Chemistry analyzers for mid- and high-volume laboratories

Part 1 of 16	MID Abbott Diagnostics Hamid Erfanian hamid.erfanian@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 847-938-9485 www.abbottdiagnostics.com	MID Abbott Diagnostics Hamid Erfanian hamid.erfanian@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 847-938-9485 www.abbottdiagnostics.com
Name of instrument/First year sold in U.S.	ARCHITECT c4000 and ci4100/2009	ARCHITECT c8000 and ci8200/2003
List price/Total No. sold in 2009	c4000: $180,000; ci4100: $275,000/—	c8000: $200,000/15; ci8200: $375,000/25
No. units in clinical use in U.S./Outside U.S.	—	c8000: 398/2,354; ci8200: 305/1,538
Country where designed/Manufactured/Where reagents mftd.	U.S., Japan/U.S., Japan/U.S.	U.S., Japan/U.S., Japan/U.S.
Operational type/Reagent type	continuous random access/self-contained multi-use cartridges, open reagent system	continuous random access/self-contained multi-use cartridges, open reagent system
Sample handling system/Model type	3-dimensional robotic sample handler/floor standing	3-dimensional robotic sample handler/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	c4000: 49 × 63 × 36/21; ci4100: 49 × 111 × 36/37	c8000: 48 × 79 × 49/26; ci8200: 48 × 127 × 49/42
No. of tests for which analyzer has FDA-cleared applications	128	128
Tests clinically released in last 12 months	acetaminophen, amphetamine/methamphetamine, barbiturates, benzodiazepines, benzodiazepines-serum, cannabinoids, cocaine, ecstasy, ethanol, methadone, opiates, phencyclidine (PCP), propoxyphene, salicylate, tricyclic antidepressants, acid phosphatase, alanine aminotransferase (ALT), albumin BCG, albumin BCP, alkaline phosphatase, ammonia, amylase, aspartate aminotransferase (AST), HE4, folate, others	next gen. calcium, next gen creatinine, tobramycin, HE4, folate
Tests cleared but not clinically released	HIV Ag/Ab	HIV Ag/Ab
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	AFP, proGRP, NGAL, anti-HAV IgG, anti-HBc, anti-HBs, HBsAg, HBsAg confirmatory, MPO, SCC, testosterone, CMV IgG, CMV IgG avidity, CMV IgM, rubella IgG, rubella IgM, toxo IgG, toxo IgG avidity, toxo IgM, syphilis, HIV Ag/Ab combo, alpha-1-antitrpysin, alpha-1-glycoprotein, ASO, beta 2 microglobulin, ceruloplasim, IgE, kappa light chain, lambda light chain, Lp(a), rheumatoid factor, myoglobin	AFP, proGRP, NGAL, anti-HAV IgG, anti-HBc, anti-HBs, HBsAg, HBsAg confirmatory, MPO, SCC, testosterone, CMV IgG, CMV IgG avidity,CMV IgM, rubella IgG, rubella IgM, toxo IgG, toxo IgG avidity, toxo IgM, syphilis, HIV Ag/Ab combo, alpha-1-antitrpysin, alpha-1-glycoprotein, ASO, beta 2 microglobulin, ceruloplasim, IgE, kappa light chain, lambda light chain, Lp(a), rheumatoid factor, myoglobin
Research-use-only assays	—	—
Tests in development	Tg, AFP, anti-HAV IgG, anti-HBc, vitamin D, NGAL, carbamazepine, gentamicin, methotrexate, vitamin B12	Tg, AFP, anti-HAV IgG, anti-HBc, vitamin D, NGAL, carbamazepine, gentamicin, methotrexate, vitamin B12
User-defined methods implemented for what analytes	yes, varies	yes, varies
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/chemiluminescence with flexible protocols	photometry, potentiometry, turbidimetric/chemiluminescence with flexible protocols
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	c4000: 58; ci4100: 83	c8000: 68; ci8200: 93
No. of different assays programmed, calibrated at once	c4000: 220; ci4100: 320	c8000: 220; ci8200: 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	c4000: varies 50–1,700; ci4100: varies 50 –1,700 chemistry, 100 immunoassay	c8000: 65/50–1,700; ci8200: 90/50–1,170 (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	c4000: varies/100/62,000+; ci4100: varies/180/64,000+	c8000: varies/215/69,000+; ci8200: varies/365/81,000–93,000
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/yes, immunoassay/300	c8000: no/—; ci8200: yes/1,200 immunoassay
Uses washable cuvettes/Replacement frequency	yes, chemistry/minimum 1-year guarantee	yes, chemistry/minimum 1-year 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/15 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 (for chemistry)	yes/yes (for chemistry)
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes, for chemistry only/yes	yes, for chemistry only/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hr/30 days/7 days/14 days	24 hr/30 days/7 days/14 days
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2.5 min, 200 specimens, 800 tests	2.4 min, 200 specimens, 800 tests
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	8.4 min, 80 specimens, 560 tests	8.4 min, 160 specimens, 1,120 tests
• Album., bili. direct & total, AST, ALT, ALP	9.6 min, 67 specimens, 400 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	no	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	>2 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/yes	yes/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site, 5 days at vendor offices/yes	5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	flexible options available	flexible options available
Distinguishing features (provided by vendor)	integration of CC and IA w/o compromising stat TAT, results, or throughput; robotic sample handler design w/SmartWash technology allows IA and CC testing in any order for overall TAT; features and benefits standardized across Architect instruments for consistent user experience, reduced variation in operator procedures, fewer errors, and consistent results; large reagent, routine and stat sample load-up capacity for efficient processing of samples for patient results; see operations manual for additional information	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; see operations manual for additional information

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Survey Editor: Raymond Aller, MD

Chemistry analyzers for mid- and high-volume laboratories

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	HIGH	MID
	Abbott Diagnostics Hamid Erfanian hamid.erfanian@abbott.com 100 Abbott Park Rd. Abbott Park, IL 60064 847-938-9485 www.abbottdiagnostics.com	Awareness Technology Inc. Robert Guerin 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.	ARCHITECT c16000 and ci16200/2007	ChemWell 2902, 2910/1999
List price/Total No. sold in 2009	c16000: $325,000/98; ci16200: $475,000/3	starts at $20,000/>500
No. units in clinical use in U.S./Outside U.S.	c16000: 15/267; ci16200: 8/201	50+/2,200+
Country where designed/Manufactured/Where reagents mftd.	U.S., Japan/U.S., Japan/U.S.	U.S./U.S./open system
Operational type/Reagent type	continuous random access/open reagent system	batch, random access, continuous random access/open reagent system
Sample handling system/Model type	3-dimensional robotic sample handler and carousel/floor-standing	rack/benchtop
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	c16000: 48 × 79 × 49/26; ci16200: 48 × 127 × 49/42	19 × 36 × 22/7
No. of tests for which analyzer has FDA-cleared applications	128	22
Tests clinically released in last 12 months	next gen. calcium, next gen creatinine, tobramycin, HE4, folate	—
Tests cleared but not clinically released	HIV Ag/Ab	—
Tests not available in U.S. but submitted for 510(k) clearance	—	18 EIA kits manufactured by BioCheck have been submitted
Tests not available in U.S. but available in other countries	AFP, proGRP, NGAL, anti-HAV IgG, anti-HBc, anti-HBs, HBsAg, HBsAg confirmatory, MPO, SCC, testosterone, CMV IgG, CMV IgG avidity,CMV IgM, rubella IgG, rubella IgM, toxo IgG, toxo IgG avidity, toxo IgM, syphilis, HIV Ag/Ab combo, alpha-1-antitrpysin, alpha-1-glycoprotein, ASO, beta 2 microglobulin, ceruloplasim, IgE, kappa light chain, lambda light chain, Lp(a), rheumatoid factor, myoglobin	open system
Research-use-only assays	—	open system
Tests in development	Tg, AFP, anti-HAV IgG, anti-HBc, vitamin D, NGAL, carbamazepine, gentamicin, methotrexate, vitamin B12	—
User-defined methods implemented for what analytes	yes, varies	all colorimetric biochemistry & EIA that read between 340 and 700 nm
Methods supported/immunoassay methods	photometry, potentiometry (ISE), turbidmetric/chemiluminescence with flexible protocols (CHEMIFEX)	photometry/microwell assays
No. of direct ion selective electrode channels	3	0
No. of different measured assays onboard simultaneously	c16000: 68; ci16200: 93	27 std, 44 optional
No. of different assays programmed, calibrated at once	c16000: 220; ci16200: 320	unlimited
No. of user-definable (open) channels/No. active simultaneously	220/220	unlimited/27 std, 44 optional
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	c16000: 65/50–1,700 (chemistry); ci16200: 93/50–1,700 (chemistry), 100–500 (immunoassay)	27 std, 44 optional/reagent dependent
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/28 days/yes (2° to 8°C)	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	c16000: varies/215/69,000+; ci16200: varies/365/81,000–93,000	not limited/96/not limited
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	c16000: no/—; ci16200: yes/1,200 immunoassay	yes (optional)/96
Uses washable cuvettes/Replacement frequency	yes/minimum 1-year guarantee	yes (optional)/weekly
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	no/no
Requires dedicated water system/Water consumption per hour	yes/59 L	no/<1 L
Noise generated in decibels	normal operation: ≤48 peak; 70 for max 10 sec	60
Dedicated pediatric sample cup/Dead volume	yes/50 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 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, 2-D bar codes	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 (for chemistry)	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	24 hr/30 days/7 days/14 days	user-defined for all
Automatic shutdown/Startup programmable	no/no	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2.4 min, 200 specimens, 800 Tests	—
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	8.4 min, 190 specimens, 1,330 Tests	—
• Album., bili. direct & total, AST, ALT, ALP	9.6 min, 200 specimens, 1,200 Tests	5.5 min, 28 specimens
Typical time delay from ordering stat test to aspiration of sample	<20 sec	15 sec
How often QC required/Onboard SW capability to review QC	shortest interval: 8 hr; 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	optional add-on (addt'l price varies; SW mftr: Abbott)	onboard/yes (included in price)
Interfaces up and running in active user sites with	Cerner, Mysis, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Citation, CHCS, Antek, Orchard, others	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
How labs get LOINC codes for reagent kits	package insert	supplied by reagent manufacturer
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/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	—/—	depends on user and varies/depends on problem and varies
Average time to complete maintenance by lab personnel	daily: 15 min; weekly: <45 min; monthly: 15 min	daily: <5 min; weekly: about 15 min; monthly: about 30 min or less
Onboard maintenance records/Maint. training demo module	yes/yes	no/no
Training provided with purchase/Advanced oper. training avail.	5 days on site, 5 days at vendor offices/yes	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)	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; CHEMIFEX and FlexRate technologies deliver assay extended linearities and enhanced sensitivities; see operations manual for additional information	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

Part 3 of 16	MID Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com	MID Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold in U.S.	AU480/2009	AU680/2008
List price/Total No. sold in 2009	$140,000/—	$213,000/30
No. units in clinical use in U.S./Outside U.S.	30/50	125/>50
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	47.5 × 57.1 × 30/47	42.5 × 76.8 × 50/94.5
No. of tests for which analyzer has FDA-cleared applications	125	125
Tests clinically released in last 12 months	total bile acids for veterinary use only, ferritin	total bile acids for veterinary use only, ferritin
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	HbA1c (next gen)	HbA1c (next gen)
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 63
No. of different assays programmed, calibrated at once	120	120
No. of user-definable (open) channels/No. active simultaneously	117/60	116/60
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	76/100 to 1,333	63/100 to 1,500
Shortest/median onboard reag. stability/Refrigerated onboard	5 days/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 102/varies	varies/up to 172/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	yes/permanent	yes/permanent
Minimum sample volume aspirated precisely at one time	1 µL	1 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes (no w/ optional water pump)	no (optional)/yes (no w/ optional water pump)
Requires dedicated water system/Water consumption per hour	yes/20 L per hr average peak consumption	yes/40 L per hr peak consumption
Noise generated in decibels	60	60
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 to 20 days	1 day/30 days/14 days/14 to 20 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	<5 min, 200 specimens	<4 min, 200 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	<5 min, 80 specimens	<5 min, 160 specimens
• Album., bili. direct & total, AST, ALT, ALP	<9 min, 67 specimens	9 min, 133 specimens
Typical time delay from ordering stat test to aspiration of sample	<2 min	1 min
How often QC required/Onboard SW capability to review QC	per CLIA & laboratory's decision/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technology, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innovations), CPSI, Meditech, Misys, Citation, SCC	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technology, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innovations), CPSI, Meditech, Misys, Citation, SCC
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<24 hr/yes	<24 hr/yes
Mean time between failures/To repair failures	average 2 calls per yr/<24 hr	average 2 calls per year/<24 hr
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 12 min; monthly: 45 min	daily: 4 min; weekly: 27 min; monthly: 45 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	3–5 days on site, 5 days at vendor offices/yes	3–5 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	inquire
Distinguishing features (provided by vendor)	standardization with family of chemistry immuno systems—the AU680, AU2700, and AU5400; broad test menu of 130 methods provides standardized results for improved patient management and streamlined operation	standardization with its family of chemistry immuno systems—the AU480, AU2700, and AU5400; broad test menu of 130 methods; 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

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Chemistry analyzers for mid- and high-volume laboratories

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	HIGH	HIGH
	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold in U.S.	AU2700/2000	AU5421 with dual ISE/2001
List price/Total No. sold in 2009	$320,000/22	$465,000/—
No. units in clinical use in U.S./Outside U.S.	130/>700	225/450
Country where designed/Manufactured/Where reagents mftd.	—	Japan/Japan/U.S. & Ireland
Operational type/Reagent type	random access, discrete, continuous random access/open reagent system	random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	rack & stat carousel/floor standing	rack/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	50 × 79 × 45/92	50 × 148 × 45/46.25
No. of tests for which analyzer has FDA-cleared applications	125	125
Tests clinically released in last 12 months	total bile acids for veterinary use only, ferritin	total bile acids for veterinary use only, ferritin
Tests cleared but not clinically released	—	—
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	HbA1c (next gen)	HbA1c (next gen)
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, calculated tests/homogeneous
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	up to 51	99
No. of different assays programmed, calibrated at once	99	99
No. of user-definable (open) channels/No. active simultaneously	95/48	95/95
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	48/100 to 4,000	48 × 2/100 to 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 322/varies	varies/up to 300/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	yes/permanent	yes/permanent
Minimum sample volume aspirated precisely at one time	1 µL	1 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes	no (optional)/yes
Requires dedicated water system/Water consumption per hour	yes/65 L per hr peak consumption	yes/120 L
Noise generated in decibels	<65	<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.)/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 to 20 days	1 day/30 days/14 days/14 to 20 days
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	<4 min, 267 specimens	—, max 600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	<4 min, 267 specimens	—, max 600 specimens
• Album., bili. direct & total, AST, ALT, ALP	9 min, 267 specimens	—, max 533 specimens
Typical time delay from ordering stat test to aspiration of sample	1 min	—
How often QC required/Onboard SW capability to review QC	per CLIA & laboratory's decision/yes	per CLIA & laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technology, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innovations), CPSI, Meditech, Misys, Citation, SCC	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technology, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innovations), 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	<4 calls per year/<24 hr	<9 calls per year/<24 hr
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 42 min; monthly: 15 min	daily: 30 min; weekly: 81 min; monthly: 40 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	3–5 days on site, 5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	inquire	inquire
Distinguishing features (provided by vendor)	standardization with its family of chemistry immuno systems—the AU480, AU2700, and AU5400; broad test menu of 130 methods provides standardized results for improved patient management and streamlined operation	standardization with its family of chemistry immuno systems—the AU480, AU680, AU2700, and AU5400; broad test menu of 130 methods provides standardized results for improved patient management and streamlined operation

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

Chemistry analyzers for mid- and high-volume laboratories

Part 5 of 16

	HIGH	MID
	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold in U.S.	AU5431 with dual ISE/2001	UniCel DxC 600/2004
List price/Total No. sold in 2009	$575,000/—	$261,000/—
No. units in clinical use in U.S./Outside U.S.	225/450	>1300 />2500
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/U.S. & Ireland	U.S./U.S./U.S. & Ireland
Operational type/Reagent type	random access, discrete, continuous random access/open reagent system	continuous random access/open reagent system
Sample handling system/Model type	rack/floor standing	racks, centrifugable/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	50 × 200 × 45/62.5	62 × 62 × 41/17.7
No. of tests for which analyzer has FDA-cleared applications	130	>100
Tests clinically released in last 12 months	HbA1c automated pretreatment, cystatin C, homocysteine, total bile acids, TIBC, master curve cal set (C3, C4, transferrin, ASO)	alpha 1-acid glycoprotein, ceruloplasmin, buprenorphine, kappa light chains, lambda light chains, amylase G7, enzymatic creatinine
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	none	—
Tests in development	—	enzymatic CO2, HbA1c (next gen)
User-defined methods implemented for what analytes	fructosamine, oxycodone, topiramate	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC
Methods supported/immunoassay methods	photometry, potentiometry, calculated tests/homogeneous	photometry, potentiometry, near-infrared bidentate turbidimetric/particle enhanced turbidimetric, enzyme immunoassay, near-infrared particle immunoassay
No. of direct ion selective electrode channels	3	5
No. of different measured assays onboard simultaneously	up to 99	65
No. of different assays programmed, calibrated at once	99	100
No. of user-definable (open) channels/No. active simultaneously	95/95	100/65
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	48 × 3/100 to 4,000	65/about 3,500 modular; about 600 cartridges
Shortest/median onboard reag. stability/Refrigerated onboard	120 hr/30 days/yes (4° to 12°C)	168 hr/30 days/yes (2° to 8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	no
Walkaway capacity in minutes/Specimens/Tests-assays	varies/up to 300/varies	83/132/5,280
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	—
Uses washable cuvettes/Replacement frequency	yes/permanent	yes/2-year warranty, semi-permanent
Minimum sample volume aspirated precisely at one time	1 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes	optional/no
Requires dedicated water system/Water consumption per hour	yes/180 L	yes/16 L
Noise generated in decibels	—	60
Dedicated pediatric sample cup/Dead volume	no/—	yes/40 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/yes
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	1 day/30 days/14 days/14 to 20 days	1 day/up to 90 days/up to 60 days/14 days
Automatic shutdown/Startup programmable	yes/yes	none required
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	—, max 600 specimens	6:15 min. from standby, 96 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	—, max 600 specimens	6:15 min. from standby, 96 specimens
• Album., bili. direct & total, AST, ALT, ALP	—, max 800 specimens	13:07 min. from standby, 57 specimens
Typical time delay from ordering stat test to aspiration of sample	—	16 sec
How often QC required/Onboard SW capability to review QC	per CLIA & laboratory's decision/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard & optional add-on (SW mftr: Beckman Coulter)/yes (addt'l cost)
Interfaces up and running in active user sites with	all common interfaces including Cerner, Antrim, CCA, Chemware, Dawning Technology, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innovations), CPSI, Meditech, Misys, Citation, SCC	Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	—	customer request
Interface avail. (or will be) to automated specimen handling system	yes	yes (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	<24 hr/yes	metro: same day, rural: same or next day/yes
Mean time between failures/To repair failures	<9 calls per year/<24 hr	—/—
Average time to complete maintenance by lab personnel	daily: 30 min; weekly: 81 min; monthly: 40 min	daily: none; weekly: 7 min (tech time); monthly: 11 min (tech time)
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	—
Distinguishing features (provided by vendor)	standardization with its family of chemistry immuno systems—the AU480, AU680, AU2700, and AU5400; broad test menu of 130 methods provides standardized results for improved patient management and streamlined operation	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

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Chemistry analyzers for mid- and high-volume laboratories

Part 6 of 16

	HIGH	MID
	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold in U.S.	UniCel DxC 800/2005	Unicel DxC 600i/2006
List price/Total No. sold in 2009	$340,000/not available	$400,000/—
No. units in clinical use in U.S./Outside U.S.	>700/>1,000	>400/100
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 × 70 × 41/19.9	62 × 128 × 48/42.7
No. of tests for which analyzer has FDA-cleared applications	>100	>150
Tests clinically released in last 12 months	alpha 1-acid glycoprotein, ceruloplasmin, buprenorphine, amylase G7, enzymatic creatinine	—
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	—	HAV Ab, HAV IgM, HBcAb, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM (BVID assays can only be run on the Access 2 portion of DxC 600i in standalone mode)
Research-use-only assays	—	IL-6, PAPP-A
Tests in development	enzymatic CO2, HbA1c (next gen)	PIGF, sVEGF R1, vitamin D
User-defined methods implemented for what analytes	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC
Methods supported/immunoassay methods	photometry, potentiometry (ISE), near-infrared bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near-infrared particle immunoassay	photometry, potentiometry (ISE), turbidimetric, enzyme immunoassay/ chemiluminescence
No. of direct ion selective electrode channels	5	5
No. of different measured assays onboard simultaneously	70	89
No. of different assays programmed, calibrated at once	100	>150
No. of user-definable (open) channels/No. active simultaneously	100/70	100/65
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	70/approx. 3,500 (modular); 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	no	yes/294 (immuno)
Uses washable cuvettes/Replacement frequency	yes/2-year warranty, semi-permanent	yes/2-year 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 (samples directly from bullet)	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	2:23 min. (from standby), 91 specimens	8:15 min. from standby, 96 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	2:22 min. (from standby), 91 specimens	8:15 min. from standby, 96 specimens
• Album., bili. direct & total, AST, ALT, ALP	12:32 min. (from standby), 76 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 (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: 10 min (tech time); monthly: 18 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 & correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; stat TAT; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification	parallel processing of immunoassay & chemistry tests on a single system; ClozCap technology (closed-tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry & immunoassay reagent packs identical across UniCel systems; immunossay: high-throughput analyzer; uses chemiluminescent assay technology and reagent packs for consistent results; loads consumables on the fly; chemistry: closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring w/semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat TAT

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Chemistry analyzers for mid- and high-volume laboratories

Part 7 of 16

	HIGH	HIGH
	Beckman Coulter, Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter, Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold in U.S.	UniCel DxC 660i Synchron Access Clinical System/2009	UniCel DxC 680i Synchron Access Clinical System/2009
List price/Total No. sold in 2009	$575,000/—	$610,000/—
No. units in clinical use in U.S./Outside U.S.	>5/<5	4/2
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S., France, Ireland	U.S./U.S./U.S., France, Ireland
Operational type/Reagent type	batch, random access, continuous random access/immunoassay: self-contained singe-use cartridges, packages, slides; chemistry: open reagent system	batch, random access, continuous random access/immunoassay: self-contained single-use cartridges, packages, sides; chemistry: open reagent system
Sample handling system/Model type	rack closed-tube/floor-standing	rack closed-tube/floor-standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	68 × 147 × 48/49	68 × 153 × 48/51
No. of tests for which analyzer has FDA-cleared applications	>150	>150
Tests clinically released in last 12 months	soluble transferrin receptor	soluble transferrin receptor
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	HAV Ab, HAV IgM, HBcAb, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM	HAV Ab, HAV IgM, HBcAb, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM
Research-use-only assays	IL-6, PAPP-A	IL-6, PAPP-A
Tests in development	PIGF, sVEGF R1, vitamin D	PIGF, sVEGF R1, vitamin D
User-defined methods implemented for what analytes	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC
Methods supported/immunoassay methods	photometry, potentiometry (ISE), turbidimetric/ particle enhanced, turbidimetric, enzyme immunoassay, near-infrared particle immunoassay, chemiluminescence, magnetic particle	photometry, potentiometry (ISE), turbidimetric/ particle enhanced, turbidimetric, enzyme immunoassay, near-infrared particle immunoassay, chemiluminescence, magnetic particle
No. of direct ion selective electrode channels	5	5
No. of different measured assays onboard simultaneously	115	115
No. of different assays programmed, calibrated at once	115	115
No. of user-definable (open) channels/No. active simultaneously	100/100	100/100
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	115/immunoassay: 100 tests/kit; general chemistry: 300 tests/container	115/immunoassay: 100 tests/kit; general chemistry: 300 tests/container
Shortest/median onboard reag. stability/Refrigerated onboard	28 days/yes (2° to 10°C)	28 days/yes (2° to 10°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	assay mix dependent/—/assay dependent	assay mix dependent/—/assay dependent
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/125	no/125
Uses washable cuvettes/Replacement frequency	yes/—	yes/—
Minimum sample volume aspirated precisely at one time	3 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	yes/up to 16 L	yes/up to 16 L
Noise generated in decibels	64	64
Dedicated pediatric sample cup/Dead volume	yes/20	yes/20
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability/Autodiscrimination	2 or 5 interl., UPC, Codabar, codes 39 128/yes	2 or 5 interl., UPC, Codabar, codes 39 & 128/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	—	—
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	—/—/assay dependent/assay dependent	—/—/assay dependent/assay dependent
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	—	—
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	—	—
• Album., bili. direct & total, AST, ALT, ALP	—	—
Typical time delay from ordering stat test to aspiration of sample	—	—
How often QC required/Onboard SW capability to review QC	24 hours/yes	24 hours/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard & optional add-on (sw mftr: Beckman Coulter/Normand)/yes (additional cost)	onboard & optional add-on (sw mftr: Beckman Coulter/Normand)/yes (additional cost)
Interfaces up and running in active user sites with	most commercially available LIS	most commercially available LIS
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Interface avail. (or will be) to automated specimen handling system	yes	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	metro: same day; rural: same or next day/yes	metro: same day; rural: same or next day/yes
Mean time between failures/To repair failures	—	—
Average time to complete maintenance by lab personnel	daily: <10 min; weekly: <10 min; monthly: <18 min	daily: <10 min; weekly: <10 min; monthly: <18 min
Onboard maintenance records/Maint. training demo module	yes, includes audit trai/yes	yes, includes audit trai/yes
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	contract dependent	contract dependent
Distinguishing features (provided by vendor)	parallel processing of immunoassay & chemistry tests on a single system; ClozCap technology (closed-tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry & immunoassay reagent packs identical across UniCel systems; immunossay: high-throughput analyzer; uses chemiluminescent assay technology and reagent packs for consistent results; loads consumables on the fly; chemistry: closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring w/semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat TAT; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification	parallel processing of immunoassay & chemistry tests on a single system; ClozCap technology (closed-tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry & immunoassay reagent packs identical across UniCel systems; immunossay: high-throughput analyzer; uses chemiluminescent assay technology and reagent packs for consistent results; loads consumables on the fly; chemistry: closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring w/semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat TAT; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification

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

Chemistry analyzers for mid- and high-volume laboratories

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	HIGH	HIGH
	Beckman Coulter, Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com	Beckman Coulter Inc. Joel Greiner jcgreiner@beckman.com 250 S. Kraemer Blvd. Brea, CA 92821 714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold in U.S.	UniCel DxC 860i Synchron Access Clinical System/2009	UniCel DxC 880i Synchron Access Clinical System/2008
List price/Total No. sold in 2009	$615,000/—	$650,000/—
No. units in clinical use in U.S./Outside U.S.	1/1	>65/>65
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S., France, Ireland	U.S./U.S./U.S., Ireland and France
Operational type/Reagent type	batch, random access, continuous random access/immunoassay: self-contained single-use cartridges, packages, sides; chemistry: open reagent system	continuous random access/open reagent system for chemistry; self-contained single use cartridges for immunoassay
Sample handling system/Model type	rack closed-tube/floor-standing	rack closed tube/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	68 × 155 × 48/51.7	68 × 161 × 48/53.7
No. of tests for which analyzer has FDA-cleared applications	>150	>150
Tests clinically released in last 12 months	soluble transferrin receptor	soluble transferrin receptor
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	HAV Ab, HAV IgM, HBcAb, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM	HAV Ab, HAV IgM, HBcAb, HBc IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM
Research-use-only assays	IL-6, PAPP-A	IL-6, PAPP-A
Tests in development	PIGF, sVEGF R1, vitamin D	PIGF, sVEGF R1, vitamin D
User-defined methods implemented for what analytes	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC	cyclosporine, serum tox benz, barb, tricyclics; amikacin, amylase G7, quinidine, cystatin-C, buprenorphine, oxycodone, ecstasy, lithium, homocysteine, free kappa light chain, free lambda light chain, UIBC
Methods supported/immunoassay methods	photometry, potentiometry (ISE), turbidimetric/ particle enhanced, turbidimetric, enzyme immunoassay, near-infrared particle immunoassay, chemiluminescence, magnetic particle	photometry, potentiometry (ISE), turbidimetric/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	120	120
No. of different assays programmed, calibrated at once	120	120
No. of user-definable (open) channels/No. active simultaneously	100/100	100/100
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	120/immunoassay: 100 tests/kit; general chemistry: 300 tests/container	120/100 tests/kit (immunoassay); 300 test/container (general chem)
Shortest/median onboard reag. stability/Refrigerated onboard	28 days/yes (2° to 10°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	yes	no
Walkaway capacity in minutes/Specimens/Tests-assays	assay mix dependent/—/assay dependent	assay mix dependent/112/assay dependent
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/125	no/—
Uses washable cuvettes/Replacement frequency	yes/—	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	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	yes/up to 16 L	yes/up to 16 L
Noise generated in decibels	64	64
Dedicated pediatric sample cup/Dead volume	yes/20	yes/20 µL (chemistry)
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability/Autodiscrimination	2 or 5 interl., UPC, Codabar, codes 39 & 128/yes	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	—	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	—/—/assay dependent/assay dependent	every 24 hours/up to 90 days/up to 60 days/up to 90 days
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	—	<1 min, 90 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	—	<1 min, 90 specimens
• Album., bili. direct & total, AST, ALT, ALP	—	approx. 6.5 min, 90 specimens
Typical time delay from ordering stat test to aspiration of sample	—	<1 min
How often QC required/Onboard SW capability to review QC	24 hours/yes	24 hours/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard & optional add-on (sw mftr: Beckman Coulter/Normand)/yes (additional cost)	onboard & optional add-on (Beckman Coulter)/yes (additional cost)
Interfaces up and running in active user sites with	most commercially available LIS	Cerner, Misys, Meditech, Citation, Medlab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	—	customer request
Interface avail. (or will be) to automated specimen handling system	yes	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: <10 min; weekly: <10 min; monthly: <18 min	daily: <10 min; weekly: <10 min; monthly: <18 min
Onboard maintenance records/Maint. training demo module	yes, includes audit trai/yes	yes (includes audit 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)	contract dependent	—
Distinguishing features (provided by vendor)	parallel processing of immunoassay & chemistry tests on a single system; ClozCap technology (closed-tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry & immunoassay reagent packs identical across UniCel systems; immunossay: high-throughput analyzer; uses chemiluminescent assay technology and reagent packs for consistent results; loads consumables on the fly; chemistry: closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring w/semi-permanent glass cuvettes	parallel processing of immunoassay & chemistry tests on a single system; ClozCap technology (closed-tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry & immunoassay reagent packs identical across UniCel systems; immunossay: high-throughput analyzer; uses chemiluminescent assay technology and reagent packs for consistent results; loads consumables on the fly; chemistry: closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks; no-wait autoloader; calibration data provided on disk; Peltier ring w/semi-permanent glass cuvettes

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Chemistry analyzers for mid- and high-volume laboratories

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MID

The Binding Site
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San Diego, CA 92121
800-633-4484 ext. 337 www.bindingsite.com

MID

Carolina Liquid Chemistries Corp.
Patti Shugart contactsales@carolinachemistries.com
391 Technology Way
Winston-Salem, NC 27101
877-722-8910 www.carolinachemistries.com

Name of instrument/First year sold in U.S.	SPA PLUS (Specialist Protein Analyzer)/2007	BioLis 24i/2008
List price/Total No. sold in 2009	—	$75,000/50
No. units in clinical use in U.S./Outside U.S.	—	200/>3,000
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/United Kingdom	Japan/Japan/U.S.
Operational type/Reagent type	batch, random access/self-contained multi-use cartridges, packages, slides	batch, random access, discrete, continuous random access/open reagent system
Sample handling system/Model type	2 sample carousels each hold 45 samples: 30 primary tubes and 15 non-bar-coded sample tubes, cups/benchtop	cup, bar-coded tubes, stat/benchtop
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	20.5 × 31.5 × 25.2/14	20 × 31 × 25/5
No. of tests for which analyzer has FDA-cleared applications	Freelite kappa (free kappa light chain), Freelite lambda (free lambda light chain) beta-2-microglobulin, IgG, IgM, IgA, IgD, IgG1, IgG2, IgG3, IgG4, cystatin C	100
Tests clinically released in last 12 months	IgD	direct (no-pretreatment) HbA1c and cystatin C, 1,5AG (GlycoMark)
Tests cleared but not clinically released	—	Lp-PLA2
Tests not available in U.S. but submitted for 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	IgA1, IgA2	—
Research-use-only assays	tetanus toxoid, T. tox plasma screen only (RUO)	—
Tests in development	Hevylite IgG kappa & lambda, Hevylite IgA kappa & lambda, Hevylite IgM kappa & lambda, C3, C4, CH50	vitamin D, RPR syphilis
User-defined methods implemented for what analytes	—	—
Methods supported/immunoassay methods	—/turbidimetry	photometry, potentiometry/—
No. of direct ion selective electrode channels	—	3
No. of different measured assays onboard simultaneously	24	39
No. of different assays programmed, calibrated at once	—	39
No. of user-definable (open) channels/No. active simultaneously	—	39/39
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	24/100	39/300 (3 × 100)
Shortest/median onboard reag. stability/Refrigerated onboard	672 hours/30 days/yes (9° to 12°C)	7 days/14 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	no	yes
Walkaway capacity in minutes/Specimens/Tests-assays	~60/45/6	4 hours/40/39
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/60	no/—
Uses washable cuvettes/Replacement frequency	yes/checks OD and when it reaches threshold OD (0.33) cuvettes should be changed	yes/6 months
Minimum sample volume aspirated precisely at one time	3 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no
Requires dedicated water system/Water consumption per hour	no/3.5 L	no/3.5 L
Noise generated in decibels	—	—
Dedicated pediatric sample cup/Dead volume	no/—	yes/30 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, as sample is being aspirated, on sample transport, shortly before sample is aspirated (Codabar, codes 39 & 128)/—	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved)/—
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	—	yes
Onboard test auto inventory (determines volume in container)	no	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/no	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes/yes	yes/no
Autocalibration or autocalibration alert	yes	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	—	24 hours/14 days/14 days/14 days
Automatic shutdown/Startup programmable	no/no	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	—	12 min, 160 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	—	1 hour, 60 specimens
• Album., bili. direct & total, AST, ALT, ALP	—	18 min, 240 specimens
Typical time delay from ordering stat test to aspiration of sample	—	5 min
How often QC required/Onboard SW capability to review QC	—	2 levels per operational shift; shortest interval: 8 hours; longest: 24 hours/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/no	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes, onboard (optional add-on)/no	yes, onboard/yes (additional cost)
Interfaces up and running in active user sites with	Cerner, Soft Computer Concepts, Cyberlab, SunQuest, Meditech, Middleware, Creative Computing Applications Inc., Data Innovations	all common LISs
Bidirectional interface capability	yes (broadcast download, host query)	yes (broadcast download, host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	—
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/no/no	no/no/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	24 hours/yes	within 24 hours/yes
Mean time between failures/To repair failures	258 days with two scheduled preventive maintenance visits/4 hours on site	—/—
Average time to complete maintenance by lab personnel	daily: <10 min; weekly: <10 min; monthly: <15 min	weekly: 20 min; monthly: visual inspections, <5 min
Onboard maintenance records/Maint. training demo module	no/no	yes (includes audit trail of who replaced parts)/no
Training provided with purchase/Advanced oper. training avail.	5 days (includes installation)/yes	5 days on site/yes
Annual service contract cost (24 h/7 d)	—	$7,500
Distinguishing features (provided by vendor)	prozone detection, autodilution; dual compartment reaction cuvette, air pressure mixing system and extensive washing processes, ideal for latex assays; low maintenance	small size and large menu; 39 onboard chemistries; can run general and special chemistries from CMPs to D-dimer, cystatin C, insulin and drugs of abuse, both qualitative and quantitative, and more than 80 other tests

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Chemistry analyzers for mid- and high-volume laboratories

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	HIGH	MID
	Ortho-Clinical Diagnostics Mark Steelman msteelma@its.jnj.com 1001 U.S. Route 202 Raritan, NJ 08869 585-453-3420 www.orthoclinical.com	Ortho-Clinical Diagnostics Kunal Chokshi kchokshi@its.jnj.com 1001 U.S. Route 202 Raritan, NJ 08869 908-218-8172 www.orthoclinical.com
Name of instrument/First year sold in U.S.	VITROS 5600 Integrated System/2008	VITROS 350/2005
List price/Total No. sold in 2009	$410,000/—	$110,000/—
No. units in clinical use in U.S./Outside U.S.	>500 worldwide	—/—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. & United Kingdom	U.S./U.S./U.S.
Operational type/Reagent type	random access/self-contained multi-use cartridges, packages, slides	batch, random access, discrete, continuous random access/self-contained single-use cartridges, packages, slides
Sample handling system/Model type	universal sample tray/floor-standing	rack/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	68 × 110 × 34.9/26.7	47 × 45.5 × 28/8.8
No. of tests for which analyzer has FDA-cleared applications	>110	>40
Tests clinically released in last 12 months	HCV, HBsAg, HIV-1/2, anti-HBs	—
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	HBeAg, aHBe, rub IgM, tox IgG, tox IgM, CMV IgG, CMV IgM	—
Research-use-only assays	—	—
Tests in development	HIV combo, syphilis (ex-US), intact PTH, aHBE, HBeAg	—
User-defined methods implemented for what analytes	—	—
Methods supported/immunoassay methods	photometry, potentiometry (ISE), thin film reflectance/homogeneous EMIT, microparticle agglutination, enhanced chemiluminescence	potentiometry, colorimetric, rate, immuno-rate
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	106	up to 60
No. of different assays programmed, calibrated at once	106	up to 60
No. of user-definable (open) channels/No. active simultaneously	20/10	—/—
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	106/100	up to 60/18, 50, 60
Shortest/median onboard reag. stability/Refrigerated onboard	48 hours/30 days/yes (2° to 8°C)	48 hr/14 days/no
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	no	—
Walkaway capacity in minutes/Specimens/Tests-assays	varies/90/11,440	varies/40/3,600
System is liquid or dry	liquid and dry	dry
Uses disposable cuvettes/Max. No. stored	yes/348	—
Uses washable cuvettes/Replacement frequency	no/—	—
Minimum sample volume aspirated precisely at one time	2	6 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	available (not included)/no
Requires dedicated water system/Water consumption per hour	no/0	no/—
Noise generated in decibels	idle: 60 dB; operational: 65 dB	61
Dedicated pediatric sample cup/Dead volume	yes/35 µL	no special sample cup required/35 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/no
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	no/no	yes/no
Autocalibration or autocalibration alert	yes	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	reagent lot change/reagent lot change/reagent lot change/reagent lot change	reagent lot changes
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	5.5 min, 400 specimens	6 min, 240 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.75 min, 625 specimens	6 min 24 sec, 287 specimens
• Album., bili. direct & total, AST, ALT, ALP	7.5 min, 360 specimens	6 min 40 sec, 261 specimens
Typical time delay from ordering stat test to aspiration of sample	approx. 10 seconds	12 sec
How often QC required/Onboard SW capability to review QC	once per 24 hours/yes	24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	onboard/no (optional)
Interfaces up and running in active user sites with	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	LOINC database	—
Interface avail. (or will be) to automated specimen handling system	yes, enGEN	yes
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	4 to 8 hours/yes	varies by location, usually 4 to 8 hours/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	—	daily: 2 min; weekly: 5 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	yes, includes audit trail/yes	no/yes
Training provided with purchase/Advanced oper. training avail.	5 days on site, 5 days at vendor offices/yes	3 days on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	varies	varies
Distinguishing features (provided by vendor)	capability to add or remove reagents, consumables, and empty solid and liquid waste while operating; sample-centered processing integration approach eliminates need to move sample trays or aliquote samples between chemistry and immunoassay processing modules; ability to integrate chemistry, immunoassay, and infectious-disease testing, and process them in parrallel; integrated MicroTip technology expands menu availability, such as DATs, TDMs, specific proteins, %hbA1c and user-defined channels; MicroSensor technology detects interfering levels of hemolysis, icterus, and turbidity; eConnectivity assists with remote diagostics, software, and test parameter downloads and updates	MicroSlide technology delivers low cost per reportable result and high reagent efficiency without the maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required once each day and calibration intervals up to six months with minimal interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily

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Chemistry analyzers for mid- and high-volume laboratories

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HIGH

Ortho-Clinical Diagnostics
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MID

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Name of instrument/First year sold in U.S.	VITROS 5,1 FS Chemistry System/2004	RX Imola/2006
List price/Total No. sold in 2009	$225,000/—	—/—
No. units in clinical use in U.S./Outside U.S.	>1,500 worldwide	—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S.	Japan/Japan/United Kingdom
Operational type/Reagent type	random access, discrete, continuous random access/self-contained single-use cartridges, packages, slides; user-defined assay capability	random access/self-contained multi-use cartridges, packages, slides
Sample handling system/Model type	universal sample tray/floor standing	ring/benchtop
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	52.5 × 92.2 × 33.4/21.4	23 × 38 × 28/2.3
No. of tests for which analyzer has FDA-cleared applications	>70	48
Tests clinically released in last 12 months	—	amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, ecstasy, EDDP, methadone, opiates
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	—	amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, ecstasy, EDDP, methadone, opiates
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays	—	acetic acid, apo E, apo CIII, apo AII, alpha-1-antitrypsin, alpha-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, alpha-hydroxybutyrate, glutathione peroxidase, glycerol, non-esterfied fatty acids, Superoxide dismutase, zinc
Tests in development	—	haptoglobin, oxycodone, propoxyphene, caeruloplasmin, D-dimer, salicylate, paracetomol, cotinine, fully automated HbA1c
User-defined methods implemented for what analytes	—	acetaminophen, salicylate, cyclosporin, alcohol, glycerol-3-phosphate, oxidase, phospholipids, maltose, T4, T-Uptake, aldehyde, chromate, cyclosporin, nitrite, pH, serum amyloid A, sorbitol dehydrogenase, specific gravity, C1 inhibitor, oxalate, citric acid
Methods supported/immunoassay methods	photometry, potentiometry, immuno-rate, turbidimetric, colorimetric, spectrophotometeric/—	photometry, potentiometry (ISE), latex enhanced immunoturbidimetric/—
No. of direct ion selective electrode channels	3 (direct)	3
No. of different measured assays onboard simultaneously	up to 125	63
No. of different assays programmed, calibrated at once	up to 125	63
No. of user-definable (open) channels/No. active simultaneously	20/10	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	up to 125/up to 100	63/50 to 11,250
Shortest/median onboard reag. stability/Refrigerated onboard	48 hr/14 days/yes (10°C)	8 hr/28 days/yes (8° to 15°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	no
Walkaway capacity in minutes/Specimens/Tests-assays	varies/160/8,940	664/72/76,115
System is liquid or dry	dry, liquid ready to use	liquid
Uses disposable cuvettes/Max. No. stored	yes/348	no/90
Uses washable cuvettes/Replacement frequency	no/disposable	yes/minimum 5 years
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	available (not included)/no	no/yes
Requires dedicated water system/Water consumption per hour	no/—	yes/18 L
Noise generated in decibels	<60	75
Dedicated pediatric sample cup/Dead volume	no special sample cup required/35 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated, by handheld scanner as tube are loaded onto instrument(2 of 5 interl, UPC, Codabar, codes 39 &128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	—
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	system autodilutes	yes/yes
Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	reagent lot changes	daily/28 days/7 days/28 days
Automatic shutdown/Startup programmable	no/no (instrument maintained in ready mode)	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	5.5 min, 400 specimens	13 min 15 sec, 80 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.75 min, 625 specimens	13 min 43 sec, 80 specimens
• Album., bili. direct & total, AST, ALT, ALP	7.5 min, 360 specimens	13 min 15 sec, 67 specimens
Typical time delay from ordering stat test to aspiration of sample	~10 sec	30 sec
How often QC required/Onboard SW capability to review QC	once per 24 hr/yes	recommend 2 levels run per day/shortest: daily; longest: customer's discretion/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes/yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard (optional add-on)/no	onboard/no
Interfaces up and running in active user sites with	all major LIS vendors	no
Bidirectional interface capability	yes (broadcast download & host query)	yes (host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	LOINC database	—
Interface avail. (or will be) to automated specimen handling system	yes (enGen, plus any open point in space systems)	no
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	no/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	varies by location; usually 4 to 8 hours/yes	within 24 hours/yes
Mean time between failures/To repair failures	—/—	2 per 3 years/within 8 working hours
Average time to complete maintenance by lab personnel	daily: 9 min; weekly: 5 min; monthly: 31 min	daily 5 min; weekly: 15 min; monthly: 1 hour
Onboard maintenance records/Maint. training demo module	in development/yes	no/no
Training provided with purchase/Advanced oper. training avail.	yes/yes	3 days on site/yes
Annual service contract cost (24 h/7 d)	varies	—
Distinguishing features (provided by vendor)	MicroSlide technology delivers low cost per reportable result and high reagent efficiency without the maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC required once each day and calibration intervals up to lot change with min. interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides or disposable cuvette; eConnectivity interactive management system onboard	benchtop analyzer provides consolidation of testing in an established compact platform; dedicated multi-speed paddle mixers allow optimum mixing for each assay; direct ISE module prevents pseudohyponatremia

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Chemistry analyzers for mid- and high-volume laboratories

Part 12 of 16

	MID	MID
	Roche Diagnostics Adam Sterle adam.sterle@roche.com 9115 Hague Rd., P.O. Box 50457 Indianapolis, IN 46250 800-428-5074 www.roche.com	Roche Diagnostics Sheila Brewer sheila.brewer@roche.com 9115 Hague Rd. Indianapolis, IN 46250 317-521-2000 us.labsystems.roche.com
Name of instrument/First year sold in U.S.	COBAS Integra 800 CTS/2001 (COBAS Integra introduced 1995)	cobas c501 analyzer/2006
List price/Total No. sold in 2009	$265,000/—	—/>250
No. units in clinical use in U.S./Outside U.S.	>600/>2,000	>550/—
Country where designed/Manufactured/Where reagents mftd.	Switzerland/Switzerland/Germany	Japan/Japan/U.S. & Germany
Operational type/Reagent type	random access, discrete, continuous random access/self-contained multi-use cartridges-packages-slides	continuous random access/self-contained multi-use cartridges-packages-slides, open channels available
Sample handling system/Model type	sample racks: RD 5-position rack/floor standing	five-position rack/floor-standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	47.3 × 74.8 × 35.4/139	49.2 × 71.8 × 40/19.9
No. of tests for which analyzer has FDA-cleared applications	166	88
Tests clinically released in last 12 months	glucose STAT, EDDP, microalbumiun gen 2, oxycodone	quinidine, amikacin, EDDP, oxycodone
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	LDH (P›L), ALP (DGKC), AT3, CHE-D, GLDH, HBDH, lipoprotein(a), kappa/lambda light chains	alpha-1 microglobulin, %CDT, HBDH, AT3, ACP, kappa, lambda, GLDH
Research-use-only assays	sirolimus, tacrolimus, EDDP, oxycodone	—
Tests in development	DAT adulterants, syphilis	trig GB, cyclosporine
User-defined methods implemented for what analytes	photometry	photometry
Methods supported/immunoassay methods	turbidimetric, potentiometry, fluorescence polarization, photometry	photometry, potentiometry (ion selective electrode)/micro-particle
No. of direct ion selective electrode channels	4	3
No. of different measured assays onboard simultaneously	72	up to 63
No. of different assays programmed, calibrated at once	72	>100
No. of user-definable (open) channels/No. active simultaneously	20/20	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	72/50–800	up to 60 (plus 3 ISE)/varies (100–800)
Shortest/median onboard reag. stability/Refrigerated onboard	4 weeks/12 weeks/yes (8°C)	21 days/>60/yes (5° to 12°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	450/180/4,000 (varies by test mix)	varies/250/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	yes/3,600	no
Uses washable cuvettes/Replacement frequency	no/—	yes/monthly
Minimum sample volume aspirated precisely at one time	2 µL	1.5 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	yes (direct connection, type I CLSI)/5–7 L	yes/40 max, 20 mean
Noise generated in decibels	58.5	<65
Dedicated pediatric sample cup/Dead volume	yes/approx. 50–70 µL	yes/50µL
Primary tube sampling/Pierces caps on primary tubes	yes/yes (HbA1c only)	yes/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes (on sample transport, shortly before sample is aspirated, 2 of 5 interl., Codabar, code 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	5 hr/once per lot/140 days/60 days	24 hr/once per lot/varies/once per lot
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	8.6 min, 118 specimens	5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	8.6 min, 99 specimens	7 min, 150 specimens
• Album., bili. direct & total, AST, ALT, ALP	9.8, 118 specimens	10 min, 100 specimens
Typical time delay from ordering stat test to aspiration of sample	1 min	<1 min
How often QC required/Onboard SW capability to review QC	typically once per 24 hr/yes	typically once per 24 hr/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/yes (addt'l cost)	onboard/no (included)
Interfaces up and running in active user sites with	Cerner, CHCS, Citation, Compton, CompuLab, DynaMedix, EDS, Fletcher Flora, McKesson (ALG, PathLabs, StarLabs), HMS, Intellilabs, Isys, LabDaq, Labforce, Labfusion, LabSoft, LCI, Meditech, Northern Soft, Orsys, Seacoast, Siemens, Soft Computer, Misys	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (both supported)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	—	Web site
Interface avail. (or will be) to automated specimen handling system	no	yes, Roche Diagnostics MPA system
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	8 hr or next business day/yes	≤8 hr
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: <1 min; weekly: <5 min; monthly: none	daily: 20 min; weekly: 25 min; montly: 40 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes (onscreen help with diagrams & maintenance wizard)	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	1 day on site, 5 days at vendor offices/yes	days on site varies, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	varies	varies
Distinguishing features (provided by vendor)	comprehensive test menu includ. closed-tube 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	flexible/modular system; can be upgraded on site; ready-to-use bar-coded reagents; connectivity to Roche Preanalytics; requires small sample volumes, <2 to 10 µL

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Chemistry analyzers for mid- and high-volume laboratories

Part 13 of 16

HIGH

Roche Diagnostics
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800-428-5074 ext. 3099
us.labsystems.roche.com

MID

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

Name of instrument/First year sold in U.S.	MODULAR ANALYTICS/1998	cobas c501/e601/2006
List price/Total No. sold in 2009	varies	—/>250
No. units in clinical use in U.S./Outside U.S.	>800/>5,000	>1,200/>6,000
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/Germany	Japan/Japan/U.S., Germany
Operational type/Reagent type	continuous random access/self-contained multiuse cartridges, packages, slides	continuous random access/self-contained multi-use cartridges, packages, slide
Sample handling system/Model type	5-position rack/floor standing	five-position rack/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	varies per configuration/varies	4.1 ft × variable × 3.3 ft (base = 9.9 ft)/32.67
No. of tests for which analyzer has FDA-cleared applications	>140	>140
Tests clinically released in last 12 months	toxo IgG, anti-TSH receptor, rubella IgG, toxo IgG	quinidine, amikacin, EDDP, oxycodone, e601 STAT assays (CKMB, Myog, HCG, PTH, TnI), TnI, anti-TSHR, rubella IgG & IgM, toxoIgG, HBsAg, anti-HBs, cystatin C, anti-CCP
Tests cleared but not clinically released	anti-HCV	HbA1c, hemolysate
Tests not available in U.S. but submitted for 510(k) clearance	rubella IgM, toxo IgM	toxoplasma IgM, rubella IgM, anti-HCV
Tests not available in U.S. but available in other countries	Lp(a), kappa, lambda, P/NP, TG	alpha-1 microglobulin, %cDT, HBDH, AT3, ACP, kappa, lambda, GLDH
Research-use-only assays	—	—
Tests in development	PAPP-A, P1NP, anti-CMV IgG, anti-CMV IgM, homocysteine, mycophenolic acid, tacrolimus, hepatitis A, hepatitis B, HIV combi, IL-6, sCD40 ligand, CA 72-4	P1NP, thyroglobulin, CA 72-4, NSE, cyfra 21-1, anti-CMV IgG, anti-CMV IgM, HIV combi, anti-HAV, anti-HAV IgM, anti-Hbc, anti-HBc IgM, anti-HBe, HBeAg, oxycodone, cyclosporine, mycophenolic acid, sirolimus, tacrolimus
User-defined methods implemented for what analytes	photometry	photometry
Methods supported/immunoassay methods	photometry, potentiometry/HbA1c	photometry, potentiometry (ion selective electrode)/micro-particle, ECL
No. of direct ion selective electrode channels	3	3
No. of different measured assays onboard simultaneously	47–>100	88
No. of different assays programmed, calibrated at once	47–>100	>100
No. of user-definable (open) channels/No. active simultaneously	varies	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	47–100/100–3,000	up to 85 (plus 3 ISE)/varies (100–800)
Shortest/median onboard reag. stability/Refrigerated onboard	72 hr/28 days/yes (2° to 12°C)	21 days/>60 days/yes (5° to 20°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	limited	yes
Walkaway capacity in minutes/Specimens/Tests-assays	varies/300/varies	varies/250/varies
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/—	no
Uses washable cuvettes/Replacement frequency	yes/monthly	yes/once per month
Minimum sample volume aspirated precisely at one time	2 µL	1.5 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes	yes/yes
Requires dedicated water system/Water consumption per hour	yes/varies (50 L/hr/mod)	yes/40 L per hour (e501), 20 L per hour (e601)
Noise generated in decibels	<62	≤65
Dedicated pediatric sample cup/Dead volume	yes/50 µL	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hr/varies/bottle change/lot change	24 hr/once per lot/varies/once per lot
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	3.5 min, 300–600 specimens	5 min, 300–600 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 min, 160–600 specimens	7 min, 150 specimens
• Album., bili. direct & total, AST, ALT, ALP	10.5 min, 133–1,200 specimens	10 min, 100 specimens
Typical time delay from ordering stat test to aspiration of sample	<1 min	<1 min
How often QC required/Onboard SW capability to review QC	24 hr/yes	typically once per 24 hours
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	onboard/no
Interfaces up and running in active user sites with	all major LIS vendors	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	yes
How labs get LOINC codes for reagent kits	database	Web site
Interface avail. (or will be) to automated specimen handling system	yes (Roche Pre-Analytical Modular)	yes, Roche MPA system
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	8 hr/yes	<8 hr/yes
Mean time between failures/To repair failures	260 days/3.5 hr	—
Average time to complete maintenance by lab personnel	daily: 5 min; weekly: 10 min; monthly: 15 min	—
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	varies on site, 5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	varies	varies
Distinguishing features (provided by vendor)	Roche Hitachi chemistry and automation reliability and more than 20 years of experience; capable of consolidating 95 percent of test menu on one high-throughput integrated modular system; system can be connected directly to preanalytical automation, with 12 modules per configuration; flexible, expandable to lab's changing needs; up to four modules per system	flexible modular system—can be upgraded on-site; second-generation, integrated platform; ready-to-use bar-coded reagents; automation connectivity; small sample size

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Chemistry analyzers for mid- and high-volume laboratories

Part 14 of 16	MID Siemens Healthcare Diagnostics Inc. Pamela Curtin pamela.curtin@siemens.com 1717 Deerfield Rd. Deerfield, IL 60015 914-524-3824 www.usa.siemens.com/diagnostics	MID Siemens Healthcare Diagnostics Inc. Eric LaFleche eric.lafleche@siemens.com 1717 Deerfield Rd. Deerfield, IL 60015 914-524-3823 www.usa.siemens.com/diagnostics
Name of instrument/First year sold in U.S.	Dimension Vista 500 Intelligent Lab System/2009	ADVIA 1800/2006
List price/Total No. sold in 2009	$278,271/—	$299,000/—
No. units in clinical use in U.S./Outside U.S.	117/22	—/—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S., Germany	Japan/Japan/Ireland
Operational type/Reagent type	continuous random access/self-contained multi-use flex containers	random access/open reagent system
Sample handling system/Model type	rack and aliquot plate system	carousel rack handler option, automation option/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	55.5 × 84.75 × 43.875/26	45 × 58 × 34/14
No. of tests for which analyzer has FDA-cleared applications	>125, includes vendor-supported applications	>100
Tests clinically released in last 12 months	10	no pretreat HbA1C serum benzo, barb, TCA, cystatin C, concentrated chemistry reagents
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	IgG subclasses	neonatal bilirubin, tricyclics, serum benzo, serum barb
Tests not available in U.S. but available in other countries	TPSA, FPSA, IgG subclasses	—
Research-use-only assays	—	—
Tests in development	CA 125, CA 15-3, CA 19-9, additional cancer markers, fertility panel, plasma proteins, hormones, infectious disease	ecstasy
User-defined methods implemented for what analytes	specialty chemistry, plasma proteins, some TDMs and DATs	open system architecture, CK-MB, myoglobin, fructosamine, caffeine, TCA, Lp(a), β-2-mincroglobulin, D-dimer
Methods supported/immunoassay methods	nephelometry/LOCI advanced chemiluminescence, EMIT technology, particle enhanced turbidimetric immunoassay (PETINIA), affinity column mediated immunoassay (ACMIA)	photometry, potentiometry, turbidimetrics
No. of direct ion selective electrode channels	3 (indirect)	3
No. of different measured assays onboard simultaneously	>100	52 colorimetric, 3 ISE
No. of different assays programmed, calibrated at once	>100	100
No. of user-definable (open) channels/No. active simultaneously	10/>100	100/52 (plus 3 ISE)
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	100/20 to 1,200	52/850
Shortest/median onboard reag. stability/Refrigerated onboard	24 hours/30 days/yes (2° to 8°C)	7 days/45 days/yes
Multiple reag. configurations supported	no	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	>45/150/61,404	32,000 photometrics
System is liquid or dry	liquid	liquid
Uses disposable cuvettes/Max. No. stored	yes/>1,600 washed disposal cuvettes and 1,000 LOCI vessels	no/221
Uses washable cuvettes/Replacement frequency	yes/automatic as needed	yes/every 4 months
Minimum sample volume aspirated precisely at one time	50 µL	2 µL of diluted specimen
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/yes
Requires dedicated water system/Water consumption per hour	no/10.8 L	yes/25 L
Noise generated in decibels	<65	<45
Dedicated pediatric sample cup/Dead volume	no/10 µL, if using small sample cup	yes/<50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., UPC, Codabar, codes 39 & 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 inter., Codabar, codes 39 & 128)/—
Reagent bar-code reading capability	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes
Automatic detection of adequate reag. for aspiration & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	no/no	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	4 hours, automatic/30 to 90 days/30 days/30 days	daily/45 days/30 days/30 days
Automatic shutdown/Startup programmable	no/no	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	2 min, 166 panels	5 min, —
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 min, 125 specimens	10 min, —
• Album., bili. direct & total, AST, ALT, ALP	9.4 min, 83 specimens	10 min, —
Typical time delay from ordering stat test to aspiration of sample	<2 min	10 sec
How often QC required/Onboard SW capability to review QC	24 hours/yes	per laboratory protocol
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	yes/—
Interfaces up and running in active user sites with	all major LIS vendors	Soft, Misys, Cerner, Meditech, Multidata, Seacoast, Triple G, CCA, Computer Service & Support Q, Fletcher Flora, HDS, PSA consultants, Siemens, others
Bidirectional interface capability	yes	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
How labs get LOINC codes for reagent kits	—	via e-mail & software
Interface avail. (or will be) to automated specimen handling system	yes, StreamLab Automation connectivity is in development	yes (all systems)
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	2–8 hours/yes	—/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: <10 mins, monthly: 10–20 mins	automated daily maintenance
Onboard maintenance records/Maint. training demo module	no/yes	yes/yes
Training provided with purchase/Advanced oper. training avail.	4 days at vendor offices/yes	yes/yes
Annual service contract cost (24 h/7 d)	varies, multiple types	—
Distinguishing features (provided by vendor)	ultra-integrated chemistry platform with LOCI advanced chemiluminescence and nephelometry onboard; enhanced workflow efficiency with automated features, such as autocalibration, auto QC, and system twinning; proactive service and support through RealTime Solutions services	comprehensive menu; >100 assays, including chemistry, special chemistry, TDMs, DAUs, special proteins; long-life ISEs; 90,000 tests; unlimited open channels; third-party applications available; 3-second cycle time; 1,800 tests per hour; automation ready; concentrated reagents available for high-volume chemistries, walkaway capability; clot detect; liquid level sense; auto reruns, dilutions, and repeats

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Chemistry analyzers for mid- and high-volume laboratories

Part 15 of 16

	HIGH	MID
	Siemens Healthcare Diagnostics Inc. Eric LaFleche eric.lafleche@siemens.com 1717 Deerfield Rd. Deerfield, IL 60015 914-524-3823 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Inc. Christina Tassone christina.tassone@siemens.com 1717 Deerfield Rd. Deerfield, IL 60015 847-236-7222 www.usa.siemens.com/diagnostics
Name of instrument/First year sold in U.S.	ADVIA 2400/2003	Dimension RxL Max/Max Suite Integrated Chemistry System/2003/Dimension RxL Integrated Chemistry System/1997
List price/Total No. sold in 2009	$305,000/—	—/—
No. units in clinical use in U.S./Outside U.S.	—/—	—
Country where designed/Manufactured/Where reagents mftd.	Japan/Japan/Ireland	U.S./U.S./U.S.
Operational type/Reagent type	random access/open reagent system	batch, random access, continuous random access/self-contained multi-use flex containers
Sample handling system/Model type	carousel, rack handler option, automation option/floor standing	segmented sample wheel/floor standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	1,157 × 1,711 × 934 mm/—	44 × 62.5 × 30.5/13.2
No. of tests for which analyzer has FDA-cleared applications	>100	>90
Tests clinically released in last 12 months	no pretreat HbA1C serum benzo, barb, TCA, cystatin C, concentrated chemistry reagents	revised CSA, sirolimus, myeloperoxidase, revised HDL
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	—	MPA
User-defined methods implemented for what analytes	open system architecture, CK-MB, myoglobin, fructosamine, caffeine, TCA, Lp(a), β-2-microglobulin, D-dimer	propoxyphene, methaqualone, serum tricyclic antidepressant, serum barbiturate, serum benzodiazepine
Methods supported/immunoassay methods	photometry, potentiometry turbidimetric/—	ACMIA, EMIT, PETINIA, photometry, potentiometry/heterogeneous, magnetic particle
No. of direct ion selective electrode channels	3	3 (indirect) ECO2 photometric
No. of different measured assays onboard simultaneously	46 colormetric, 3 ISE	47/91 with optional inventory management system
No. of different assays programmed, calibrated at once	100	190
No. of user-definable (open) channels/No. active simultaneously	100/49	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	49/850	44–88/max. 360
Shortest/median onboard reag. stability/Refrigerated onboard	7 days/45 days/yes	48 hours/30 days/yes (2° to 8°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	32,000 photometric	can be hours/60/>2,000 or >5,000 (with RMS)
System is liquid or dry	liquid	liquid, reconstitutes onboard
Uses disposable cuvettes/Max. No. stored	no/340	yes/12,000
Uses washable cuvettes/Replacement frequency	yes/every 4 months	no/—
Minimum sample volume aspirated precisely at one time	2 µL of diluted specimen	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/yes (or sink)	yes/no
Requires dedicated water system/Water consumption per hour	yes/40 L	yes/3.2 L (3.2 to 5.0 L with optional inventory management system)
Noise generated in decibels	<50	<70
Dedicated pediatric sample cup/Dead volume	yes/~50 µL	yes/10-20 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes, 5, 7, 10 mL/no
Sample bar-code reading capability/Autodiscrimination	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	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures no. tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/no
Automatic detection of adequate reag. for 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	yes (with 7.4 software)
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes (Na, K, Cl)/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	daily/45 days/30 days/30 days	every 2 hr-autocalibrate/—/60 to 90 days/30 days
Automatic shutdown/Startup programmable	yes/yes	—/—
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TCO2	5 min, —	36 sec (Na, K, Cl)/2 min w/ECO2, 300 ISE or 500 photometric tests/hr, 100 panels
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	10 min, —	5.5 min, 300 ISE or 500 photometric tests/hr, 100 panels
• Album., bili. direct & total, AST, ALT, ALP	10 min, —	9 min, 500 tests/hr or 83 panels
Typical time delay from ordering stat test to aspiration of sample	10 sec	24 sec
How often QC required/Onboard SW capability to review QC	per laboratory protocol/yes	24 hrs/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	no/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	yes/—	optional add-on (EasyLink, Siemens)/yes (addt'l cost)
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	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	yes	no
How labs get LOINC codes for reagent kits	via software	—
Interface avail. (or will be) to automated specimen handling system	yes (with ADVIA WorkCell as of October 2003)	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	varies by location, generally <4 hr/yes	2–8 hr/yes
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	automated daily maintenance	daily: 5 min; weekly: 10 min; monthly: 15 min
Onboard maintenance records/Maint. training demo module	—/yes	no/no
Training provided with purchase/Advanced oper. training avail.	yes/yes	5 days on site, 4 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	—	multiple types
Distinguishing features (provided by vendor)	system provides workstation consolidation with a comprehensive menu, including routine chemistry, TDMs, TAUs, special chemistry, and special proteins; provides unlimited open channels and walkaway capability (>450 specimens) when combined with the universal rack handler; offers micro-volume sample and reagent technology, multiple reagent wedge sizes, 2-second cycle time; fast throughput; sample-saver technology allows automatic repeats, dilutions, and reflex testing	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

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Chemistry analyzers for mid- and high-volume laboratories

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	HIGH	MID
	Siemens Healthcare Diagnostics Inc. Colleen Grier colleen.grier@siemens.com 1717 Deerfield Rd. Deerfield, IL 60015 302-631-8773 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Inc. Christina Tassone christina.tassone@siemens.com 1717 Deerfield Rd. Deerfield, IL 60015 847-236-7222 www.usa.siemens.com/diagnostics
Name of instrument/First year sold in U.S.	Dimension Vista Intelligent Lab System 1500/2006	Dimension EXL with LM Integrated Chemistry System/2009
List price/Total No. sold in 2009	$543,500 (USD)/—	—/—
No. units in clinical use in U.S./Outside U.S.	350/110	—/—
Country where designed/Manufactured/Where reagents mftd.	U.S./U.S./U.S. and Germany	U.S./U.S./U.S.
Operational type/Reagent type	batch, random access, continuous random access/self-contained multi-use cartridges-packages	batch, random access, continuous random access/self-contained multi-use cartridges/packages/slides
Sample handling system/Model type	sample rack and aliquot plate system/floor standing	segmented sample wheel/floor-standing
Dimensions in inches (H × W × D)/Instrument footprint in sq ft	55 × 84 × 43/26 sq ft	49 × 82 × 44 (without monitor)/25.1 (with printer shelf down)
No. of tests for which analyzer has FDA-cleared applications	>125	>90
Tests clinically released in last 12 months	10	liquid lipase, LOCI cardiac troponin I, LOCI free thyroxine, LOCI thyroid stimulating hormone, LOCI NT-proBNP, LOCI LV NT-proBNP
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for 510(k) clearance	IgG subclasses	—
Tests not available in U.S. but available in other countries	TPSA, FPSA, IgG subclasses	—
Research-use-only assays	—	—
Tests in development	CA-125, CA15-3, CA19-9, fertility panel, plasma proteins, cardiac, infectious disease, additional cancer markers	LOCI free T3, LOCI B12, LOCI folate, MPA, sirolimus, total PSA, free PSA
User-defined methods implemented for what analytes	propoxyphene, methaqualone, serum tricyclic antidepressant, serum barbiturate, serum benzodiazepine, caffeine, amikacin	serum TCA, serum barbiturates, serum benzodiazepine, propoxyphene, methaqualone
Methods supported/immunoassay methods	photometry, potentiometry (ISE), advanced LOCI chemiluminescence technology, nephelometry, EMIT, PETINIA, PETIA, ACMIA, turbidimetric	photometry, potentiometry, others/LOCI, ACMIA, EMIT, PETINIA and turbidimetric
No. of direct ion selective electrode channels	3 (indirect)	3
No. of different measured assays onboard simultaneously	>100 methods simultaneously/>100 methods	91
No. of different assays programmed, calibrated at once	>100	190
No. of user-definable (open) channels/No. active simultaneously	10/>100	10/10
No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set	>100/20 to 1,200	91/15–360
Shortest/median onboard reag. stability/Refrigerated onboard	24 hours/30 days/yes (2° to 8°C)	24 hours/30 days/yes (2° to 8°C)
Multiple reag. configurations supported	no	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	yes
Walkaway capacity in minutes/Specimens/Tests-assays	>45 min/150/61,404	can be hours/60/>2,000
System is liquid or dry	liquid	liquid, reconstitutes onboard (no reagent prep required by the operator)
Uses disposable cuvettes/Max. No. stored	yes/>1,600 washed, disposable cuvettes and 1,000 LOCI vessels	yes/12,000
Uses washable cuvettes/Replacement frequency	yes/automatic	no/—
Minimum sample volume aspirated precisely at one time	50 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption per hour	no/21.6 L per hour	yes/up to 5 L
Noise generated in decibels	67	<75
Dedicated pediatric sample cup/Dead volume	no (can use routine sample cup)/10-20 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 interl., 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)	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	yes/yes
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced/Increased to rerun out-of-linear-range high/low results	no/no	yes/no
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes (Na, K, Cl)/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	automatic every 4 hr/30 to 90 days/30 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, 166	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, 125	5.5 min (ECO2 not TCO2 [enzymatic]), 62 specimens, 187 ISE and 437 photometric tests
• Album., bili. direct & total, AST, ALT, ALP	9.4 min, 83	—
Typical time delay from ordering stat test to aspiration of sample	<2 min	24 seconds
How often QC required/Onboard SW capability to review QC	24 hrs/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, via EasyLink	no
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/—	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	yes, Siemens StreamLab, SpecTrak; Advia automation in development	—
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	2–8 hr/yes	2–8 hours/—
Mean time between failures/To repair failures	—/—	—/—
Average time to complete maintenance by lab personnel	daily: 10 min; weekly: none; monthly: 10–20 min	daily: 5 min; weekly: 10 min; monthly: 23 min
Onboard maintenance records/Maint. training demo module	in development/yes	no/no
Training provided with purchase/Advanced oper. training avail.	4 days on site, 4 days at vendor office/yes (online training available)	5 days on site, 4 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	varies—multiple types	multiple types
Distinguishing features (provided by vendor)	intelligent lab systems with customer-driven design, ultra-integration of technologies; LOCI advanced chemiluminescence and automation onboard for efficiency, simplicity, sensitivity, and convenience—all to provide a more efficient workflow for the laboratory; autocalibration and auto QC onboard; proactive services and support through RealTime Solutions	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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