

## Chemistry analyzers for mid- and high-volume laboratories

Part 1 of 11	<b>MID</b>	<b>MID</b>	<b>HIGH</b>
	<b>Abbott Diagnostics</b> Pamela Sunderman pamelasunderman@abbott.com 100 Abbott Park Rd., Abbott Park, IL 60064 847-937-4689 www.abbottdiagnostics.com	<b>Abbott Diagnostics</b> Pamela Sunderman pamelasunderman@abbott.com 100 Abbott Park Rd., Abbott Park, IL 60064 847-937-4689 www.abbottdiagnostics.com	<b>Abbott Diagnostics</b> Pamela Sunderman pamelasunderman@abbott.com 100 Abbott Park Rd., Abbott Park, IL 60064 847-937-4689 www.abbottdiagnostics.com
Name of instrument/First year sold in U.S. List price/Total No. sold in 2010 Number of units in clinical use in U.S./Outside U.S. Where designed/Manufactured/Where reagents manufactured Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Footprint in square feet	ARCHITECT c4000 and ci4100/2009 c4000: \$180,000; ci4100: \$275,000/— 170 (c4000) 382 (i1000sr)/417 (c4000), 2459 (i1000sr) U.S., Japan/U.S., Japan/U.S., Ireland, Germany continuous random access/self-contained multi-use cartridges, open reagent system 3-dimensional robotic sample handler/floor standing c4000: 49 x 63 x 36/21; ci4100: 49 x 111 x 36/37	ARCHITECT c8000 and ci8200/2003 c8000: \$200,000/15; ci8200: \$375,000/25 390 (c8000), 474 (i2000sr)/2201 (c8000), 5658 (i2000sr) U.S., Japan/U.S., Japan/U.S., Ireland, Germany continuous random access/self-contained multi-use cartridges, open reagent system 3-dimensional robotic sample handler/floor standing c8000: 48 x 79 x 49/26; ci8200: 48 x 127 x 49/42	ARCHITECT c16000 and ci16200/2007 c16000: \$325,000/98; ci16200: \$475,000/3 20 (c16000) 474 (i2000SR)/360 (c16000) 5658 (i2000SR) U.S., Japan/U.S., Japan/U.S., Ireland, Germany continuous random access/open reagent system 3-dimensional robotic sample handler and carousel/floor standing c16000: 48 x 79 x 49/26; ci16200: 48 x 127 x 49/42
Number of tests for which analyzer has FDA-cleared applications Tests released for clinical use in last 12 months Tests cleared but not released for clinical use 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	138 (86 clinical chemistry and 52 immunoassay) HIV AgAb combo — vitamin D and vitamin B12 AFP, proGRP, SCC, anti-HAV IgG, CMV IgG and IgM, rubella IgG and IgM, toxo IgG and IgM, CMV avidity, toxo avidity, HCV Ag, pepsinogen I and II, NGAL, kappa light chain, lambda light chain, cholinesterase, cystatin C, and others — anti-HAV IgG, NGAL, methotrexate, Tg, AFP	138 (86 clinical chemistry and 52 immunoassay) HIV AgAb combo — vitamin D and vitamin B12 AFP, proGRP, SCC, anti-HAV IgG, CMV IgG and IgM, rubella IgG and IgM, toxo IgG and IgM, CMV avidity, toxo avidity, HCV Ag, pepsinogen I and II, NGAL, kappa light chain, lambda light chain, cholinesterase, cystatin C, and others — anti-HAV IgG, NGAL, methotrexate, Tg, AFP	138 (86 clinical chemistry and 52 immunoassay) HIV AgAb combo — vitamin D and vitamin B12 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, others — Tg, AFP, anti-HAV IgG, anti-HBc, vitamin D, NGAL, carbamazepine, gentamicin, methotrexate, vitamin B12
Methodologies supported/Immunoassay methodologies Number of direct ion-selective electrode channels Number of different measured assays onboard simultaneously Number of different assays programmed and calibrated at once Number of user-definable (open) channels/Number active simultaneously Number of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when third-party reagents used Walkaway capacity in minutes/Specimens/Tests or assays Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	photometry, potentiometry, turbidimetric/ chemiluminescence with flexible protocols 3 c4000: 58; ci4100: 83 c4000: 220; ci4100: 320 220/220 c4000: varies/50–1,700; ci4100: varies/ 50–1,700 chemistry, 100 immunoassay 7 days/28 days/yes (2°–8°C) yes yes yes c4000: —/100/62,000+; ci4100: —/180/64,000+ no (chemistry) and yes (immunoassay)/300 yes, chemistry/minimum 1-year guarantee 2 µL yes/no yes/15 L normal operation: ≤48; peak: 70 for max 10 seconds yes/50 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 and 128)/yes yes, 2-D bar codes yes	photometry, potentiometry, turbidimetric/ chemiluminescence with flexible protocols 3 c8000: 68; ci8200: 93 c8000: 220; ci8200: 320 220/220 c8000: 65/50–1,700; ci8200: 90/50–1,170 (chemistry), 100–500 (immunoassay) 7 days/28 days/yes (2°–8°C) yes yes yes c8000: —/215/69,000+; ci8200: varies/365/81,000– 93,000 no (chemistry) and yes (immunoassay)/1,200 yes, chemistry/minimum 1-year guarantee 2 µL yes/no yes/30.5 L normal operation: ≤48; peak: 70 for maximum 10 seconds yes/50 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 and 128)/yes yes, 2-D bar codes yes	photometry, potentiometry (ISE), turbidimetric/ chemiluminescence with flexible protocols (CHEMIFEX) 3 c16000: 68; ci16200: 93 c16000: 220; ci16200: 320 220/220 c16000: 65/50–1,700 (chemistry); ci16200: 93/50–1,700 (chemistry), 100–500 (immunoassay) 7 days/28 days/yes (2°–8°C) yes yes yes c16000: —/215/69,000+; ci16200: varies/365/81,000–93,000 no (chemistry) and yes (immunoassay)/1,200 yes/minimum 1-year guarantee 2 µL yes/yes yes/59 L normal operation: ≤48 peak; 70 for maximum 10 seconds yes/50 µL yes/no yes, on sample transport, shortly before sample is aspi- rated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes, 2-D bar codes yes
Onboard test auto inventory (determines volume in container) Measures number of tests remaining/Short sample detection/Clot detection Hemolysis/Turbidity detection-quantitation Sample volume can be reduced Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown programmable/Startup programmable	yes yes/yes/yes yes/yes yes yes (for chemistry) yes yes, for chemistry only/yes 24 hours/30 days/7 days/14 days no/no	yes yes/yes/yes yes/yes yes yes (for chemistry) yes yes, for chemistry only/yes 24 hours/30 days/7 days/14 days no/no	yes yes/yes/yes yes/yes yes yes (for chemistry) yes yes/yes 24 hours/30 days/7 days/14 days no/no
Stat time to completion of all analytes and throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., direct and total bilirubin, AST, ALT, ALP Typical time delay from ordering stat test to aspiration of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot numbers per analyte System can automatically transfer QC results to LIS	2.6 minutes ISE, 5.9 minutes with TC02; 200 specimens, 800 tests 8.3 minutes, 80 specimens, 560 tests 9.8 minutes, 67 specimens, 400 tests <20 seconds shortest interval: 8 hours; longest: 24 hours/yes yes/yes yes	2.6 minutes ISE, 5.9 minutes with TC02; 200 specimens, 800 tests 8.3 minutes, 160 specimens, 1,120 tests 9.8 minutes, 133 specimens, 800 tests <20 seconds shortest interval: 8 hours; longest: 24 hours/yes yes/yes yes	2.6 minutes ISE, 5.9 minutes with CO2; 200 specimens, 800 tests 8.3 minutes, 200 specimens, 1,400 tests 9.8 minutes, 200 specimens, 1,200 tests <20 seconds shortest interval: 8 hours; longest: 24 hours/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface Interfaces to what LISs up and running in active user sites Bidirectional interface capability Uses LOINC to transmit orders and results across interface How labs get LOINC codes for reagent kits	yes (additional cost, SW manufacturer: Abbott)/ optional, at additional cost Cerner, Misys, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Triple G, CIS, others yes (broadcast download and host query) — package insert	yes (additional cost, SW manufacturer: Abbott)/ optional, at additional cost Cerner, Misys, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Triple G, CIS, others yes (broadcast download and host query) — package insert	optional add-on (additional price varies; SW manufacturer: Abbott)/optional, at additional cost Cerner, Misys, Fletcher Flora, Data Innovations, Soft, CPSI, Meditech, Siemens, Citation, CHCS, Antek, Orchard, others yes (broadcast download and host query) — package insert
Interface available (or will be) to automated specimen-handling system	no	yes	yes
Modern servicing available/System can diagnose own malfunctions/ System can determine malfunctioning component On-site time of service engineer Mean time between failures/Mean time to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with instrument purchase	yes/yes/yes per negotiated contract 23 weeks (c4000), 26 weeks (i1000sr)/varies daily: <15 minutes; weekly: <35 minutes; monthly: <15 minutes yes/yes yes	yes/yes/yes per negotiated contract 17 weeks (c8000), 11 weeks (i2000sr)/varies daily: 15 minutes; weekly: <45 minutes; monthly: 15 minutes yes/yes yes	yes/yes/yes per negotiated contract 14 weeks (c16000), 11 weeks (i2000SR)/varies daily: 15 minutes; weekly: <45 minutes; monthly: 15 minutes yes/yes 5 days on site, 5 days at vendor offices
Distinguishing features (provided by vendor)	integration of CC and IA without compromising stat turnaround time, results, or throughput; robotic sample handler design with SmartWash technology allows IA and CC testing in any order for overall turnaround time; 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; refer to the operations manual for operational precautions, limitations, and hazards	integration of CC and IA without compromising stat turnaround time, 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; refer to the operations manual for operational precautions, limitations, and hazards	high-speed integration of CC and IA without compro- mising stat turnaround time, results, or throughput due to robotic sample handler design 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 provide assay extended linearities and enhanced sensitivities
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

## Chemistry analyzers for mid- and high-volume laboratories

Part 2 of 11	<b>MID</b>	<b>Awareness Technology Inc.</b>	<b>MID</b>	<b>Beckman Coulter Inc.</b>	<b>MID</b>	<b>Beckman Coulter Inc.</b>
		Robert Guerin info@awaretech.com P.O. Box 1679, Palm City, FL 34991 772-283-6540 www.awaretech.com		Burch Ekener bekener@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-6698 www.beckmancoulter.com		Burch Ekener bekener@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-6698 www.beckmancoulter.com
Name of instrument/First year sold in U.S. List price/Total No. sold in 2010 Number of units in clinical use in U.S./Outside U.S. Where designed/Manufactured/Where reagents manufactured Operational type/Reagent type		ChemWell 2902, 2910/1999 starts at \$20,000/>500 50+/ <sup>2</sup> ,200+ U.S./U.S./open system batch, random access, continuous random access/ open reagent system rack/benchtop		AU480/2009 \$140,000/— 120/>300 Japan/Japan/U.S. and Ireland random access, discrete, continuous random access/ open reagent system rack and stat carousel/floor standing		AU680/2008 \$213,000/30 200/>400 Japan/Japan/U.S. and Ireland random access, discrete, continuous random access/ open reagent system rack and stat carousel/floor standing
Sample handling system/Model type Dimensions in inches (H × W × D)/Footprint in square feet		rack/benchtop 19 × 36 × 22/7		rack and stat carousel/floor standing 47.5 × 57.1 × 30/11.9		rack and stat carousel/floor standing 50 × 76 × 45/23.7
Number of tests for which analyzer has FDA-cleared applications Tests released for clinical use in last 12 months Tests cleared but not released for clinical use Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries		22 — — 18 EIA kits manufactured by BioCheck have been submitted open system		125 — — — —		125 — — — —
Research-use-only assays Tests in development		open system —		— —		— —
Methodologies supported/Immunoassay methodologies		photometry/microwell assays		photometry, potentiometry, calculated tests/ homogeneous		photometry, potentiometry, calculated tests/ homogeneous
Number of direct ion-selective electrode channels Number of different measured assays onboard simultaneously Number of different assays programmed and calibrated at once Number of user-definable (open) channels/Number active simultaneously Number of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when third-party reagents used Walkaway capacity in minutes/Specimens/Tests or assays Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination		0 27 standard, 44 optional unlimited unlimited/27 standard, 44 optional 27 standard, 44 optional/reagent dependent reagent dependent/—/yes (15°C below ambient) optional yes reagent dependent yes not limited/96/not limited yes (optional)/96 yes (optional)/weekly 2 µL no/no no/<1 L 60 no/— yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 or 5 interl., UPC, Codabar, codes 39 and 128)/autodiscrimination depends on handheld scanner models		3 up to 63 120 117/60 76/100 to 1,333 5 days/30 days/yes (4°–12°C) yes yes yes varies/up to 102/varies no/— yes/permanent 1 µL no (optional)/yes (no with optional water pump) yes/20 L per hr average peak consumption 60 no/— yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 and 128)/ yes		3 up to 63 120 116/60 63/100 to 1,500 120 hr/30 days/yes (4°–12°C) yes yes yes varies/up to 172/varies no/— yes/permanent 1 µL no (optional)/yes (no with optional water pump) yes/28 L per hour peak consumption 60 no/— yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 and 128)/ yes
Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A		no no		yes yes		yes yes
Onboard test auto inventory (determines volume in container) Measures number of tests remaining/Short sample detection/Clot detection Hemolysis/Turbidity detection-quantitation Sample volume can be reduced Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown programmable/Startup programmable		yes yes/yes/no no/no yes no yes yes/yes user defined for all yes/yes		yes yes/yes/yes yes/yes yes yes yes/yes 1 day/30 days/14 days/14 to 20 days yes/yes		yes yes/yes/yes yes/yes yes yes yes/yes 1 day/30 days/14 days/14 to 20 days yes/yes
Stat time to completion of all analytes and throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., direct and total bilirubin, AST, ALT, ALP Typical time delay from ordering stat test to aspiration of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot numbers per analyte System can automatically transfer QC results to LIS		— — 5.5 minutes, 28 specimens 15 seconds reagent dependent/yes yes/yes yes		including TC02, TAT <9 minutes*, 200 specimens including TC02, TAT <9 minutes, 80 specimens <9 minutes, 67 specimens <2 minute per CLIA and laboratory's decision/yes yes/yes yes		including TC02, TAT <9 minutes, 200 specimens including TC02, TAT <9 minutes, 160 specimens 9 minutes, 133 specimens 1 minute per CLIA and laboratory's decision/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface		onboard/yes (included in price)		onboard/no (optional)		onboard/no (optional)
Interfaces to what LISs up and running in active user sites		—		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 Uses LOINC to transmit orders and results across interface How labs get LOINC codes for reagent kits		yes (broadcast download) no supplied by reagent manufacturer		yes (broadcast download and host query) no —		yes (broadcast download and host query) no —
Interface available (or will be) to automated specimen-handling system		no		yes		yes
Modem servicing available/System can diagnose own malfunctions/ System can determine malfunctioning component On-site time of service engineer Mean time between failures/Mean time to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with instrument purchase		yes/yes/sometimes 48 hours depends on user and varies/depends on problem and varies daily: <5 minutes; weekly: about 15 minutes; monthly: about 30 minutes or less no/no 2 days on site, 3 days at vendor offices		yes/yes/yes <24 hours average 2 calls per yr/<24 hours daily: 5 minutes; weekly: 12 minutes; monthly: 45 minutes yes (includes audit trail of who replaced parts)/yes 3–5 days on site, 5 days at vendor offices		yes/yes/yes <24 hours average 2 calls per year/<24 hours daily: 4 minutes; weekly: 27 minutes; monthly: 45 minutes yes (includes audit trail of who replaced parts)/yes 3–5 days on site, 5 days at vendor offices
Distinguishing features (provided by vendor)		one instrument for EIA and biochemistry; open and user programmable; discounts for biochemistry only; calculates indices; flexible formatting of reports		standardization with its 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 AU680, AU2700, and AU5400; broad test menu of 130 methods; fully automated HbA1c option available; reduced sampling volume; laboratory-definable enhanced options for reflex, repeat, pre-dilution, auto-calibration, auto-QC, and multi-lot advanced calibration

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

\*TC02 is photometric assay

## Chemistry analyzers for mid- and high-volume laboratories

Part 3 of 11	<b>HIGH</b>	<b>HIGH</b>	<b>HIGH</b>
	Beckman Coulter Inc. Burch Ekener bekener@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-6698 www.beckmancoulter.com	Beckman Coulter Inc. Burch Ekener bekener@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-6698 www.beckmancoulter.com	Beckman Coulter Inc. Burch Ekener bekener@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-6698 www.beckmancoulter.com
Name of instrument/First year sold in U.S. List price/Total No. sold in 2010 Number of units in clinical use in U.S./Outside U.S. Where designed/Manufactured/Where reagents manufactured Operational type/Reagent type	AU2700/2000 \$320,000/22 130/>700 Japan/Japan/U.S. and Ireland random access, discrete, continuous random access/ open reagent system rack and stat carousel/floor standing	AU5421 with dual ISE/2001 \$465,000/— 225/450 Japan/Japan/U.S. and Ireland random access, discrete, continuous random access/ open reagent system rack/floor standing	AU5431 with dual ISE/2001 \$575,000/— 225/450 Japan/Japan/U.S. and Ireland random access, discrete, continuous random access/ open reagent system rack/floor standing
Sample handling system/Model type Dimensions in inches (H × W × D)/Footprint in square feet	50 × 79 × 45/24.7	50 × 148 × 45/46.25	50 × 200 × 45/62.5
Number of tests for which analyzer has FDA-cleared applications Tests released for clinical use in last 12 months	125 —	125 —	130 —
Tests cleared but not released for clinical use Tests not available in U.S. but submitted for 510(k) clearance	— 0	— —	— —
Tests not available in U.S. but available in other countries	—	—	—
Research-use-only assays Tests in development	— —	— —	— —
Methodologies supported/Immunoassay methodologies	photometry, potentiometry, calculated tests/ homogeneous	photometry, potentiometry, calculated tests/ homogeneous	photometry, potentiometry, calculated tests/ homogeneous
Number of direct ion-selective electrode channels	3	3	3
Number of different measured assays onboard simultaneously	up to 51	99	up to 99
Number of different assays programmed and calibrated at once	99	99	99
Number of user-definable (open) channels/Number active simultaneously	95/48	95/95	95/95
Number of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	48/100–4,000	48 × 2/100–4,000	48 × 3/100–4,000
Shortest/Median onboard reagent stability/Refrigerated onboard	120 hours/30 days/yes (4°–12°C)	120 hours/30 days/yes (4°–12°C)	120 hours/30 days/yes (4°–12°C)
Multiple reagent configurations supported	yes	yes	yes
Reagent container placed directly on system for use	yes	yes	yes
Instrument has same capabilities when third-party reagents used	yes	yes	yes
Walkaway capacity in minutes/Specimens/Tests or assays	varies/up to 322/varies	varies/up to 300/varies	varies/up to 300/varies
Uses disposable cuvettes/Maximum number stored	no/—	no/—	no/—
Uses washable cuvettes/Replacement frequency	yes/permanent	yes/permanent	yes/permanent
Minimum sample volume aspirated precisely at one time	1.6 µL	1.6 µL	1.6 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/yes	no (optional)/yes	no (optional)/yes
Requires dedicated water system/Water consumption per hour	yes/55 L per hour peak consumption	yes/110 L per hour peak consumption	yes/165 L per hour average peak consumption
Noise generated in decibels	<65	<65	—
Dedicated pediatric sample cup/Dead volume	no/—	no/—	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Reagent bar-code reading capability	yes	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures number of tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/yes	yes/yes/yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes	yes/yes
Sample volume can be reduced	yes	yes	yes
Increased to rerun out-of-linear-range high/low results	yes	yes	yes
Autocalibration or autocalibration alert	yes	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	1 day/30 days/14 days/14 to 20 days	1 day/30 days/14 days/14 to 20 days	1 day/30 days/14 days/14 to 20 days
Automatic shutdown programmable/Startup programmable	yes/yes	yes/yes	yes/yes
Stat time to completion of all analytes and throughput per hour for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., direct and total bilirubin, AST, ALT, ALP	includ. photometric assays, TAT 4–9 min., 267 specimens includ. photometric assays, TAT 4–9 min., 267 specimens 9 minutes, 267 specimens	—, maximum 600 specimens —, maximum 600 specimens —, maximum 533 specimens	—, maximum 600 specimens —, maximum 600 specimens —, maximum 800 specimens
Typical time delay from ordering stat test to aspiration of sample	1 minute	—	—
How often QC required/Onboard SW capability to review QC	per CLIA and laboratory's decision/yes	per CLIA and laboratory's decision/yes	per CLIA and laboratory's decision/yes
Onboard real-time QC/Support multiple QC lot numbers per analyte	yes/yes	yes/yes	yes/yes
System can automatically transfer QC results to LIS	yes	yes	yes
Data management capability/Instrument vendor supplies LIS interface	onboard/no (optional)	onboard/no (optional)	onboard/no (optional)
Interfaces to what LISs up and running in active user sites	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	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 and host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
Uses LOINC to transmit orders and results across interface	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Interface available (or will be) to automated specimen-handling system	yes	yes	yes
Modem servicing available/System can diagnose own malfunctions/ System can determine malfunctioning component	yes/yes/yes	yes/yes/yes	yes/yes/yes
On-site time of service engineer	<24 hours	<24 hours	<24 hours
Mean time between failures/Mean time to repair failures	<4 calls per year/<24 hours	<9 calls per year/<24 hours	<9 calls per year/<24 hours
Average time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 42 minutes; monthly: 15 minutes	daily: 30 minutes; weekly: 81 minutes; monthly: 40 minutes	daily: 30 minutes; weekly: 81 minutes; monthly: 40 minutes
Onboard maintenance records/Maintenance training demo module	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes	yes (includes audit trail of who replaced parts)/yes
Training provided with instrument purchase	3–5 days on site, 5 days at vendor offices	5 days at vendor offices	5 days at vendor offices
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	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

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

## Chemistry analyzers for mid- and high-volume laboratories

Part 4 of 11	<b>MID</b>	<b>HIGH</b>	<b>MID</b>
	Beckman Coulter Inc. Burch Ekener bekener@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-6698 www.beckmancoulter.com	Beckman Coulter Inc. Burch Ekener bekener@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-6698 www.beckmancoulter.com	Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-3140 www.beckmancoulter.com
Name of instrument/First year sold in U.S. List price/Total No. sold in 2010 Number of units in clinical use in U.S./Outside U.S. Where designed/Manufactured/Where reagents manufactured Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Footprint in square feet	UniCel DxC 600/2004 \$261,000/— >1,800 />2,900 U.S./U.S./U.S. and Ireland continuous random access/open reagent system racks, centrifugable/floor standing 62 x 62 x 41/17.7	UniCel DxC 800/2005 \$340,000/not available >700/>2,000 U.S./U.S./U.S. and Ireland continuous random access/open reagent system racks, centrifugable/floor standing 62 x 70 x 41/19.9	UniCel DxC 600i/2006 \$400,000/— >400/100 U.S./U.S./U.S., Ireland, France continuous random access/open reagent system racks, closed-tube/floor standing 62 x 128 x 48/42.7
Number of tests for which analyzer has FDA-cleared applications Tests released for clinical use in last 12 months  Tests cleared but not released for clinical use 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	>100 —  — — —  — HbA1c (next generation)	>100 —  — — —  — HbA1c (next generation)	>150 —  — — —  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) IL-6, PAPP-A PIGF, sVEGF R1, vitamin D
Methodologies supported/Immunoassay methodologies  Number of direct ion-selective electrode channels Number of different measured assays onboard simultaneously Number of different assays programmed and calibrated at once Number of user-definable (open) channels/Number active simultaneously Number of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when third-party reagents used Walkaway capacity in minutes/Specimens/Tests or assays Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination  Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	photometry, potentiometry, near-infrared bidentate turbidimetric/particle enhanced turbidimetric, enzyme immunoassay, near-infrared particle immunoassay  5 65 100 100/65 65/about 3,500 modular; about 600 cartridges  168 hours/30 days/yes (2°–8°C) yes yes no 83/132/5,280 — yes/2-year warranty, semi-permanent 3 µL optional/no yes/16 L 60 yes/40 µL yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes	photometry, potentiometry (ISE), near-infrared bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric/enzyme immunoassay, near-infrared particle immunoassay  5 70 100 100/70 70/about 3,500 (modular); 600 cartridges  168 hours/30 days/yes (2°–8°C) yes yes no 83/132/5,280 no yes/2-year warranty, semi-permanent 3 µL optional/no yes/16 L 60 yes/40 µL (samples directly from bullet) yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes	photometry, potentiometry (ISE), turbidimetric, enzyme immunoassay/chemiluminescence  5 89 >150 100/65 89/about 300 cartridges (chemistry), 50 per pack (immunoassay) 168 hours/28 days/yes (2°–10°C) yes yes no 180/96/5,280 yes/294 (immunoassay) yes/2-year warranty (chemistry) 3 µL optional/yes yes/16 L — yes/— yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes
Onboard test auto inventory (determines volume in container) Measures number of tests remaining/Short sample detection/Clot detection Hemolysis/Turbidity detection-quantitation Sample volume can be reduced Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown programmable/Startup programmable	yes yes/yes/yes yes/yes yes yes yes no/yes 1 day/up to 90 days/up to 60 days/14 days none required	yes yes/yes/yes yes/yes yes yes yes no/yes 1 day/up to 90 days/up to 60 days/14 days none required	yes yes/yes/yes yes/yes yes no no no/yes 1 day/90 days/up to 60 days/14 days none required
Stat time to completion of all analytes and throughput per hour for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., direct and total bilirubin, AST, ALT, ALP Typical time delay from ordering stat test to aspiration of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot numbers per analyte System can automatically transfer QC results to LIS	6:15 minutes from standby, 96 specimens 6:15 minutes from standby, 96 specimens 13:07 minutes from standby, 57 specimens 16 seconds 24 hr/yes yes/yes yes	2:23 minutes from standby, 91 specimens 2:22 minutes from standby, 91 specimens 12:32 minutes from standby, 76 specimens 16 seconds 24 hours/yes yes/yes yes	<1 minute, 90 specimens <1 minute, 90 specimens 1.1 minute, — 2:16 24 hours/— yes/yes yes/yes
Data management capability/Instrument vendor supplies LIS interface  Interfaces to what LISs up and running in active user sites  Bidirectional interface capability Uses LOINC to transmit orders and results across interface How labs get LOINC codes for reagent kits	onboard and optional add-on (SW mfr: Beckman Coulter)/yes (additional cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps yes (broadcast download and host query) yes via e-mail	onboard and optional add-on (Beckman Coulter)/yes (additional cost) Cerner, Misys, Meditech, Citation, Medlab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps yes (broadcast download and host query) yes via e-mail	onboard and optional add-on (SW manufacturer: Beckman Coulter)/— Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps yes (broadcast download and host query) yes via e-mail
Interface available (or will be) to automated specimen-handling system	yes, Beckman Coulter automation	yes, Beckman Coulter automation	no
Modem servicing available/System can diagnose own malfunctions/ System can determine malfunctioning component On-site time of service engineer Mean time between failures/Mean time to repair failures Average time to complete maintenance by lab personnel  Onboard maintenance records/Maintenance training demo module Training provided with instrument purchase	yes/yes/yes  metro: same day, rural: same or next day — daily: none; weekly: 7 minutes (tech time); monthly: 11 minutes (tech time) yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices	yes/yes/yes  metro: same day; rural: same or next day — weekly: 10 minutes (tech time); monthly: 18 minutes (tech time) yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices	yes/yes/yes  metro: same day; rural: same day or next — daily: <15 minutes, weekly: 36 minutes; monthly: 11 minutes yes (includes audit trail of who replaced parts)/no 10 days at vendor offices
Distinguishing features (provided by vendor)	closed-tube sampling; serum indices/polychromatic correction; clot detection and correction; centrifugable racks, no-wait autoloader; calibration data provided on disk; Peltier ring with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification	closed-tube 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; stat turnaround time; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification	parallel processing of immunoassay and chemistry tests on a single system; ClozCap technology (closed-tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry and immunoassay reagent packs identical across UniCel systems; immunoassay: 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 with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat turnaround time

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

## Chemistry analyzers for mid- and high-volume laboratories

Part 5 of 11	<b>HIGH</b>	<b>HIGH</b>	<b>HIGH</b>
	<b>Beckman Coulter, Inc.</b> Angela Suh asuh@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-3140 www.beckmancoulter.com	<b>Beckman Coulter, Inc.</b> Angela Suh asuh@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-3140 www.beckmancoulter.com	<b>Beckman Coulter, Inc.</b> Angela Suh asuh@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-3140 www.beckmancoulter.com
<b>Name of instrument/First year sold in U.S.</b> <b>List price/Total No. sold in 2010</b> <b>Number of units in clinical use in U.S./Outside U.S.</b> <b>Where designed/Manufactured/Where reagents manufactured</b> <b>Operational type/Reagent type</b>	UniCel DxC 660i Synchron Access Clinical System/2009 \$575,000/— 100/>150 U.S./U.S./U.S., France, Ireland batch, random access, continuous random access/ immunoassay: self-contained single-use cartridges, packages, slides; chemistry: open reagent system rack closed-tube/floor standing	UniCel DxC 680i Synchron Access Clinical System/2009 \$610,000/— >350/>500 U.S./U.S./U.S., France, Ireland batch, random access, continuous random access/ immunoassay: self-contained single-use cartridges, packages, slides; chemistry: open reagent system rack closed-tube/floor standing	UniCel DxC 860i Synchron Access Clinical System/2009 \$615,000/— >6/>20 U.S./U.S./U.S., France, Ireland batch, random access, continuous random access/ immunoassay: self-contained single-use cartridges, packages, slides; chemistry: open reagent system rack closed-tube/floor standing
<b>Sample handling system/Model type</b> <b>Dimensions in inches (H x W x D)/Footprint in square feet</b>	rack closed-tube/floor standing 68 x 147 x 48/49	rack closed-tube/floor standing 68 x 153 x 48/51	rack closed-tube/floor standing 68 x 155 x 48/51.7
<b>Number of tests for which analyzer has FDA-cleared applications</b> <b>Tests released for clinical use in last 12 months</b> <b>Tests cleared but not released for clinical use</b> <b>Tests not available in U.S. but submitted for 510(k) clearance</b> <b>Tests not available in U.S. but available in other countries</b>	>150 — — — HAV Ab, HAV IgM, HBcAb, HBe IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM	>150 — — — HAV Ab, HAV IgM, HBcAb, HBe IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM	>150 — — — HAV Ab, HAV IgM, HBcAb, HBe IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM
<b>Research-use-only assays</b> <b>Tests in development</b>	IL-6, PAPP-A PIGF, sVEGF R1, vitamin D	IL-6, PAPP-A PIGF, sVEGF R1, vitamin D	IL-6, PAPP-A PIGF, sVEGF R1, vitamin D
<b>Methodologies supported/Immunoassay methodologies</b>	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	photometry, potentiometry (ISE), turbidimetric/ particle enhanced, turbidimetric, enzyme immunoassay, near- infrared particle immunoassay, chemiluminescence, magnetic particle
<b>Number of direct ion-selective electrode channels</b> <b>Number of different measured assays onboard simultaneously</b> <b>Number of different assays programmed and calibrated at once</b> <b>Number of user-definable (open) channels/Number active simultaneously</b> <b>Number of different analytes for which system accommodates reagent            containers onboard at once/Tests per container set</b> <b>Shortest/Median onboard reagent stability/Refrigerated onboard</b> <b>Multiple reagent configurations supported</b> <b>Reagent container placed directly on system for use</b> <b>Instrument has same capabilities when third-party reagents used</b> <b>Walkaway capacity in minutes/Specimens/Tests or assays</b> <b>Uses disposable cuvettes/Maximum number stored</b> <b>Uses washable cuvettes/Replacement frequency</b> <b>Minimum sample volume aspirated precisely at one time</b> <b>Supplied with UPS (backup power)/Requires floor drain</b> <b>Requires dedicated water system/Water consumption per hour</b> <b>Noise generated in decibels</b> <b>Dedicated pediatric sample cup/Dead volume</b> <b>Primary tube sampling/Pierces caps on primary tubes</b> <b>Sample bar-code reading capability/Autodiscrimination</b>	5 115 115 100/100 115/immunoassay: 100 tests/kit; general chemistry: 300 tests/container 28 days/yes (2°–10°C) yes yes yes assay mix dependent/—/assay dependent no/125 yes/— 3 µL yes/yes yes/up to 16 L 64 yes/20 yes/yes 2 or 5 interl., UPC, Codabar, codes 39 128/yes	5 115 115 100/100 115/immunoassay: 100 tests/kit; general chemistry: 300 tests/container 28 days/yes (2°–10°C) yes yes yes assay mix dependent/—/assay dependent no/125 yes/— 3 µL yes/yes yes/up to 16 L 64 yes/20 yes/yes 2 or 5 interl., UPC, Codabar, codes 39 and 128/yes	5 120 120 100/100 120/immunoassay: 100 tests/kit; general chemistry: 300 tests/container 28 days/yes (2°–10°C) yes yes yes assay mix dependent/—/assay dependent no/125 yes/— 3 µL yes/yes yes/up to 16 L 64 yes/20 yes/yes 2 or 5 interl., UPC, Codabar, codes 39 and 128/yes
<b>Reagent bar-code reading capability</b> <b>Bar code placement per CLSI standard Auto2A</b>	yes yes	yes yes	yes yes
<b>Onboard test auto inventory (determines volume in container)</b> <b>Measures number of tests remaining/Short sample detection/Clot detection</b> <b>Hemolysis/Turbidity detection-quantitation</b> <b>Sample volume can be reduced</b> <b>Increased to rerun out-of-linear-range high/low results</b> <b>Autocalibration or autocalibration alert</b> <b>Calibrants stored onboard/Multipoint calibration supported</b> <b>Typical calib. frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse</b> <b>Automatic shutdown programmable/Startup programmable</b>	yes yes/yes/yes yes/yes yes yes — no/yes —/—/assay dependent/assay dependent no/no	yes yes/yes/yes yes/yes yes yes — no/yes —/—/assay dependent/assay dependent no/no	yes yes/yes/yes yes/yes yes yes — no/yes —/—/assay dependent/assay dependent no/no
<b>Stat time to completion of all analytes and throughput per hour for:</b> • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., direct and total bilirubin, AST, ALT, ALP  <b>Typical time delay from ordering stat test to aspiration of sample</b> <b>How often QC required/Onboard SW capability to review QC</b> <b>Onboard real-time QC/Support multiple QC lot numbers per analyte</b> <b>System can automatically transfer QC results to LIS</b>	<1 minute, 90 specimens <1 minute, 90 specimens 1.1 minute, — — 24 hours/yes yes/yes yes	<1 minute, 90 specimens <1 minute, 90 specimens 1.1 minute, — — 24 hours/yes yes/yes yes	<1 minute, 90 specimens <1 minute, 90 specimens 1.1 minute, — — 24 hours/yes yes/yes yes
<b>Data management capability/Instrument vendor supplies LIS interface</b>	onboard and optional add-on (sw mfr: Beckman Coulter/Normand)/yes (additional cost)	onboard and optional add-on (sw mfr: Beckman Coulter/Normand)/yes (additional cost)	onboard and optional add-on (sw mfr: Beckman Coulter/Normand)/yes (additional cost)
<b>Interfaces to what LISs up and running in active user sites</b> <b>Bidirectional interface capability</b> <b>Uses LOINC to transmit orders and results across interface</b> <b>How labs get LOINC codes for reagent kits</b>	most commercially available LIS yes (broadcast download and host query) yes via e-mail	most commercially available LIS yes (broadcast download and host query) yes via e-mail	most commercially available LIS yes (broadcast download and host query) yes via e-mail
<b>Interface available (or will be) to automated specimen-handling system</b>	yes	yes	yes
<b>Modem servicing available/System can diagnose own malfunctions/            System can determine malfunctioning component</b> <b>On-site time of service engineer</b> <b>Mean time between failures/Mean time to repair failures</b> <b>Average time to complete maintenance by lab personnel</b>  <b>Onboard maintenance records/Maintenance training demo module</b> <b>Training provided with instrument purchase</b>	yes/yes/yes metro: same day; rural: same or next day — daily: <10 minutes; weekly: <10 minutes; monthly: <18 minutes yes, includes audit trail/yes 5 days at vendor offices	yes/yes/yes metro: same day; rural: same or next day — daily: <10 minutes; weekly: <10 minutes; monthly: <18 minutes yes, includes audit trail/yes 5 days at vendor offices	yes/yes/yes metro: same day; rural: same or next day — daily: <10 minutes; weekly: <10 minutes; monthly: <18 minutes yes, includes audit trail/yes 5 days at vendor offices
<b>Distinguishing features (provided by vendor)</b>	parallel processing of immunoassay and chemistry tests on a single system; ClozCap technology (closed- tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry and immunoassay reagent packs identical across UniCel systems; immunoassay: 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 with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat turnaround time; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification	parallel processing of immunoassay and chemistry tests on a single system; ClozCap technology (closed- tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry and immunoassay reagent packs identical across UniCel systems; immunoassay: 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 with semi-permanent glass cuvettes; pulsed Xenon lamp; intuitive operator software; fast stat turnaround time; Remisol Advance Data Manager: stat notification, review by exception, reflex testing, add-on test notification	parallel processing of immunoassay and chemistry tests on a single system; ClozCap technology (closed- tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry and immunoassay reagent packs identical across UniCel systems; immunoassay: 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 with semi-permanent glass cuvettes

*Note: a dash in lieu of an answer means company did not answer question or question is not applicable*

## Chemistry analyzers for mid- and high-volume laboratories

Part 6 of 11	<b>HIGH</b>	<b>MID</b>	<b>MID</b>
Beckman Coulter Inc. Angela Suh asuh@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-3140 www.beckmancoulter.com	The Binding Site Maureen Zetlmeisl maureen.zetlmeisl@thebindingsite.com 5889 Oberlin Drive, Suite 101, San Diego, CA 92121 800-633-4484 ext. 337 www.thebindingsite.com	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. List price/Total No. sold in 2010 Number of units in clinical use in U.S./Outside U.S. Where designed/Manufactured/Where reagents manufactured Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Footprint in square feet	UniCel DxC 880i Synchron Access Clinical System/2008 \$650,000/— >24/>100 U.S./U.S./U.S., Ireland and France continuous random access/open reagent system for chemistry; self-contained single use cartridges for immunoassay rack closed tube/floor standing 68 x 161 x 48/53.7	SPA PLUS (Specialist Protein Analyzer)/2007 — — Japan/Japan/United Kingdom batch, random access/self-contained multi-use cartridges, packages, slides 2 sample carousels each hold 45 samples: 30 primary tubes and 15 non-bar-coded sample tubes, cups/benchtop 20.5 x 31.5 x 25.2/14	BioLis 24i/2008 \$75,000/50 300/4,000 Japan/Japan/U.S. batch, random access, discrete, continuous random access/open reagent system cup, bar-coded tubes, stat/benchtop 20 x 31 x 25/5
Number of tests for which analyzer has FDA-cleared applications Tests released for clinical use in last 12 months Tests cleared but not released for clinical use 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	>150 — — — HAV Ab, HAV IgM, HBcAb, HBe IgM, HBsAb, HBsAg, HBsAg confirmatory, CMV IgG, CMV IgM, rubella IgM IL-6, PAPP-A PIGF, sVEGF R1, vitamin D	free kappa light chain, free lambda light chain, IgG, IgA, IgM, IgD, IgG1, IgG2, IgG3, IgG4, IgA1, IgA2, albumin, beta-2-microglobulin, Cystatin C, C3c, C4, haptoglobin, prealbumin IgA1, IgA2, C3, C4, haptoglobin, prealbumin, albumin — CH50, Hevylite IgG kappa and lambda, Hevylite IgA kappa and lambda, Hevylite IgM kappa and lambda tetanus toxoid, T. tox plasma screen only (RUO) CSF assays, others	100 direct (no-pretreat.) HbA1c & cystatin C, 1,5AG (GlycoMark) Lp-PLA2 — — vitamin D, RPR syphilis
Methodologies supported/Immunoassay methodologies Number of direct ion-selective electrode channels Number of different measured assays onboard simultaneously Number of different assays programmed and calibrated at once Number of user-definable (open) channels/Number active simultaneously Number of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when third-party reagents used Walkaway capacity in minutes/Specimens/Tests or assays Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	photometry, potentiometry (ISE), turbidimetric/enzyme immunoassay, near-infrared particle immunoassay, chemiluminescence, magnetic particle/chemiluminescence; magnetic particle 5 120 120 100/100 120/100 tests/kit (immunoassay); 300 test/container (general chemistry) 316 hours/28 days/yes (2°-10°C) yes yes no assay mix dependent/112/assay dependent no/— yes/2-year warranty, semi-permanent 3 µL yes/yes yes/up to 16 L 64 yes/20 µL (chemistry) yes/yes yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes yes yes	—/turbidimetry — 24 — — 24/100 672 hours/30 days/yes yes yes no ~60/45/6 no/60 yes/checks OD and when it reaches threshold OD (0.33) cuvettes should be changed 3 µL yes/no no/3.5 L — no/— yes/no yes, as sample is being aspirated, on sample transport, shortly before sample is aspirated (Codabar, codes 39 and 128)/— yes —	photometry, potentiometry/— 3 39 39 39/39 39/300 (3 x 100) 7 days/14 days/yes yes yes yes 4 hours/40/39 no/— yes/6 months 3 µL no/no no/3.5 L — yes/30 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved)/— yes yes
Onboard test auto inventory (determines volume in container) Measures number of tests remaining/Short sample detection/Clot detection Hemolysis/Turbidity detection-quantitation Sample volume can be reduced Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown programmable/Startup programmable	— yes/yes/yes yes/yes yes no no no/yes 24 hours/up to 90 days/up to 60 days/up to 90 days no/no	no yes/yes/no no/no yes yes yes no/yes — no/no	yes yes/yes/yes yes/yes yes no no yes/yes 24 hours/14 days/14 days/14 days yes/yes
Stat time to completion of all analytes and throughput per hour for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., direct and total bilirubin, AST, ALT, ALP Typical time delay from ordering stat test to aspiration of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot numbers per analyte System can automatically transfer QC results to LIS	<1 minute, 90 specimens <1 minute, 90 specimens <1 minute, — <1 minute 24 hours/yes	— — — — —	12 minutes, 160 specimens 1 hour, 60 specimens 18 minutes, 240 specimens 5 minutes 2 levels per operational shift; shortest interval: 8 hours; longest: 24 hours/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface Interfaces to what LISs up and running in active user sites Bidirectional interface capability Uses LOINC to transmit orders and results across interface How labs get LOINC codes for reagent kits	onboard and optional add-on (Beckman Coulter)/yes (additional cost) Cerner, Misys, Meditech, Citation, Medlab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps yes (broadcast download and host query) yes via e-mail	yes, onboard (optional add-on)/no Cerner, Soft Computer Concepts, Cyberlab, SunQuest, Meditech, Middleware, Creative Computing Applications Inc., Data Innovations yes (broadcast download, host query) no —	yes, onboard/yes (additional cost) all common LISs yes (broadcast download, host query) — —
Interface available (or will be) to automated specimen-handling system	yes (if cleaved, Dxl and DxC systems can interface w/ Beckman Coulter automation)	no	no
Modem servicing available/System can diagnose own malfunctions/ System can determine malfunctioning component On-site time of service engineer Mean time between failures/Mean time to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with instrument purchase	yes/yes/yes metro: same day; rural: same or next day — daily: <10 minutes; weekly: <10 minutes; monthly: <18 minutes yes (includes audit trail of who replaced parts/no contract dependent)	no/no/no 24 hours 258 days with two scheduled preventive maintenance visits/4 hours on site daily: <10 minutes; weekly: <10 minutes; monthly: <15 minutes no/no 5 days (includes installation)	no/no/yes within 24 hours — weekly: 20 minutes; monthly: visual inspections, <5 minutes yes (includes audit trail of who replaced parts)/no 5 days on site
Distinguishing features (provided by vendor)	parallel processing of immunoassay and chemistry tests on a single system; ClozCap technology (closed-tube aliquotting and closed-tube sampling) eliminates manual processes; chemistry and immunoassay reagent packs identical across UniCel systems; immunoassay: high-throughput analyzer; uses chemiluminescent assay technology and reagent packs for consistent results	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

## Chemistry analyzers for mid- and high-volume laboratories

Part 7 of 11	<b>MID</b>	<b>HIGH</b>	<b>HIGH</b>
	<b>Carolina Liquid Chemistries Corp.</b> <b>Patti Shugart</b> contactsales@carolinachemistries.com 391 Technology Way, Winston-Salem, NC 27101 877-722-8910 www.carolinachemistries.com	<b>Carolina Liquid Chemistries Corp.</b> <b>Patti Shugart</b> contactsales@carolinachemistries.com 391 Technology Way, Winston-Salem, NC 27101 877-722-8910 www.carolinachemistries.com	<b>Ortho-Clinical Diagnostics</b> <b>Mark Steelman</b> msteelma@its.jnj.com 1001 U.S. Route 202, Raritan, NJ 08869 585-453-3420 www.orthoclinical.com
Name of instrument/First year sold in U.S. List price/Total No. sold in 2010 Number of units in clinical use in U.S./Outside U.S. Where designed/Manufactured/Where reagents manufactured Operational type/Reagent type	CLC 480/pending FDA 510K clearance \$75,000/— —/— Japan/Japan/U.S. batch, random access, discrete, continuous random access/open reagent system	CLC 720/pending FDA 510K clearance \$110,000/— —/— China/China/U.S. batch, random access, discrete, continuous random access/open reagent system	VITROS 4600 Chemistry System/expected Q3 2011 \$227,000/— — U.S./U.S./U.S. and United Kingdom batch, random access, discrete, continuous random access/self-contained multi-use cartridges, packages, slides 10-sample universal sample trays/floor-standing
Sample handling system/Model type Dimensions in inches (H × W × D)/Footprint in square feet	cup, primary, bar-coded tubes, stat/benchtop 20 × 31 × 25/5	carousel, all traditional sample tubes and cups/ floor-standing 46.5 × 27.5 × 45/8.9	10-sample universal sample trays/floor-standing 52.5 × 92.2 × 33.4/21.4
Number of tests for which analyzer has FDA-cleared applications Tests released for clinical use in last 12 months Tests cleared but not released for clinical use 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	90 — — — — vitamin D, RPR vitamin D, RPR	80 — — — — vitamin D, syphilis vitamin D, syphilis	>75 — — — — — —
Methodologies supported/Immunoassay methodologies	photometry, potentiometry/—	photometry, potentiometry/—	photometry, potentiometry, colorimetric, immuno-rate, turbidimetric, spectrophotometric
Number of direct ion-selective electrode channels Number of different measured assays onboard simultaneously Number of different assays programmed and calibrated at once Number of user-definable (open) channels/Number active simultaneously Number of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when third-party reagents used Walkaway capacity in minutes/Specimens/Tests or assays Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	3 39 39 39/39 39/300 7 days/14 days/yes yes yes yes 4 hours/40/39 no/— yes/~6 months 3 µL no/no no/3.5 L 40 yes/30 µL yes/no yes, on sample transport, shortly before sample is aspirated (codes 39 and 128)/—	4 77 77 77/77 77/250–300 7 days/14 days/yes (<10°C) yes yes yes —/60/77 no/— yes/~6 months 2 µL no/no yes/20 L <60 — yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes	3 125 125 20/10 125/100 48 hours/14 days/yes (10°C) yes yes yes varies/160/8,940 yes/348 no/— 2 µL available (not included)/no no/— <60 no special sample cup required/35 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes yes	yes yes	yes yes
Onboard test auto inventory (determines volume in container) Measures number of tests remaining/Short sample detection/Clot detection Hemolysis/Turbidity detection-quantitation Sample volume can be reduced Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown programmable/Startup programmable	yes yes/yes/yes yes/yes yes yes/no yes yes/yes 24 hours/14 days/14 days/7–14 days yes/yes	yes yes/yes/yes yes/yes yes yes/yes yes yes/yes daily/30 days/—/— yes/no	yes yes/yes/yes yes/yes system autodilutes no/no yes no/yes at lot change/at lot change/at lot change/at lot change no/no
Stat time to completion of all analytes and throughput per hour for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., direct and total bilirubin, AST, ALT, ALP Typical time delay from ordering stat test to aspiration of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot numbers per analyte System can automatically transfer QC results to LIS	12 minutes, 160 specimens 1 hour, 60 specimens 18 minutes, 240 specimens 5 minutes 2 levels per operational shift; shortest interval: 8 hours; longest: 24 hours/yes yes/yes yes	— — — — once per shift; shortest interval: 8 hours/yes yes/yes yes	5.5 minutes, 100 specimens 5.75 minutes, 90 specimens 7.5 minutes, 60 specimens 10 seconds once per 24 hours/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface	yes, onboard (optional add-on)/yes (additional cost)	yes, onboard/yes (additional cost)	onboard/no
Interfaces to what LISs up and running in active user sites Bidirectional interface capability Uses LOINC to transmit orders and results across interface How labs get LOINC codes for reagent kits	Lab Track, Orchard, Fletcher Flora, most common LIS yes (broadcast download and host query) yes tech representative will provide	all major LIS yes (broadcast download and host query) yes e-mail query	all major LIS vendors yes (broadcast download and host query) no LOINC database
Interface available (or will be) to automated specimen-handling system	no	no	yes (enGen LAS)
Modem servicing available/System can diagnose own malfunctions/ System can determine malfunctioning component On-site time of service engineer Mean time between failures/Mean time to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with instrument purchase	yes/no/no within 24 hours — weekly: 30 minutes; monthly: visual inspection <5 minutes yes (includes audit trail of who replaced parts)yes 2–3 days on site, 2–4 days at vendor office	yes/no/no within 24 hours — daily: 5 minutes; weekly: 10 minutes yes (includes audit trail of who replaced parts)yes 2–4 days on site, 2–4 days at vendor office	yes/yes/yes 4 to 8 hours — daily: 9 minutes; weekly: 5 minutes; monthly: 31 minutes yes, includes audit trail/yes varies on site, 5 days at vendor offices
Distinguishing features (provided by vendor)	large test menu; small size, quiet; no need for disposable reaction cuvettes	takes up little space; runs quietly on 110v; consumes very little water	standardized reagents, consumables, and software with other VITROS systems; MicroSlide technology provides 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; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides or disposable cuvette; onboard e-Connectivity interactive management system

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

# Chemistry analyzers for mid- and high-volume laboratories

Part 8 of 11	<b>HIGH</b>	<b>MID</b>	<b>HIGH</b>
	<b>Ortho-Clinical Diagnostics</b> Mark Steelman msteelma@its.jnj.com 1001 U.S. Route 202, Raritan, NJ 08869 585-453-3420 www.orthoclinical.com	<b>Ortho-Clinical Diagnostics</b> Mark Steelman msteelma@its.jnj.com 1001 U.S. Route 202, Raritan, NJ 08869 585-453-3420 www.orthoclinical.com	<b>Ortho-Clinical Diagnostics</b> Mark Steelman msteelma@its.jnj.com 1001 U.S. Route 202, Raritan, NJ 08869 585-453-3420 www.orthoclinical.com
Name of instrument/First year sold in U.S. List price/Total No. sold in 2010 Number of units in clinical use in U.S./Outside U.S. Where designed/Manufactured/Where reagents manufactured Operational type/Reagent type	VITROS 5600 Integrated System/2008 \$410,000/— >900 worldwide U.S./U.S./U.S. and United Kingdom batch, random access, discrete, continuous random access/self-contained multi-use cartridges, packages, slides	VITROS 350/2005 \$110,000/— —/— U.S./U.S./U.S. batch, random access, discrete, continuous random access/self-contained single-use cartridges, packages, slides	VITROS 5,1 FS Chemistry System/2004 \$225,000/— >1,600 worldwide U.S./U.S./U.S. random access, discrete, continuous random access/self-contained single-use cartridges, packages, slides; user-defined assay capability
Sample handling system/Model type Dimensions in inches (H x W x D)/Footprint in square feet	universal sample tray/floor standing 68 x 110 x 34.9/26.7	rack/floor standing 47 x 45.5 x 28/8.8	universal sample tray/floor standing 52.5 x 92.2 x 33.4/21.4
Number of tests for which analyzer has FDA-cleared applications Tests released for clinical use in last 12 months Tests cleared but not released for clinical use Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	>110 iPTH — — HBeAg, aHBe, rub IgM, tox IgG, tox IgM, CMV IgG, CMV IgM	>40 — — — —	>70 — — — —
Research-use-only assays Tests in development	— syphilis (ex-US), aHBE, HBeAg, total vitamin D	— —	— —
Methodologies supported/Immunoassay methodologies	photometry, potentiometry (ISE), thin film reflectance/homogeneous EMIT, microparticle agglutination, enhanced chemiluminescence	potentiometry, colorimetric, rate, immuno-rate	photometry, potentiometry, immuno-rate, turbidimetric, colorimetric, spectrophotometric/—
Number of direct ion-selective electrode channels Number of different measured assays onboard simultaneously Number of different assays programmed and calibrated at once Number of user-definable (open) channels/Number active simultaneously Number of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	3 150 150 20/10 150/100	3 60 60 — 60/18, 50, 60	3 (direct) 125 125 20/10 125/up to 100
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when third-party reagents used Walkaway capacity in minutes/Specimens/Tests or assays Uses disposable cuvettes/Maximum number stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour Noise generated in decibels	48 hours/30 days/yes (2°-8°C) yes yes yes varies/90/11,440 yes/348 no/— 2 µL available (not included)/no no/0 idle: 60; operational: 65	48 hours/14 days/no yes yes — varies/40/3,600 — 6 µL available (not included)/no no/— 61	48 hours/14 days/yes (10°C) yes yes yes varies/160/8,940 yes/348 no/disposable 2 µL available (not included)/no no/— <60
Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	no special sample cup required/35 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	no special sample cup required/35 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	no special sample cup required/35 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes yes	yes yes	yes yes
Onboard test auto inventory (determines volume in container) Measures number of tests remaining/Short sample detection/Clot detection Hemolysis/Turbidity detection-quantitation Sample volume can be reduced Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	yes yes/yes/yes yes/yes system autodilutes no yes no/yes reagent lot change/reagent lot change/reagent lot change/reagent lot change	yes yes/yes/yes no/no no no no/yes reagent lot changes	yes yes/yes/yes yes/yes system autodilutes no no no/yes reagent lot changes
Automatic shutdown programmable/Startup programmable	no/no	no/no	no/no (instrument maintained in ready mode)
Stat time to completion of all analytes and throughput per hour for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., direct and total bilirubin, AST, ALT, ALP	5.5 minutes, 100 specimens 5.75 minutes, 90 specimens 7.5 minutes, 60 specimens	6 minutes, 60 specimens 6 minutes 24 seconds, 40 specimens 6 minutes 40 seconds, 44 specimens	5.5 minutes, 100 specimens 5.75 minutes, 90 specimens 7.5 minutes, 60 specimens
Typical time delay from ordering stat test to aspiration of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot numbers per analyte System can automatically transfer QC results to LIS	about 10 seconds once per 24 hours/yes yes/yes yes	12 seconds 24 hours/yes yes/yes yes	~10 seconds once per 24 hours/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface	onboard/no	onboard/no (optional)	onboard (optional add-on)/no
Interfaces to what LISs up and running in active user sites	all major LIS vendors	all major LIS vendors	all major LIS vendors
Bidirectional interface capability Uses LOINC to transmit orders and results across interface How labs get LOINC codes for reagent kits	yes (broadcast download and host query) no LOINC database	yes (broadcast download) no —	yes (broadcast download and host query) no LOINC database
Interface available (or will be) to automated specimen-handling system	yes (enGen LAS)	yes (enGen LAS)	yes (enGen LAS)
Modem servicing available/System can diagnose own malfunctions/ System can determine malfunctioning component On-site time of service engineer Mean time between failures/Mean time to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with instrument purchase	yes/yes/yes 4 to 8 hours — — yes, includes audit trail/yes 5 days on site, 5 days at vendor offices	no/yes/yes varies by location, usually 4 to 8 hours — — no/yes 3 days on site, 5 days at vendor offices	yes/yes/yes varies by location; usually 4 to 8 hours — — no/yes yes
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 parallel; integrated MicroTip technology expands menu availability, such as DATs, TDMs, specific proteins, %hA1c and user-defined channels; MicroSensor technology detects interfering levels of hemolysis, icterus, and turbidity; eConnectivity assists with remote diagnostics, software, and test parameter downloads and updates	MicroSlide technology provides low cost per reportable result and high reagent efficiency without the maintenance, preparation, carryover, and interference associated with traditional water-based and indirect ISE systems; QC procedures are required once each day and calibration intervals up to six months with minimal interferences from hemolysis, lipemia; no plumbing, drains, vents, or deionized water required; all waste is contained in used test slides that are disposed of daily	MicroSlide technology provides 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 minute 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

*Note: a dash in lieu of an answer means company did not answer question or question is not applicable*



## Chemistry analyzers for mid- and high-volume laboratories

Part 9 of 11	<b>MID</b>	<b>HIGH</b>	<b>MID</b>
	<b>Randox Laboratories Ltd</b> Graeme McNeill graeme.mcneill@randox.com 515 Industrial Blvd., Kearneysville, WV 25430 304-728-2890 www.randox.com	<b>Roche Diagnostics</b> Sheila Brewer sheila.brewer@roche.com 9115 Hague Rd., Indianapolis, IN 46250 317-521-2000 us.labsystems.roche.com	<b>Roche Diagnostics</b> Sheila Brewer sheila.brewer@roche.com 9115 Hague Rd., Indianapolis, IN 46250 317-521-2000 us.labsystems.roche.com
<b>Name of instrument/First year sold in U.S.</b>	RX Imola/2006	cobas 8000 modular analyzer series (cobas c 702, cobas c 701, cobas c 502, cobas e 602)/2010	cobas 6000 analyzer series (cobas c 501, e 601)/2006
<b>List price/Total No. sold in 2010</b>	—/—	—/—	—/250
<b>Number of units in clinical use in U.S./Outside U.S.</b>	—	>13/>570	>1,385/>7,600
<b>Where designed/Manufactured/Where reagents manufactured</b>	Japan/Japan/United Kingdom	Japan/Japan/Germany	Japan/Japan/U.S., Germany
<b>Operational type/Reagent type</b>	random access/self-contained multi-use cartridges, packages, slides	random access, continuous random access/self-contained single-use cartridges/packages/slides	continuous random access/self-contained multi-use cartridges, packages, slide
<b>Sample handling system/Model type</b>	ring/benchtop	five-position rack/floor standing	five-position rack/floor standing
<b>Dimensions in inches (H × W × D)/Footprint in square feet</b>	23 × 38 × 28/2.3	—	—/32.67
<b>Number of tests for which analyzer has FDA-cleared applications</b>	>100	>145	>155
<b>Tests released for clinical use in last 12 months</b>	haptoglobin, ceruloplasmin, salicylate, acetaminophen, txb cardio, H-FABP	148	clinical chemistry: albumin bromocresol purple, triglycerides/glycerol blanked, amphetamines II; immunoassay: anti HAV IgM, troponin T Stat, anti HAV total
<b>Tests cleared but not released for clinical use</b>	—	DAT oral fluids: amphetamines, phencyclidine, opiates, cocaine, methamphetamines	DAT oral fluids (amphetamines, phencyclidine, opiates, cocaine, methamphetamines)
<b>Tests not available in U.S. but submitted for 510(k) clearance</b>	—	thyroglobulin, folate RBC	thyroglobulin
<b>Tests not available in U.S. but available in other countries</b>	—	free β-HCG, PAPP-Am, PTH (1-84), anti-HBc, anti-HBc IgM, HBeAg, anti-HBe, HIV Ag, HIV Ag confirmatory test, HIV combi, HSV type 1, HSV type 2, toxo IgM, CMV IgG, CMV IgM	free β-HCG, PAPP-A, PTH (1-84), anti-HBc, anti-HBc IgM, HBeAg, anti-HBe, HIV Ag, HIV Ag confirmatory test, HIV combi, HSV Type 1, HSV type 2, toxo IgM, CMV IgG, CMV IgM
<b>Research-use-only assays</b>	—	CA 72-4, cyfra 21-1, NSE, HE4, digitoxin, troponin T high sensitive, troponin T high sensitive stat, Tg confirmatory test, PLGF, SFLT-1, procalcitonin, interleukin 6, others	CA 72-4, cyfra 21-1, NSE, HE4, digitoxin, troponin T high sensitive, troponin T high sensitive stat, Tg confirmatory test, PLGF, SFLT-1, procalcitonin, others
<b>Tests in development</b>	liquid CK, liquid CK-MB, D-dimer	—	HBsAg quant
		anti HBc, anti HBc IgM, total vitamin D, HSV type 1, HSV type 2, IGF-1, tacrolimus, sirolimus, cyclosporine	anti HBc, anti HBc IgM, total vitamin D, HSV type 1, HSV type 2, IGF-1, tacrolimus, sirolimus, cyclosporine
		HIV combi, toxo IgM, CMV IgG, CMV IgM, HE4	HIV combi, toxo IgM, CMV IgG, CMV IgM, HE4, troponin T high sensitive, troponin T high sensitive stat, PLGF
		Troponin T high sensitive, troponin T high sensitive stat, PLGF, SFLT-1, procalcitonin, PTH 1-84, others	SFLT-1, procalcitonin, PTH 1-84
<b>Methodologies supported/Immunoassay methodologies</b>	photometry, potentiometry (ISE), latex enhanced immunoturbidimetric/—	photometry, potentiometry (ISE), electrochemiluminescence/electrochemiluminescence on cobas e 602	photometry, potentiometry (ISE), electrochemiluminescence/electrochemiluminescence on cobas e 601
<b>Number of direct ion-selective electrode channels</b>	3	3 indirect	3
<b>Number of different measured assays onboard simultaneously</b>	63	up to 283	88
<b>Number of different assays programmed and calibrated at once</b>	63	>300	>100
<b>Number of user-definable (open) channels/Number active simultaneously</b>	10/10	—/all	40 per system/all
<b>Number of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</b>	63/50 to 11,250	283/3,000	148 (plus 3 ISE)/100–800
<b>Shortest/Median onboard reagent stability/Refrigerated onboard</b>	8 hours/28 days/yes (8°–15°C)	96 hours/60 days/yes (5°–20°C)	21 days/>60 days/yes (5°–20°C)
<b>Multiple reagent configurations supported</b>	yes	yes	yes
<b>Reagent container placed directly on system for use</b>	yes	yes	yes
<b>Instrument has same capabilities when third-party reagents used</b>	no	yes	yes
<b>Walkaway capacity in minutes/Specimens/Tests or assays</b>	664/72/76,115	varies based on configuration/300/—	varies/250/—
<b>Uses disposable cuvettes/Maximum number stored</b>	no/90	no	no
<b>Uses washable cuvettes/Replacement frequency</b>	yes/5 years	yes/monthly	yes/once per month
<b>Minimum sample volume aspirated precisely at one time</b>	2 µL	0.1 µL	1.5 µL
<b>Supplied with UPS (backup power)/Requires floor drain</b>	no/yes	yes/yes	yes/yes
<b>Requires dedicated water system/Water consumption per hour</b>	yes/18 L	yes/10–36 L	yes/10–12 L
<b>Noise generated in decibels</b>	75	<85	≤65
<b>Dedicated pediatric sample cup/Dead volume</b>	yes/50 µL	yes/50 µL	yes/50 µL
<b>Primary tube sampling/Pierces caps on primary tubes</b>	yes/no	yes/no	yes/no
<b>Sample bar-code reading capability/Autodiscrimination</b>	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes	on sample transport, shortly before sample is aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
<b>Reagent bar-code reading capability</b>	yes	yes	yes
<b>Bar code placement per CLSI standard Auto2A</b>	—	yes	yes
<b>Onboard test auto inventory (determines volume in container)</b>	yes	yes	yes
<b>Measures number of tests remaining/Short sample detection/Clot detection</b>	yes/yes/yes	yes/yes/yes	yes/yes/yes
<b>Hemolysis/Turbidity detection-quantitation</b>	yes/yes	yes/yes	yes/yes
<b>Sample volume can be reduced</b>	yes	yes	yes
<b>Increased to rerun out-of-linear-range high/low results</b>	yes	yes	yes
<b>Autocalibration or autocalibration alert</b>	yes	yes	yes
<b>Calibrants stored onboard/Multipoint calibration supported</b>	yes/yes	no/yes	no/yes
<b>Typical calib. frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse</b>	daily/28 days/7 days/28 days	24 hours/typically by lot/bottle change/typically by lot	24 hours/once per lot/varies/once per lot
<b>Automatic shutdown programmable/Startup programmable</b>	yes/yes	yes/yes	yes/yes
<b>Stat time to completion of all analytes and throughput per hour for:</b>			
• Sodium, potassium, chloride, TCO2	13 minutes 15 seconds, 80 specimens	4.5 minutes, 600 specimens	5.5 minutes, 133–266 specimens
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	13 minutes 43 seconds, 80 specimens	4.5 minutes, 600–1,800 specimens	7.5 minutes, 150–300 specimens
• Album., direct and total bilirubin, AST, ALT, ALP	13 minutes 15 seconds, 67 specimens	10.5 minutes, 285–855 specimens	10.5 minutes, 85–170 specimens
<b>Typical time delay from ordering stat test to aspiration of sample</b>	30 seconds	<1 minute	<1 minute
<b>How often QC required/Onboard SW capability to review QC</b>	recommend 2 levels run per day/shortest: daily; longest: customer's discretion/yes	24 hours/shortest: 24 hours; longest: 24 hours	typically once per 24 hours
<b>Onboard real-time QC/Support multiple QC lot numbers per analyte</b>	yes/yes	yes/yes	yes/yes
<b>System can automatically transfer QC results to LIS</b>	yes/yes	yes/yes	yes
<b>Data management capability/Instrument vendor supplies LIS interface</b>	onboard/no	onboard (optional add-on)/no	onboard (optional add-on)/no
<b>Interfaces to what LISs up and running in active user sites</b>	no	all major LIS vendors	all major LIS vendors
<b>Bidirectional interface capability</b>	yes (host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
<b>Uses LOINC to transmit orders and results across interface</b>	no	yes	yes
<b>How labs get LOINC codes for reagent kits</b>	—	Web site	Web site
<b>Interface available (or will be) to automated specimen-handling system</b>	no	yes, Roche Diagnostics MPA system	yes, Roche Diagnostics MPA system
<b>Modem servicing available/System can diagnose own malfunctions/ System can determine malfunctioning component</b>	no/yes/yes	yes/yes/yes	yes/yes/yes
<b>On-site time of service engineer</b>	within 24 hours	<8 hours	<8 hours
<b>Mean time between failures/Mean time to repair failures</b>	2 per 3 years/within 8 working hours	—	core: 180 days; cobas c 501: 124 days; cobas e 601: 209 days
<b>Average time to complete maintenance by lab personnel</b>	daily 5 minutes; weekly: 15 minutes; monthly: 1 hour	daily: 5–31 minutes; weekly: 17–91 minutes; monthly: 6–70 minutes	daily: 7–14 minutes; weekly: 20–45 minutes; monthly: 15–55 minutes
<b>Onboard maintenance records/Maintenance training demo module</b>	no/no	yes/yes	yes (includes audit trail of who replaced parts)/yes
<b>Training provided with instrument purchase</b>	3 days on site	varies on site, 5 days at vendor offices	varies on site, 5 days at vendor offices
<b>Distinguishing features (provided by vendor)</b>	benchtop analyzer provides consolidation of testing in an established compact platform; dedicated multi-speed mixers allow optimum mixing for each assay; direct ISE prevents pseudo-hyponatremia; crash, liquid level, bubble, and clot detection; large clinical test menu; stat capabilities; user-friendly software	24 unique modular configurations to suit a range of throughput and consolidation needs; up to four modules per system; high speed: up to 9,800 tests per hour; innovative design elements: intelligent sample routing with fast transportation and return lines, independent processing lines within each module, the Module Sample Buffer, ready-to-use harmonized reagent cassette concept	flexible modular system—can be upgraded on site; second-generation, integrated platform; ready-to-use bar-coded reagents; automation connectivity; small sample size

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

## Chemistry analyzers for mid- and high-volume laboratories

Part 10 of 11	<b>MID</b>	<b>MID</b>	<b>HIGH</b>
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Name of instrument/First year sold in U.S. List price/Total No. sold in 2010 Number of units in clinical use in U.S./Outside U.S. Where designed/Manufactured/Where reagents manufactured Operational type/Reagent type	Dimension Vista 500 Intelligent Lab System/2009 \$278,271/— >300/>80 U.S./U.S./U.S., Germany batch, continuous random access/self-contained multi-use flex containers	ADVIA 1800/2006 \$299,000/— —/— Japan/Japan/Ireland random access/open reagent system	ADVIA 2400/2003 \$305,000/— —/— Japan/Japan/Ireland random access/open reagent system
Sample handling system/Model type	sample rack and aliquot plate system/floor standing	carousel rack handler option, automation option/floor standing	carousel, rack handler option, automation option/floor standing
Dimensions in inches (H × W × D)/Footprint in square feet	55.5 × 84.75 × 43.875/26	45 × 58 × 34/14	1,157 × 1,711 × 934 mm/—
Number of tests for which analyzer has FDA-cleared applications Tests released for clinical use in last 12 months Tests cleared but not released for clinical use 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	>125, includes vendor-supported applications 10 — — — — fertility panel, plasma proteins, hormones, infectious disease	>100 no pretreat HbA1C serum benzo, barb, TCA, cystatin C, concentrated chemistry reagents — neonatal bilirubin, tricyclics, serum benzo, serum barb — — ecstasy	>100 no pretreat HbA1C serum benzo, barb, TCA, cystatin C, concentrated chemistry reagents — — — —
Methodologies supported/Immunoassay methodologies	nephelometry/LOCI advanced chemiluminescence, EMIT technology, particle enhanced turbidimetric immunoassay (PETINIA), affinity column mediated immunoassay (ACMIA)	photometry, potentiometry, turbidimetric	photometry, potentiometry turbidimetric/—
Number of direct ion-selective electrode channels Number of different measured assays onboard simultaneously Number of different assays programmed and calibrated at once Number of user-definable (open) channels/Number active simultaneously Number of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when third-party reagents used Walkaway capacity in minutes/Specimens/Tests or assays Uses disposable cuvettes/Maximum number stored	3 (indirect) >100 >100 10/>100 100/20 to 1,200 24 hours/30 days/yes (2°–8°C) no yes yes >45/150/61,404 yes/>1,600 washed disposal cuvettes and 1,000 LOCI vessels	3 52 colorimetric, 3 ISE 100 100/52 (plus 3 ISE) 52/850 7 days/45 days/yes yes yes yes 32,000 photometric no/221	3 46 colorimetric, 3 ISE 100 100/49 49/850 7 days/45 days/yes yes yes yes 32,000 photometric no/340
Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption per hour	yes/automatic as needed 50 µL yes/no no/10.8 L	yes/every 4 months 2 µL of diluted specimen yes/yes yes/25 L	yes/every 4 months 2 µL of diluted specimen yes/yes (or sink) yes/40 L
Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	<65 no/10 µL, if using small sample cup yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes	<45 yes/<50 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/—	<50 yes/~50 µL yes/no yes/—
Reagent bar-code reading capability Bar code placement per CLSI standard Auto2A	yes yes	yes yes	yes yes
Onboard test auto inventory (determines volume in container) Measures number of tests remaining/Short sample detection/Clot detection Hemolysis/Turbidity detection-quantitation Sample volume can be reduced Increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown programmable/Startup programmable	yes yes/yes/yes yes/yes no no yes yes/yes 4 hours, automatic/30 to 90 days/30 days/30 days no/no	yes yes/yes/yes yes/yes yes yes yes yes/yes daily/45 days/30 days/30 days yes/yes	yes yes/yes/yes yes/yes yes yes yes yes/yes daily/45 days/30 days/30 days yes/yes
Stat time to completion of all analytes and throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., direct and total bilirubin, AST, ALT, ALP Typical time delay from ordering stat test to aspiration of sample How often QC required/Onboard SW capability to review QC Onboard real-time QC/Support multiple QC lot numbers per analyte System can automatically transfer QC results to LIS	2 minutes, 166 panels 5.5 minutes, 125 specimens 9.4 minutes, 83 specimens <2 minutes 24 hours/yes yes/yes yes	5 minutes, — 10 minutes, — 10 minutes, — 10 seconds per laboratory protocol/— yes/yes yes	5 minutes, — 10 minutes, — 10 minutes, — 10 seconds per laboratory protocol/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface Interfaces to what LISs up and running in active user sites	onboard/no all major LIS vendors	yes/— Soft, Misys, Cerner, Mediatech, Multidata, Seacoast, Triple G, CCA, Computer Service and Support Q, Fletcher Flora, HDS, PSA consultants, Siemens, others	yes/— Soft, Misys, Cerner, Mediatech, Multidata, Seacoast, Triple G, CCA, Computer Service and Support Q, Fletcher Flora, HDS, PSA consultants, Siemens, others
Bidirectional interface capability Uses LOINC to transmit orders and results across interface How labs get LOINC codes for reagent kits	yes (broadcast download and host query) no —	yes (broadcast download and host query) yes via e-mail and software	yes (broadcast download and host query) yes via software
Interface available (or will be) to automated specimen-handling system	yes, StreamLab Automation connectivity in development	yes (all systems)	yes (with ADVIA WorkCell)
Modem servicing available/System can diagnose own malfunctions/ System can determine malfunctioning component On-site time of service engineer Mean time between failures/Mean time to repair failures Average time to complete maintenance by lab personnel	yes/yes/yes 2–8 hours — daily: <10 minutes; weekly: 10 minutes; monthly: 20 minutes	yes/yes/yes — — automated daily maintenance	yes/yes/yes varies by location, generally <4 hours — automated daily maintenance
Onboard maintenance records/Maintenance training demo module Training provided with instrument purchase	no/yes 4 days at vendor offices	yes/yes yes	—/yes yes
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 service	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	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

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

# Chemistry analyzers for mid- and high-volume laboratories

	<b>MID</b>	<b>HIGH</b>	<b>MID</b>
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Name of instrument/First year sold in U.S.	Dimension RxL Max/Max Suite Integrated Chemistry System/2003/Dimension RxL Integrated Chemistry System/1997	Dimension Vista Intelligent Lab System 1500/2006	Dimension EXL with LM Integrated Chemistry System/2009
List price/Total No. sold in 2010	—/—	\$543,500 (USD)/—	—/—
Number of units in clinical use in U.S./Outside U.S.	—	>500/>250	—
Where designed/Manufactured/Where reagents manufactured	U.S./U.S./U.S.	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 flex containers	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	segmented sample wheel/floor standing	sample rack and aliquot plate system/floor standing	segmented sample wheel/floor-standing
Dimensions in inches (H × W × D)/Footprint in square feet	44 × 62.5 × 30.5/13.2	55 × 84 × 43/26	49 × 82 × 44 (without monitor)/25.1 (with printer shelf down)
Number of tests for which analyzer has FDA-cleared applications	>90	>125	>90
Tests released for clinical use in last 12 months	—	10	total PSA, free PSA, LOCI free T3, sirolimus
Tests cleared but not released for clinical use	—	—	—
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	fertility panel, plasma proteins, cardiac, infectious disease	LOCI B12, LOCI folate, MPA, LOCI BNP
Methodologies supported/Immunoassay methodologies	ACMIA, EMIT, PETINIA, photometry, potentiometry/heterogeneous, magnetic particle	photometry, potentiometry (ISE), advanced LOCI chemiluminescence technology, nephelometry, EMIT, PETINIA, PETIA, ACMIA, turbidimetric	photometry, potentiometry, others/LOCI, ACMIA, EMIT, PETINIA and turbidimetric
Number of direct ion-selective electrode channels	3 (indirect) ECO2 photometric	3 (indirect)	3
Number of different measured assays onboard simultaneously	47/91 with optional inventory management system	>100 methods simultaneously/>100 methods	91
Number of different assays programmed and calibrated at once	190	>100	190
Number of user-definable (open) channels/Number active simultaneously	10/10	10/>100	10/10
Number of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	44–88/maximum 360	>100/20 to 1,200	91/15–360
Shortest/Median onboard reagent stability/Refrigerated onboard	48 hours/30 days/yes (2°–8°C)	24 hours/30 days/yes (2°–8°C)	24 hours/30 days/yes (2°–8°C)
Multiple reagent configurations supported	yes	no	yes
Reagent container placed directly on system for use	yes	yes	yes
Instrument has same capabilities when third-party reagents used	yes	yes	yes
Walkaway capacity in minutes/Specimens/Tests or assays	can be hours/60/>2,000 or >5,000 (with RMS)	>45 minutes/150/61,404	can be hours/60/>2,000
Uses disposable cuvettes/Maximum number stored	yes/12,000	yes/>1,600 washed, disposable cuvettes and 1,000 LOCI vessels	yes/12,000
Uses washable cuvettes/Replacement frequency	no/—	yes/automatic	no/—
Minimum sample volume aspirated precisely at one time	2 µL	50 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no	yes/no
Requires dedicated water system/Water consumption per hour	yes/3.2 L (3.2–5.0 L with optional inventory management system)	no/21.6 L	yes/up to 5 L
Noise generated in decibels	<70	67	<75
Dedicated pediatric sample cup/Dead volume	yes/10–20 µL	no (can use routine sample cup)/10–20 µL	yes/30 µL
Primary tube sampling/Pierces caps on primary tubes	yes, 5, 7, 10 mL/no	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 and 128)/yes
Reagent bar-code reading capability	yes	yes	yes
Bar code placement per CLSI standard Auto2A	yes	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes	yes
Measures number of tests remaining/Short sample detection/Clot detection	yes/yes/no	yes/yes/yes	yes/yes/yes
Hemolysis/Turbidity detection-quantitation	yes/yes	yes/yes	yes/yes
Sample volume can be reduced	yes	no	yes
Increased to rerun out-of-linear-range high/low results	no	no	no
Autocalibration or autocorrection alert	yes	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes (Na, K, Cl)/yes	yes/yes	yes (Na, K, Cl)/yes
Typical calib. frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	autocalibration every 2 hours/—/60 to 90 days/30 days	automatic every 4 hours/30 to 90 days/30 days/30 days	autocalibration every 2 hours/60–90 days/30 days
Automatic shutdown programmable/Startup programmable	—/—	no/no	no/no
Stat time to completion of all analytes and throughput per hour for:			
• Sodium, potassium, chloride, TCO2	36 sec (Na, K, Cl)/2 minutes with ECO2, 300 ISE or 500 photometric tests/hour, 100 panels	2 minutes, 166 panels	2 minutes (not TCO2, ECO2 for enzymatic), 62 specimens, 187 ISE and 437 photometric tests
• Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	5.5 minutes, 300 ISE or 500 photometric tests/hour, 100 panels	5.5 minutes, 125 specimens	5.5 min (ECO2 not TCO2 [enzymatic]), 62 specimens, 187 ISE and 437 photometric tests
• Album., direct and total bilirubin, AST, ALT, ALP	9 minutes, 500 tests/hour or 83 panels	9.4 minutes, 83 specimens	—
Typical time delay from ordering stat test to aspiration of sample	24 seconds	<2 minutes	24 seconds
How often QC required/Onboard SW capability to review QC	24 hours/yes	24 hours/yes	24 hours or with lot change /yes
Onboard real-time QC/Support multiple QC lot numbers per analyte	no/yes	yes/yes	yes/yes
System can automatically transfer QC results to LIS	yes	yes, via EasyLink	no
Data management capability/Instrument vendor supplies LIS interface	optional add-on (EasyLink, Siemens)/yes (additional cost)	onboard/no	yes, onboard, optional add-on (EasyLink Informatics System, SW mfr: Siemens Healthcare Diagnostics)/yes (additional cost)
Interfaces to what LISs up and running in active user sites	all major LIS vendors	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	yes (broadcast download and host query)	yes (broadcast download and host query)	yes (broadcast download, host query)
Uses LOINC to transmit orders and results across interface	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Interface available (or will be) to automated specimen-handling system	yes	yes, Siemens StreamLab, SpecTrak; Advia automation in development	—
Modem servicing available/System can diagnose own malfunctions/ System can determine malfunctioning component	yes/yes/yes	yes/yes/yes	yes/yes/yes
On-site time of service engineer	2–8 hours	2–8 hours	2–8 hours
Mean time between failures/Mean time to repair failures	—/—	—	—
Average time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes	daily: 10 minutes; weekly: 10 minutes; monthly: 20 minutes	daily: 5 minutes; weekly: 10 minutes; monthly: 23 minutes
Onboard maintenance records/Maintenance training demo module	no/no	in development/yes	no/no
Training provided with instrument purchase	5 days on site, 4 days at vendor offices	4 days on site, 4 days at vendor office	5 days on site, 4 days at vendor offices
Distinguishing features (provided by vendor)	integrates heterogenous immunoassays onboard with other chemistries; allows single platform for more than 95 percent of most requested tests; eliminates sample splitting between general tests and immunoassays	intelligent lab systems with customer-driven design, ultra-integration of technologies; LOCI advanced chemiluminescence and automation onboard for efficiency, simplicity, sensitivity, and convenience to provide an efficient workflow for the laboratory; autocorrection and auto QC onboard; proactive services and support through RealTime Solution	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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