinically released	—	LOCI free T4, LOCI TSH
Tests not available in U.S. but submitted for 510(k) clearance	—	LOCI troponin I
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	—	—
Tests in development	MPA, sirolimus, myeloperoxidase, liquid lipase	LOCI NT-proBNP, LOCI free T3, LOCI B12, LOCI folate, MPA, sirolimus, myeloperoxidase, liquid lipase
User-defined methods implemented for what analytes	serum TCA, serum barbiturates, serum benzodiazepine, propoxyphene, methaqualone	serum TCA, serum barbiturates, serum benzodiazepine, propoxyphene, methaqualone
Methods supported/immunoassay methods	photometry, potentiometry, others/ACMIA, EMIT, PETINIA and turbidimetric	photometry, potentiometry, others/LOCI, ACMIA, EMIT, PETINIA and turbidimetric
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	91	91
No. of different assays programmed, calibrated at once	190	190
No. of user-definable (open) channels/No. active simultaneously	10/10	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	91/15–360	91/15–360
Shortest/median onboard reag. stability/Refrigerated onboard	48 hours/30 days/yes (2° to 8°)	48 hours/30 days/yes (2° to 8°)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	can be hours/60/>2,000	can be hours/60/>2,000
System is liquid or dry	liquid, reconstitutes onboard (no reagent prep required by the operator)	liquid, reconstitutes onboard (no reagent prep required by the operator)
Uses disposable cuvettes/Max. No. stored	yes/12,000	yes/12,000
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption per hour	yes/up to 5 L	yes/up to 5 L
Noise generated in decibels	<75	<75
Dedicated pediatric sample cup/Dead volume	yes/30 µL	yes/30 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	—	—
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/no	yes/yes/no
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/no	yes/no
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes (NA, K, CL)/yes	yes (NA, K, CL)/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	autocalibration every two hours/60–90 days/30 days	autocalibration every two hours/60–90 days/30 days
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2 min (not TCO2, ECO2 for enzymatic), 62 specimens, 187 ISE and 437 photometric tests	2 min (not TCO2, ECO2 for enzymatic), 62 specimens, 187 ISE and 437 photometric tests
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 min (ECO2 not TCO2 [enzymatic]), 62 specimens, 187 ISE and 437 photometric tests	5.5 min (ECO2 not TCO2 [enzymatic]), 62 specimens, 187 ISE and 437 photometric tests
• Album., bili. direct & total, AST, ALT, ALP	—	—
Typical time delay from ordering stat test to aspiration of sample	24 seconds	24 seconds
How often QC required/Onboard SW capability to review QC	24 hours or with lot change/yes	24 hours or with lot change /yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes, onboard, optional add-on (EasyLink Informatics System, SW mftr: Siemens Healthcare Diagnostics)/yes (additional cost)	yes, onboard, optional add-on (EasyLink Informatics System, SW mftr: Siemens Healthcare Diagnostics)/yes (additional cost)
Interfaces up and running in active user sites with	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	yes (broadcast download, host query)	yes (broadcast download, host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	—	—
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	2–8 hours/—	2–8 hours/—
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 15 min	daily: 5 min; weekly: 10 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	no/no	no/no
Training provided with purchase/Advanced oper. training avail.	5 days on site, 4 days at vendor offices/yes	5 days on site, 4 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	multiple types	multiple types
Distinguishing features (provided by vendor)	analyzer integrates general chemistry with heterogeneous immunoassays onboard; upgradeable with LOCI module; allows a single platform for more than 95 percent of most requested tests; eliminates sample splitting between general chemistry tests and immunoassays; fully automated onboard ISD assays; QCC PowerPak onboard; Reagent Management System standard	analyzer integrates general chemistry with homogeneous LOCI and heterogeneous immunoassays onboard; allows a single platform for more than 95 percent of most requested tests; eliminates sample splitting between general chemistry tests and immunoassays; fully automated onboard ISD assays; QCC PowerPak onboard; Reagent Management System standard

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Chemistry analyzers for mid- and high-volume labs

MID

Part 16 of 16

Teco Diagnostics
Owen Bry obry@tecodiag.com
1268 N Lakeview Ave
Anaheim, CA 92705
714-463-1115 www.tecodiag.com

Name of instrument/First year sold in U.S.	TC-Matrix/2007
List price/Total No. sold in 2007	$25,000; $30,000 with ISE/50
No. units in clinical use in U.S./Outside U.S.	20/30
Country where designed/Manufactured/Where reagents mftd.	China/China/U.S.
Operational type/Reagent type	random access, discrete/open reagent system
Sample handling system/Model type	ring/benchtop
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	25 × 31 × 27/6.6
No. of tests for which analyzer has FDA-cleared applications	32
Tests clinically released in last 12 months	albumin, alkaline phosphatase, amylase, ALT, AST, BUN, total bilirubin, direct bilirubin, chloride, calcium, cholesterol, creatinine, CK-NAC, carbon dioxide, glucose, glucose hexokinase, glucose oxidase, GGT, HDL, HbA1C, hemoglobin, phosphorous, iron, LDL, LDH, magnesium, potassium, total protein, sodium, triglycerides, CSF/urine protein, uric acid
Tests cleared but not clinically released	—
Tests not available in U.S. but submitted for 510(k) clearance	—
Tests not available in U.S. but available in other countries	—
Research-use-only assays	—
Tests in development	—
User-defined methods implemented for what analytes	ISE
Methods supported/immunoassay methods	photometry, potentiometry/turbidimetric
No. of direct ion selective electrode channels	3
No. of different measured assays onboard simultaneously	41
No. of different assays programmed, calibrated at once	41
No. of user-definable (open) channels/No. active simultaneously	41/all onboard
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	41/300–2,000
Shortest/median onboard reag. stability/Refrigerated onboard	170 hours/250 days/yes (4° to 15°C)
Multiple reag. configurations supported	yes
Reag. container placed directly on system for use	yes
Instrument has same capabilities when 3rd-party reag. used	yes
Walkaway capacity in minutes/Specimens/Tests-assays	30/40/80
System is liquid or dry	liquid
Uses disposable cuvettes/Max. No. stored	yes/80
Uses washable cuvettes/Replacement frequency	yes/6 months
Minimum sample volume aspirated precisely at one time	3 µL
Supplied with UPS (backup power)/Requires floor drain	no/no
Requires dedicated water system/Water consumption per hour	no/3.5 L
Noise generated in decibels	73
Dedicated pediatric sample cup/Dead volume	no/—
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, by handlheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128/no
Reagent bar-code reading capability	no
Bar code placement per CLSI standard Auto2A	no
Onboard test auto inventory (determines volume in container)	—
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/no
Automatic detection of adequate reag. for aspiration & analysis	yes
Hemolysis/Turbidity detection-quantitation	no/no
Dilution of patient samples onboard/Automatic rerun capability	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	daily/every 7–14 days/—/—
Automatic shutdown/Startup programmable	no/no
Stat time to completion of all analytes, throughput per hr. for:	
• Sodium, potassium, chloride, TCO2	—
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	—
• Album., bili. direct & total, AST, ALT, ALP	—
Typical time delay from ordering stat test to aspiration of sample	—
How often QC required/Onboard SW capability to review QC	every new lot of reagent; shortest: daily; longest: monthly/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes
QC results transferred automatically to LIS	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes (onboard, SW mftr: Mindray)/yes (included in instrument price)
Interfaces up and running in active user sites with	most
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	yes
How labs get LOINC codes for reagent kits	e-mail
Interface avail. (or will be) to automated specimen handling system	yes (Planned)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	2–3 days/yes
Mean time between failures/To repair failures	—/less than 1 hour
Average time to complete maintenance by lab personnel	once per year
Onboard maintenance records/Maint. training demo module	no/no
Training provided with purchase/Advanced oper. training avail.	1 day on site; 1 day at vendor
Annual service contract cost (24 h/7 d)	$60 per week (service contract optional)
Distinguishing features (provided by vendor)	sample volume precision; 300 tests/hour with ISE, onboard capacity (80 cuvettes); sample probe collision protection; 9 fiber optic paths with one free position; internal and external bar code available

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