

Chemistry analyzers (for low-volume laboratories)

<p>Part 1 of 12</p> <p>See accompanying article on page 20</p>	<p>Abaxis Inc. Rick Betts rickbetts@abaxis.com 3240 Whipple Rd., Union City, CA 94587 800-822-2947 www.abaxis.com</p>	<p>Abbott Point of Care Glen Tinevez glen.tinevez@abbott.com 104 Windsor Center Dr., East Windsor, NJ 08520 800-827-7828 www.abbottpointofcare.com</p>
<p>Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint</p>	<p>Piccolo Xpress/2006 \$16,500/— 2,500/4,000 U.S./U.S./U.S. discrete/self-contained single-use cartridges-packages-slides disc loaded directly into instrument/benchtop 12.75 x 6 x 8/<1 sq. ft.</p>	<p>i-Stat 1 analyzer/2000 — 30,000+ worldwide U.S./U.S./Canada —/self-contained single-use cartridges packages-slides —/handheld 9.25 x 3.0 x 2.85/< 1 sq. ft.</p>
<p>Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development User-defined methods implemented for what analytes</p>	<p>ALP, ALT, AST, GGT, amylase, albumin, total protein, bilirubin total, BUN, creatinine, calcium, cholesterol, glucose, uric acid, sodium, creatine kinase, potassium, TC02, chloride, cholesterol, HDL ratio, HDL, LDL, triglycerides-VLDL, phosphorus, direct bilirubin, magnesium, LD, C-reactive protein — — — — —</p>	<p>tropinin I, CK-MB, lactate, BUN, creatinine, glucose, ionized calcium, sodium, potassium, chloride, hematocrit, pH, PCO2, PO2, TC02, ACTc, ACTk, PT/INR, hemoglobin, HCO3, BEcf, SO2, anion gap, BNP — — — — —</p>
<p>Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of different assays in pack • Separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates 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 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Maximum No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L 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 Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspiration and analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown/Startup programmable</p>	<p>photometry, enzymatic/— 0 (system is enzymatic) yes/from 2–14 no CLIA-waived CMP has 14 analytes 14 0/— 29/up to 14 —/—/yes (0°–8°C) yes yes — based on volume, most commonly \$0.51 per test/—/based on volume, most commonly \$0.71 per test 30 seconds hands-on; 12 minutes to printed result/1/up to 29 available analytes in menu, up to 14 per reagent disc liquid reconstitutes onboard no/28 cuvettes per reagent disc no/— requires 80 to 100 µL of whole blood, serum, or plasma yes/no no/— none no/— no/no Intelligent Quality Control system automatically reads bar code on disc/— yes yes — —/yes/yes yes yes/yes yes/no —/— yes yes/yes self-calibrated onboard/self-calibrated onboard/—/— yes/yes</p>	<p>potentiometry, amperometric, conductometric/— 10 no (unit-use cartridge based)/up to 13 yes — 18 — —/unit use —/14 days/no no — — based on volume/—/based on volume 2/1/up to 18 — no/— no/— 16 µL no/no no/— none no/— no/no yes (reads operator, cartridge, and patient bar code)/yes yes yes — —/yes/yes yes no/no no/no no/no yes no/yes each test/each test/—/— yes/yes</p>
<p>Stat time to completion of all analytes, throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct & 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 Nos. per analyte QC results transferred automatically to LIS</p>	<p>30 seconds hands-on, 10–12 minutes to printed result, 2–14 tests per disc 30 seconds hands-on, 10–12 minutes to printed result, 2–14 tests per disc 30 seconds hands-on, 10–12 minutes to printed result, 2–14 tests per disc 0 shortest: automatic QC onboard w/every run; longest: external high/low QC required monthly, according to CLIA guidelines/yes yes/yes yes</p>	<p>2 minutes, — 2 minutes, — — none shortest interval: 24 hours; longest interval: each new lot or reagent/yes yes/yes yes</p>
<p>Data management capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites Bidirectional interface capability Test results transmitted to LIS as soon as chemistry time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits</p>	<p>onboard/no many yes (broadcast download, host query) yes yes yes Web site, package insert, e-mail query</p>	<p>optional add-on (<\$30,000, SW mfr: Abbott Point of Care)/yes (add'l cost) all systems yes (broadcast download and host query) yes yes yes customized on site</p>
<p>Lab can control analyzer remotely Interface available (or will be) to automated specimen handling system</p>	<p>yes yes</p>	<p>yes —</p>
<p>Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of service engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced oper. training available Annual service contract cost (24 h/7 d)</p>	<p>yes/yes/yes not necessary, 24-hour RMA turnaround of loaner instruments/yes none, some in use for 5 years without failures/replacement within 24 hours daily: none; weekly: none; monthly: 1 minute to clean air filter yes/yes 1–2 hours maximum; then provided via free Webcast as needed/yes 1-year warranty standard; 3 years often free through distribution partners; \$1,195 for additional years</p>	<p>yes/yes/yes replacement within 24 hours/yes not determined/replacement within 24 hours daily: none; weekly: none; monthly: none — —/yes based on volume</p>
<p>Distinguishing features (supplied by company)</p>	<p>comprehensive CLIA-waived menu of tests; 15 available discs (11 CLIA-waived) represent most commonly ordered chemistry panels; works with three simple steps, as easy to operate as a CD player; provides lab-accurate results on site, in minutes, using 100-µL sample of whole blood, serum, or plasma; intranet connectivity helps labs extend their reach to the point of care, while maintaining centralized control of test data</p>	<p>handheld portable analyzer; unit use system can perform chemistry, blood gas, cardiac marker, and coagulation tests on two drops of whole blood or plasma</p>

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

Chemistry analyzers (for low-volume laboratories)

Part 2 of 12	Alfa Wassermann Diagnostic Technologies LLC Lauren DiPrima ldiprima@alfawassermannus.com 4 Henderson Dr., West Caldwell, NJ 07006 800-220-4488 www.alfawassermannus.com	AMS Diagnostics, LLC Bruno Borganti bb@amsdiagnostics.com 2410 Settlers Street, Charleston, SC 29492 866-419-7839 www.amsdiagnostics.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	ACE/1993; ACE Alera Clinical Chemistry System/2004 \$69,995/— 1,300/800+ U.S./U.S./U.S. batch, random access, discrete, continuous random access/stat and closed reagent system with open reagent system channel ring with up to 5 segments (15 samples per segment)/benchtop	LIASYS (330)/2009 \$39,950/— 18/1,345 Europe-U.S./Europe-U.S./Europe-U.S. batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides
Sample handling system/Model type	5 sliding racks for primary tubes from 10–16 mm diameter, from 40–100 mm height, short cups 1 mL, short cups 3 mL, conical/benchtop	16.5 × 39.3 × 25.6/4.4 sq. ft.
Dimensions in inches (H × W × D)/Instrument footprint	ACE: 15.75 × 27.25 × 22.50; ACE Alera: 23 × 27.5 × 22.5/4.3 sq. ft.	
Tests available on instrument in U.S.	albumin, gamma GT, bilirubin direct & total, calcium, creatinine, glucose, inorganic phosphorus, total iron, magnesium, total protein, BUN, uric acid, amylase, AST (GOT), alkaline phosphatase, ALT (GPT), CK, LDH, cholesterol, HDL-C, LDL-C, triglycerides, sodium, potassium, chloride, CO ₂ , T ₄ , T-uptake, HbA1c, lipase, direct TIBC, ferritin, Lp(a), microalbumin, apo A1, apo B, transferrin	general chemistries, electrolytes, enzyme assays, lipid assays, HbA1c, lipase, microalbumin, microprotein, rheumatoid factor, DOA, others
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for FDA 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	UIBC	antithrombin III, a1 antitrypsine, ceruloplasmin, chains λ, chains K, fibrinogen, haptoglobin, others
Research-use-only assays/Tests in development	—/direct A1c, enzymatic creatinine, neonatal bilirubin, hsCRP, urine applications (creatinine, urea, calcium, phosphorous)	—/vitamin D
User-defined methods implemented for what analytes	open-channel bottles are available for user-derived or third-party reagents	—
Methods supported/Immunoassay methods	photometry, potentiometry (ion-selective electrode), turbidimetric homogen. EIA	photometry, potentiometry (ion-selective electrode)/turbidimetry
No. of direct ion selective electrode channels	3	3
• Must load separate reagent pack for each specimen/No. of different assays in pack	no/—	no/—
• Separate reagent pack for each test run	no	—
No. of different measured assays onboard simultaneously	40	36
No. of different assays programmed, calibrated at once	200	36
No. of user-definable (open) channels/No. active simultaneously	15/15	200/36
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	40/30–250 tests per bottle	36/250–400
Shortest/Median onboard reagent stability/Refrigerated onboard	5 days/30 days/yes (10°–14°C)	7 days/20 days/yes (2°–8°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reagent used	yes	yes
Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes	\$0.16/—/\$3.50	from \$0.15 to \$0.40 (lowest cost of ownership)/—/—
Walkaway capacity in minutes/No. of specimens/No. of tests-assays	75/75/248	240/64/36
System is liquid, dry, or reconstituted onboard	liquid	liquid
Uses disposable cuvettes/Maximum No. stored	yes/248	no/60
Uses washable cuvettes/Replacement frequency	no/—	yes/40,000 tests
Minimum sample volume aspirated precisely at one time	3 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no
Requires dedicated water system/Water consumption in L per hour	no/—	no/0.5
Noise generated in decibels	55	45
Dedicated pediatric sample cup/Dead volume	no/—	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/yes	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, as sample is being aspirated (2 of 5 interleaved, UPC, Codabar, code 39, code 128 set B & C)/yes	yes/yes
Reagent bar-code reading capability	yes, proprietary dot coding	yes
Bar-code placement per CLSI standard Auto2A	no	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures No. of tests remaining/Short sample detection/Clot detection	yes/yes/no	yes/yes/no
Automatic detection of adequate reagent for aspiration and analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	—	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	yes/no	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	no/yes	yes/yes
Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	3 hours/30 days/45 days with 48-hour updates/—	autocalibrate/14 days/14 days/14 days
Automatic shutdown/Startup programmable	—	no/no
Stat time to completion of all analytes, throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct & 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 Nos. per analyte QC results transferred automatically to LIS	4 minutes, 35 specimens 7 minutes, 20 specimens 10 minutes, 12 specimens immediate response, as soon as 10 seconds daily/yes yes/yes yes	122 specimens/hour (1st result after 7 minute, 12 sec) namely 488 tests/hour 35 specimens/hour (1st result after 8 minute, 6 sec) namely 245 tests/hour 24 specimens/hour (1st result after 9 minute, 20 sec) namely 144 tests/hour 18 seconds 8–24 hours/yes no/yes no
Data management capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites Bidirectional interface capability Test results transmitted to LIS as soon as chemistry time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	onboard/no Antek, Apex, LabPak, Schuyler House, others yes (broadcast download) yes, when requisition is done yes no —	onboard (AMS)/yes, included Antek, Fletcher, Flora, others yes (broadcast download and host query) yes yes no —
Lab can control analyzer remotely Interface available (or will be) to automated specimen handling system	no no	yes no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of service engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced oper. training available Annual service contract cost (24 h/7 d)	no/yes/yes 24 hours/yes 8 months/1 hour daily: 15 minutes; weekly: 30 minutes; monthly: 60 minutes yes/no 4.5 days at manufacturer's facility/yes varies, several programs available	yes/yes/yes engineers are on standby/yes 11.5 months/90 minutes daily: 5 minutes; weekly: 5 minutes; monthly: 15 minutes no/— 3 days on site, 1 day at vendor offices/yes \$8,900 (M-F), warranty extension
Distinguishing features (supplied by company)	closed-tube sampling; easy-to-use multitasking software; stat interrupt capability; onboard sample and reagent refrigeration; onboard reagent inventory management; ready-to-use reagents; integrated ISE module; self-contained analyzer; no external water source or waste drainage	monitors cuvette cleanliness, flags its replacement; cuvettes can change immediately; displays all system & patient tests status on first screen; at a glance interface design saves time running chemistry panels; precision data comparison; runs three reagent methods; suitable for more esoteric testing in development; automatic samples predilution, postdilution, and post-concentration

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Part 3 of 12	Awareness Technology Rob Guerin info@awaretech.com 1935 S.W. Martin Hwy., Palm City, FL 34990 772-283-6540 www.awaretech.com	Awareness Technology Rob Guerin info@awaretech.com 1935 S.W. Martin Hwy., Palm City, FL 34990 772-283-6540 www.awaretech.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	ChemWell-T/2010 \$12,500/0 1/9 U.S./U.S./open system batch, random access, continuous random access/open reagent system	Stat Fax 4500/2009 \$2,695/— 5/325 U.S./U.S./open system —/open reagent system
Sample handling system/Model type	custom-configurable rack/benchtop	tube, cuvette, or flowcell/benchtop
Dimensions in inches (H × W × D)/Instrument footprint	20 × 21 × 16/3 sq. ft.	5 × 9 × 13.5/<1 sq. ft.
Tests available on instrument in U.S.	open system	open system
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for FDA 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays/Tests in development	—	—
User-defined methods implemented for what analytes	—	—
Methods supported/Immunoassay methods	photometry	photometry
No. of direct ion selective electrode channels	—	—
• Must load separate reagent pack for each specimen/No. of different assays in pack	—	—
• Separate reagent pack for each test run	—	—
No. of different measured assays onboard simultaneously	40	—
No. of different assays programmed, calibrated at once	—	1
No. of user-definable (open) channels/No. active simultaneously	PC-based	99/1
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	variable/—	—
Shortest/Median onboard reagent stability/Refrigerated onboard	—/—/yes (9°–12°C below ambient)	—/no
Multiple reagent configurations supported	yes	—
Reagent container placed directly on system for use	yes	—
Instrument has same capabilities when 3rd-party reagent used	yes	yes
Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes	—	—
Walkaway capacity in minutes/No. of specimens/No. of tests-assays	—/—/40	—
System is liquid, dry, or reconstituted onboard	liquid	liquid
Uses disposable cuvettes/Maximum No. stored	yes/40	yes/12
Uses washable cuvettes/Replacement frequency	yes/variable	yes/supplier-dependent
Minimum sample volume aspirated precisely at one time	2 µL	250 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	no/no
Requires dedicated water system/Water consumption in L per hour	no/—	no/—
Noise generated in decibels	—	<45
Dedicated pediatric sample cup/Dead volume	no/—	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	—/—
Sample bar-code reading capability/Autodiscrimination	no/no	no/—
Reagent bar-code reading capability	no	—
Bar-code placement per CLSI standard Auto2A	no	—
Onboard test auto inventory (determines volume in container)	yes	—
Measures No. of tests remaining/Short sample detection/Clot detection	—/yes/no	—
Automatic detection of adequate reagent for aspiration and analysis	yes	—
Hemolysis/Turbidity detection-quantitation	no/no	—
Dilution of patient samples onboard/Automatic rerun capability	yes	—
Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	yes/yes	—
Autocalibration or autocalibration alert	yes	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	—/yes
Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	—	—
Automatic shutdown/Startup programmable	no/no	no/no
Stat time to completion of all analytes, throughput per hour for:		
• Sodium, potassium, chloride, TCO ₂	—	—
• Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine	—	—
• Albumin, direct & 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	—/yes	—
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	—
QC results transferred automatically to LIS	yes	—
Data management capability/Instrument vendor supplies LIS interface	onboard/—	no/no
Lab information systems with which interfaces up and running in active user sites	—	—
Bidirectional interface capability	yes	no
Test results transmitted to LIS as soon as chemistry time complete	host query	—
LIS interface operates simultaneously with running assays	yes	—
Uses LOINC to transmit orders and results	no	—
How labs get LOINC codes for reagent kits	—	—
Lab can control analyzer remotely	no	no
Interface available (or will be) to automated specimen handling system	no	—
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	yes/yes/yes	—
On-site time of service engineer/Onboard error codes for troubleshooting	—/yes	—/yes
Mean time between failures/To repair failures	—	—
Average time to complete maintenance by lab personnel	daily: 5 minutes; monthly: 15 minutes	—
Onboard maintenance records/Maintenance training demo module	yes/no	—
Training provided with purchase/Advanced oper. training available	—/yes	—
Annual service contract cost (24 h/7 d)	varies per distributor	—
Distinguishing features (supplied by company)	versatile open system with ability to run biochemistry and turbidimetric assays; universal rack for reagent containers, controls, and calibrators for regular, stat, and pediatric samples; user decides which ones and how many rack positions to allocate for each; compact, economical instrument designed to bring automation to lower-throughput labs, and for use as a backup to larger systems	cost-effective with long-life IAD filters; self-prompting touchscreen with mouse-compatible interface for easy selections and entries; optional built-in flowcell for reduced sample volumes

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Chemistry analyzers (for low-volume laboratories)

Part 4 of 12	Beckman Coulter Inc. 200 South Kraemer Blvd., P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com	Carolina Liquid Chemistries Patricia A. Shugart contactsales@carolinachemistries.com 391 Technology Way, Suite 2, Winston Salem, NC 27101 877-722-8910 www.carolinachemistries.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type	AU480 Clinical System/2009 —/0 <10/<10 Japan/Japan/Ireland continuous random access/open reagent system continuous loading rack feeder holds up to 80 samples, while 22 samples are accommodated via stat turntable/floor-standing	BioLis 24i/2008 \$60,000/— >200/3,000 Japan/Japan/USA batch, random access, continuous random access/open reagent system sample ring/benchtop
Dimensions in inches (H × W × D)/Instrument footprint	47.5 × 57.1 × 30/18.1 sq. ft. (includes PC stand)	20 × 31 × 25/5 sq. ft.
Tests available on instrument in U.S.	125-reagent test menu available, including general chemistry: albumin, ALP, ALT, ammonia, amylase, AST, bicarbonate, bilirubin (total, direct), calcium (arsenazo), calcium (oCPC), chloride, cholesterol, cholinesterase, CK-MB, CK-NAC, creatinine, GGT, glucose, HDL cholesterol (direct), inorganic phosphorus, iron, more; special chemistry: α1-acid glycoprotein, a1-antitrypsin, anti-streptolysin O, apolipoprotein A1, apolipoprotein B, β2-microglobulin, C3 complement, C4 complement, ceruloplasmin, C-reactive protein, D-dimer, more; TDM: acetaminophen, amikacin, caffeine, carbamazepine, more	100, GlycoMark
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development User-defined methods implemented for what analytes	— — — —/HbA1c (fully automated) total open system, unlimited	Lp-PLA2 vitamin D — —/vitamin D —
Methods supported/Immunoassay methods	photometry, potentiometry (ion-selective electrode), homogenous EIA, turbidimetry, latex agglutination/—	photometry, potentiometry/—
No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of different assays in pack • Separate reagent pack for each test run	3 electrodes, indirect method no/— no	3 no/— no
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	63 63 60/all up to 60 different assays/50–1,500 (per vial)	39 39 39/39 39/3 × 300
Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes	336 hours/30 days/yes (4°–12°C) yes yes yes —	7 days/14 days/yes (2°–8°C) yes yes yes —
Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Maximum No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L 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	1 hour/80/various, depends on bottle size liquid no/— yes/permanent 1 µL no/yes yes/20 <60 yes/30 µL if using Hitachi micro cup, others can be used yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codebar, codes 39 & 128)/yes	4 hours/40/39 liquid no/— yes/— — yes/no yes, water system provided with instrument/— — yes/30 µL yes/no yes (on sample transport, shortly before sample is aspirated, codes 39 & 128)/yes
Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/ Clot detection Automatic detection of adequate reagent for aspiration and analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/ Drugs of abuse Automatic shutdown/Startup programmable	yes yes yes yes/yes/yes yes yes/yes yes/yes yes/yes yes yes/yes daily/average 14 days, user-defined/average 14 days yes/yes	yes yes/yes yes/yes yes/yes no yes/yes 24 hours/14 days/14 days/14 days yes/yes
Stat time to completion of all analytes, throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct & 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 Nos. per analyte QC results transferred automatically to LIS	7 minutes, 42 seconds to print, 200 specimens 9 minutes, 25 seconds to print, 80 specimens 9 minutes, 43 seconds to print, 50 specimens minimum: 9 seconds from when sampling commences user defined/yes yes/yes yes	12 minutes, 160 specimens 1 hour, 60 specimens 14 minutes, 240 specimens 5 minutes 8–24 hours/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites Bidirectional interface capability Test results transmitted to LIS as soon as chemistry time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	no/no, additional — yes, host query yes yes yes Web site, package insert, reagent lot and bottle info sent through interface	onboard/yes (additional cost) Fletcher Flora, Lab Track, and several other common systems yes (broadcast download, host query) yes yes — —
Lab can control analyzer remotely Interface available (or will be) to automated specimen handling system	yes no	no no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of service engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced oper. training available Annual service contract cost (24 h/7 d)	yes/yes/yes —/yes new instrument, info not available daily: 10 minutes; weekly: 59 minutes; monthly: 45 minutes yes/yes 5 days at vendor offices/yes contract dependent	no/yes/yes 24 hours/yes — daily: visual; weekly: 20 minutes; monthly: visual inspections <5 minutes yes (includes audit trail)/no 5 days on site/yes —
Distinguishing features (supplied by company)	reliable system; standardized reagents/consumables across AU family ensures high productivity and efficiency; improved GUI, Windows XP OS with touchscreen simplifies training and operation	water system eliminates need to purchase, ship, and store cubes of water; HbA1c performed directly onboard w/results equivalent to HPLC, don't need separate HbA1c analyzer; small size, large menu, 39 onboard chemistries; runs general and special chemistries from CMPs to D-dimer, cystatin C, insulin, more

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

Chemistry analyzers (for low-volume laboratories)

Part 5 of 12	HORIBA Medical Stephanie Rimer stephanie.rimer@horiba.com 34 Bunsen Dr., Irvine, CA 92618 888-903-5001 www.horiba.com/us/en/medical	3M Brian T. Anderson bbanderson@mmm.com 3M Center, 275-4W-02, St. Paul, MN 55144 651-736-2614 www.3m.com/medicaldiagnostics
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	ABX Pentra 400/2006 \$89,000/80 176/1,003 France/France/France & U.S. batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides, open reagent system rack/benchtop	3M Rapid Detection Reader/2008 \$5,300/50 50/0 Canada/Canada/Canada random access, discreet/self-contained single-use cartridges, packages, slides
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	—/benchtop 25 × 40 × 28 in/7.7 sq. ft.	—/benchtop 8 × 7.5 × 7.25/5 sq. ft.
Tests available on instrument in U.S.	albumin, calcium, sodium, alk phos, ALT, carbon dioxide, glucose (PAP), lipase, total protein, chloride, glucose (hexokinase), magnesium, triglycerides, amylase, cholesterol, nitrogen, iron, myoglobin, uric acid, total bilirubin, creatinine, lactic acid, phosphorus, direct bilirubin, potassium, HDL, CK, CRP, GGT, LDH, LDL, urea nitrogen, micro Alb, urinary protein	3M rapid detection flu A and B test, 3M rapid detection RSV test
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for FDA 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	alpha 1 antitrypsin, C3, C4, ceruloplasmin, orosomucoid, heparin, kappa chains, lambda chains	—
Research-use-only assays/Tests in development	—/TDMs, DAUs	—/other infectious disease tests
User-defined methods implemented for what analytes	alcohol, apolipoprotein A1, apolipoprotein B, beta 2, microglobulin, ferritin, fructosamine, GlycoMark, haptoglobin, Hgb A1c, homocysteine, HS CRP, IgA, IgG, IgM, pre albumin, rheumatoid factor, TIBC, transferrin, UIBC	—
Methods supported/Immunoassay methods	photometry, potentiometry (ion selective electrode), turbidimetric/—	—/quantitative lateral flow immunochromatographic assay
No. of direct ion selective electrode channels	3	—
• Must load separate reagent pack for each specimen/No. of different assays in pack	no/—	no/—
• Separate reagent pack for each test run	no	no
No. of different measured assays onboard simultaneously	55	2
No. of different assays programmed, calibrated at once	55	up to 50
No. of user-definable (open) channels/No. active simultaneously	15/15	0/—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	55/100 to 400	2/—
Shortest/Median onboard reagent stability/Refrigerated onboard	8 hours/30 days/yes (15°–32°C)	—/no
Multiple reagent configurations supported	yes	no
Reagent container placed directly on system for use	yes	requires operator prehandling, preparation
Instrument has same capabilities when 3rd-party reagent used	yes	—
Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes	—	—
Walkaway capacity in minutes/No. of specimens/No. of tests-assays	2 hours/60/—	15 minutes/2–6/1
System is liquid, dry, or reconstituted onboard	liquid	dry
Uses disposable cuvettes/Maximum No. stored	yes/432	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum sample volume aspirated precisely at one time	2 µL	—
Supplied with UPS (backup power)/Requires floor drain	no/no	no/no
Requires dedicated water system/Water consumption in L per hour	no/0.5 average	no/—
Noise generated in decibels	<66	—
Dedicated pediatric sample cup/Dead volume	no/—	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	no/no
Sample bar-code reading capability/Autodiscrimination	yes/no	by optional handheld scanner at time of sample preparation/yes
Reagent bar-code reading capability	yes	yes
Bar-code placement per CLSI standard Auto2A	yes	—
Onboard test auto inventory (determines volume in container)	yes	no
Measures No. of tests remaining/Short sample detection/Clot detection	yes/yes/yes	—
Automatic detection of adequate reagent for aspiration and analysis	yes	—
Hemolysis/Turbidity detection-quantitation	yes/yes	—
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	no/no
Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	yes/yes	—
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	—
Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	2 hours/14 days/—/—	—/once per reagent log/—/—
Automatic shutdown/Startup programmable	no/yes	no/no
Stat time to completion of all analytes, throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct & total bilirubin, AST, ALT, ALP	<5 minutes, — 7.5 minutes, 35 specimens <11 minutes, 23 specimens	— — —
Typical time delay from ordering stat test to aspiration of sample	1–2 minutes	—
How often QC required/Onboard SW capability to review QC	8 hours/yes	shortest: per local requirements; longest: each new lot or shipment/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data management capability/Instrument vendor supplies LIS interface	onboard/no	onboard/no
Lab information systems with which interfaces up and running in active user sites	Antek, Fletcher Flora, Mediatech, Orchard, Schuyler House, Sunquest, Technidata	Telcor
Bidirectional interface capability	yes	no
Test results transmitted to LIS as soon as chemistry time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders and results	no	—
How labs get LOINC codes for reagent kits	—	—
Lab can control analyzer remotely	no	no
Interface available (or will be) to automated specimen handling system	no	no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	no/—/—
On-site time of service engineer/Onboard error codes for troubleshooting	<24 hours/yes	depot service/yes
Mean time between failures/To repair failures	—/ <24 hours	—/overnight replacement
Average time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 5 minutes; monthly: 15 minutes	none required
Onboard maintenance records/Maintenance training demo module	yes/yes	no/no
Training provided with purchase/Advanced oper. training available	4 days at corporate office in California/yes	1 day on site/yes
Annual service contract cost (24 h/7 d)	—	varies
Distinguishing features (supplied by company)	benchtop design offers the flexibility to run more than 53 assays with room for 55 onboard tests operated by a user-friendly, color-coded touchscreen validation station; high throughput up to 420 tests/hr; clot level and crash protection; auto rerun, autocalibration, and autodilution; ability to run up to three reagents on a single assay; most reagents in plug-and-play cassettes	small automated reader for objective reading of results; multiple error-checking and self-diagnostic functions ensure procedural control; data-management capability

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

Chemistry analyzers (for low-volume laboratories)

Part 6 of 12	Medica Corp. Charlene Soley csoley@medicacorp.com 5 Oak Park Drive, Bedford, MA 01730 781-275-7425 www.medicacorp.com	Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Easy RA/2009 \$60,000/22 13/41 U.S./U.S./U.S. batch, random access, discrete, continuous random access/self-contained multi-use cartridges-packages-slides	Stat Profile Critical Care Xpress/2002 —/— —/— U.S./U.S./U.S. discrete/self-contained multi-use cartridges
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	two sample rings (up to 48 samples)/benchtop 15 × 40 × 26/7.2 sq. ft.	sample automatically drawn from syringe, capillary, or open tube/benchtop 17.2 × 17.3 × 22.3/2.7 sq. ft.
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development User-defined methods implemented for what analytes	albumin, alk phos, alanine aminotransferase (ALT, SGPT), aspartate aminotransferase (AST, SGOT), calcium, chloride, cholesterol, CK, creatinine (serum & urine), GGT, glucose-trinder, HDL cholesterol, LDH, lithium, potassium, sodium, total protein, blood urea nitrogen, GLU-H, direct bilirubin, total bilirubin, triglycerides, uric acid, phosphorus, magnesium, CO ₂ , CK, amylase, iron, LDL — — — —/HbA1c, microalbumin, CK-MB, lipase, hsCRP, TIBC, drugs of abuse, creatinine (jaffe)	pH, PCO ₂ , PO ₂ , SO ₂ %, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, ionized Mg, glucose, BUN, creatinine, lactate, bilirubin, deoxyhemoglobin, oxyhemoglobin, methemoglobin, carboxyhemoglobin — — — —
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of different assays in pack • Separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates 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 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Maximum No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L 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	photometry, potentiometry 4 no/— no 28 140 6/6 28/80 to 250 168 hours/30 days/yes yes yes — \$0.16/—/— 36/24/28 liquid yes/72 no/— 2 µL no/no no/— minimal no/— yes/no yes	potentiometry (ISE), optical, reflectance/— 12 no/— no 20 20 0/— 20/200–500 samples (2,600–6,500 tests), depending on lab 45 days/45 days/no — requires operator prehandling, preparation — cost varies with volume/—/— — ISE no/— no/— 60 µL no (optional)/no no/— minimal no/— yes/no yes (optional), by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes yes no yes yes/yes/yes yes yes (on co-oximeter module)/yes (on co-oximeter module) yes (on co-oximeter module)/no no/no yes yes/yes 30–120 minutes/30–120 minutes/—/— yes/yes
Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspiration and analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown/Startup programmable	no, uses RFID — yes yes/yes/no yes no/no yes/yes yes/no yes no/yes 8 hours/30 days/—/— no/no	yes no yes yes/yes/yes yes yes (on co-oximeter module)/yes (on co-oximeter module) yes (on co-oximeter module)/no no/no yes yes/yes 30–120 minutes/30–120 minutes/—/— yes/yes
Stat time to completion of all analytes, throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct & 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 Nos. per analyte QC results transferred automatically to LIS	3 minutes, 200 specimens 8 minutes, 100 specimens 9 minutes, — <1 minute CLIA minimum/yes no/yes yes	50 seconds, 26–36, depending on use mode 123 seconds, 21–24, depending on use mode —, — <2 seconds 8 hours/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites Bidirectional interface capability Test results transmitted to LIS as soon as chemistry time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	onboard/yes Orchard, Antek yes yes yes no —	onboard/no — yes yes yes no —
Lab can control analyzer remotely Interface available (or will be) to automated specimen handling system	no no	yes no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of service engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced oper. training available Annual service contract cost (24 h/7 d)	no/yes/yes — <24 hours/yes 1 year/— daily: 20 minutes; weekly: —; monthly: 30 minutes no/no yes/— varies	yes/yes/yes — <8 business hours/yes — weekly: <5 minutes; monthly: <15 minutes yes (includes audit trail of who replaced parts)/yes yes/yes —
Distinguishing features (supplied by company)	simplified user interface accessed through a touchscreen display; RFID-tagged reagents allow for reading and writing capability; all reagent parameters programmed on the wedge, no data entry; easy-to-replace components all located in a slide-out drawer; comprehensive inventories of all system components	comprehensive 20-test critical care profile, including ionized Mg, BUN, and creatinine; color touchscreen; integrated co-oximeter; open software architecture; onboard data management; automated onboard quality control; sealed waste system; auto-monitoring of QC and reagent packs; tankless gas calibration; automated maintenance

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

Chemistry analyzers (for low-volume laboratories)

Part 7 of 12	Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com	Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Stat Profile pH0x series/1998 —/— —/— U.S./U.S./U.S. discrete/self-contained multi-use cartridges-packages-slides	Nova 16/1995 —/— —/— U.S./U.S./U.S. batch, random access/self-contained multiuse cartridges
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	sample automatically drawn from syringe, capillary, or open tube/benchttop 15 × 15 × 18/1.9 sq. ft.	40-position tray, stat sampling directly from sample container/benchttop 20.5 × 19.2 × 20.7/2.75 sq. ft.
Tests available on instrument in U.S.	pH, PCO ₂ , PO ₂ , SO ₂ %, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, glucose, lactate	sodium, potassium, chloride, total CO ₂ , glucose, BUN, creatinine, Hct
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries	— — —	— — —
Research-use-only assays/Tests in development User-defined methods implemented for what analytes	— —	— —
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of different assays in pack • Separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates 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 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Maximum No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L 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 Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/ Clot detection Automatic detection of adequate reagent for aspiration and analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/ Drugs of abuse Automatic shutdown/Startup programmable	potentiometry (ISE), optical, reflectance/— 5 no/— no 11 11 0/— 11/varies by analyzer and laboratory use pattern 45 days/45 days/no — requires operator prehandling, preparation — cost varies with volume/—/— — ISE no/— no/— 45 µL no (optional)/no no/— minimal no/— yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes yes no yes yes/yes/yes yes yes*/yes* yes*/no no/no yes yes/yes 30–120 minutes/30–120 minutes/—/— yes/yes	potentiometry/— 8 no/— no 8 8 0/— 8/(at 8,000 tests/month): 2,700 tests 21 days/21 days/no — no, requires prehandling (remove clip from sealed bag & mix) — cost varies with volume/—/— 60 per tray/40 per tray/280 per tray — no/— — 50 µL no/no no/— minimal — yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes alternate method — yes no/yes/yes yes no/no yes/yes no/no yes yes/— 2 hours/2 hours/—/— —
Stat time to completion of all analytes, throughput per hour for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Albumin, direct & 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 Nos. per analyte QC results transferred automatically to LIS	50 seconds, 44 specimens —, — —, — <2 seconds 8 hours (CLIA)/yes yes/yes yes	52 seconds, 69 specimens 85 seconds, 45 specimens —, — 9 seconds CLIA minimum/yes no/yes yes
Data management capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites Bidirectional interface capability Test results transmitted to LIS as soon as chemistry time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	no/no virtually all yes (broadcast download and host query) yes yes no —	onboard and optional add-on (\$9,225, SW mfr: Nova)/no most LIS vendors including Cerner, Misys, McKesson, Soft, others yes yes no no —
Lab can control analyzer remotely Interface available (or will be) to automated specimen handling system	yes no	yes no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of service engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced oper. training available Annual service contract cost (24 h/7 d)	yes/yes/yes — <8 business hours/yes — weekly: <5 minutes; monthly: <15 minutes yes/yes yes/yes —	no/yes/yes — <8 business hours/yes — daily: <2 minutes; weekly: <5 minutes; monthly: <5 minutes no/no yes/yes —
Distinguishing features (supplied by company)	onboard quality control; liquid calibration eliminates gas tanks; remote control; remote review; space-saving design	whole blood analyzer for creatinine and TCO ₂ ; can analyze whole blood, serum, plasma, urine, CSF, and dialysate

Note: a dash in lieu of an answer means company did not answer question or question is not applicable *on co-oximeter module

Chemistry analyzers (for low-volume laboratories)

Part 8 of 12	Ortho-Clinical Diagnostics Sales Support 1001 U.S. Highway 202, Raritan, NJ 08869 800-828-6316 www.orthoclinical.com	Polymedco Melanie Rosen mrosen@polymedco.com 510 Furnace Dock Road, Cortlandt Manor, NY 10567 800-431-2123 www.polymedco.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Vitros DT 60 II Chemistry System (DT 60 II, DTE, DTSC)/1993 — 15,000 units worldwide U.S./U.S./U.S. batch, random access, discrete/self-contained single-use cartridges- packages-slides	Poly-Chem/2002 \$58,500/27 153/— Japan/Japan/U.S. batch, random access/open reagent system
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	—/benchtop 6.75 × 18.75 × 13.75/1.8 sq. ft. (DT 60 II)	rack/benchtop 22 × 30 × 24/—
Tests available on instrument in U.S.	ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN, glucose, Mg, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH, theophylline, CO2, sodium, potassium, chloride, urine creatinine, CK-MB	albumin, ALK, ALT, amylase, apolipoprotein A1, apolipoprotein B, ASO, AST, C3, C4, calcium, full range CRP, cholesterol, CO2, creatinine, CRP, direct bilirubin, direct LDL, ferritin, fructosamine, gamma GT, glucose, HbA1C, HDL cholesterol, IGA, IGG, IGM, iron, LDH, lipase, lipoprotein A, magnesium, microalbumin, phosphorus, prealbumin, rheumatoid factor, CK NAC, TIBC direct, total bilirubin, total protein, transferrin, triglyceride, BUN, uric acid
Tests cleared but not clinically released	—	—
Tests not available in U.S. but submitted for FDA 510(k) clearance	—	—
Tests not available in U.S. but available in other countries	—	—
Research-use-only assays/Tests in development	—	APOA11, APOE, APOC11, APOC111/—
User-defined methods implemented for what analytes	—	glutamine, glutamate, lactate, ammonia
Methods supported/Immunoassay methods	potentiometry, colorimetric, enzymatic/—	photometry, RISE
No. of direct ion selective electrode channels	4	3
• Must load separate reagent pack for each specimen/No. of different assays in pack	yes/1	no/—
• Separate reagent pack for each test run	yes	no
No. of different measured assays onboard simultaneously	one per module (DT 60 II, DTE II, DTSC II)	43
No. of different assays programmed, calibrated at once	1	43
No. of user-definable (open) channels/No. active simultaneously	none	60/60
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	—	40/200
Shortest/Median onboard reagent stability/Refrigerated onboard	—/—/no	4 hours/28 days/yes (8°C)
Multiple reagent configurations supported	no	yes
Reagent container placed directly on system for use	no	yes
Instrument has same capabilities when 3rd-party reagent used	—	no
Reagent only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes	—	—
Walkaway capacity in minutes/No. of specimens/No. of tests-assays	—	18 minutes to first result/40 specimens/1,000 tests
System is liquid, dry, or reconstituted onboard	dry	liquid
Uses disposable cuvettes/Maximum No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	no/—	yes/50,000 tests
Minimum sample volume aspirated precisely at one time	10 µL	2 µL
Supplied with UPS (backup power)/Requires floor drain	no/no	yes/yes
Requires dedicated water system/Water consumption in L per hour	no/none	yes/7
Noise generated in decibels	—	60
Dedicated pediatric sample cup/Dead volume	—	yes/—
Primary tube sampling/Pierces caps on primary tubes	no/no	yes/no
Sample bar-code reading capability/Autodiscrimination	no/—	on sample transport, shortly before sample is aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/no
Reagent bar-code reading capability	yes	yes
Bar-code placement per CLSI standard Auto2A	—	yes
Onboard test auto inventory (determines volume in container)	—	yes
Measures No. of tests remaining/Short sample detection/ Clot detection	—	yes/yes/no
Automatic detection of adequate reagent for aspiration and analysis	—	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	no/no	yes/yes
Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	no/no	yes/yes
Autocalibration or autocalibration alert	no	no
Calibrants stored onboard/Multipoint calibration supported	no/yes	no/yes
Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/ Drugs of abuse	reagent lot changes	daily/7–14 days/—/—
Automatic shutdown/Startup programmable	no/no	no/yes
Stat time to completion of all analytes, throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct & total bilirubin, AST, ALT, ALP	15 tests 75 tests 20 tests	2 minutes, 450 specimens 10 minutes, 180 specimens 11 minutes, 180 specimens
Typical time delay from ordering stat test to aspiration of sample	none	—
How often QC required/Onboard SW capability to review QC	every 24 hours/no	per shift—daily/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	no/no	yes/no
QC results transferred automatically to LIS	yes	yes
Data management capability/Instrument vendor supplies LIS interface	—/no	onboard/no
Lab information systems with which interfaces up and running in active user sites	—	LabDAQ, Data Innovations, Soft Computer, Misys
Bidirectional interface capability	no	broadcast download, host query
Test results transmitted to LIS as soon as chemistry time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders and results	—	no
How labs get LOINC codes for reagent kits	—	—
Lab can control analyzer remotely	no	no
Interface available (or will be) to automated specimen handling system	no	no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes	no/no/no
On-site time of service engineer/Onboard error codes for troubleshooting	—/yes	24 hours/yes
Mean time between failures/To repair failures	—	—
Average time to complete maintenance by lab personnel	daily: 5 minutes; weekly: 5 minutes; monthly: none	daily: 5 minutes; weekly: 10 minutes; monthly: 2.5 hours
Onboard maintenance records/Maintenance training demo module	no/no	no/no
Training provided with purchase/Advanced oper. training available	yes/—	3 days on site, 3 days at vendor office/yes
Annual service contract cost (24 h/7 d)	—	\$8,500 (M-F, 8 am–9 pm EST)
Distinguishing features (supplied by company)	disposable tips eliminate sample carryover; random access testing so chemistries can be run in any order, with no reagent prep.; indiv. packaged test slides eliminate waste and facilitate rapid analysis; dry-slide technology minimizes the effects of interferences to provide accurate results	small benchtop analyzer ideal for POL, as primary system in small lab, or a back-up system in a large lab; onboard reusable cuvettes provide cost savings on disposables; large reagent menu

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

Chemistry analyzers (for low-volume laboratories)

Part 9 of 12	Polymedco Melanie Rosen mrosen@polymedco.com 510 Furnace Dock Road, Cortlandt Manor, NY 10567 800-431-2123 www.polymedco.com	Randox Laboratories Graeme McNeill graeme.mcneill@randox.com 515 Industrial Blvd., Kearneysville, WV 25430 304-728-2890 www.randox.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	SPOTCHEM EZ/2006 \$9,400/50 95/— Japan/Japan/U.S. discrete/single-use strips tray/benchtop 6.5 × 13.5 × 8/—	Rx Daytona/2005 — >1,000 units worldwide Japan/Japan/U.K. random access/self-contained multi-use cartridges-packages-slides ring/benchtop 30.3 × 24.4 × 19.7/3.338 sq. ft.
Tests available on instrument in U.S.	albumin, ALT, amylase, AST, ALP, BUN, calcium, CPK, creatinine, GGT, LDH, magnesium, phosphorous, total bilirubin, total protein, uric acid, panel 1 (BUN, glu, cre, cal, alb), panel 2 (ALP, T-BIL, T-ALT, T-protein, AST), lipid panel (chol, trig, HDL, LDL)	acetic acid, acid phosphatase, albumin, aldolase, ALK PHOS, alpha 1 acid glycoprotein, alpha 1 antitrypsin, ALT, ammonia, amphetamines, amylase, amylase pancreatic, APO A-1, APO AII, APO B, APO CII, APO CIII, APO E, ASO, AST, B2 microglobulin, barbiturates, benzodiazepines, bile acids, total bilirubin, direct bilirubin, butyryl-cholinesterase, calcium, cannabinoids, carbamazepine, chloride, cholesterol, CK-MB, CK-NAC, CO2, cocaine metabolite, C3, C4, copper, creatinine, CRP, high-sensitivity CRP, full range CRP, cystatin C, digoxin, ecstasy, EDDP, more
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance	— —	— —
Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development	— —/LDL	— acetic acid, Apo E, apo CIII, apo AII, alpha-1-antitrypsin, alpha-1-acid glycoprotein, bile acids, butyryl cholinesterase, enzymatic chloride, glutamate, more/haptoglobin, oxycodone, propoxyphene, caeruloplasmin, D-dimer, salicylate, more acetaminophen, salicylate, cyclosporin, alcohol, glycerol-3-phosphate, oxidase, phospholipids, maltose, T4, T-uptake, aldehyde, chromate, cyclosporin, more
User-defined methods implemented for what analytes	—	—
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of different assays in pack • Separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates 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 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Maximum No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L 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	optical measurement of reflection intensity of reagent color reaction — yes/single strips and panel strips available yes 9 card calibration, 21 — — —/—/no no yes no — up to 15/1/up to 9 dry no/— no/— 5 µL no/no no/— — no/— no/no no/no by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes yes no no no/yes/no no no/no no no/no —/per box/—/— no/no	photometry, potentiometry (ISE), latex-enhanced immunoturbidimetry/— 3 no/— no 43 60 10/10 43/50–11,250 8 hrs/28 days/yes (8°–15°C) yes yes yes — 664/40/76,115 liquid no/45 yes/minimum 5 years 2 µL no/no yes/7.5 60 yes/50 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes yes — yes yes/yes/no yes yes/yes yes/yes yes/yes yes yes/yes daily/28 days/7 days/28 days yes/yes
Stat time to completion of all analytes, throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct & 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 Nos. per analyte QC results transferred automatically to LIS	— 9 minutes, 48 samples per hour 9 minutes, 48 samples per hour — daily/no no/no no	13 minutes, 50 seconds, — 14 minutes, 50 seconds, — 14 minutes, 30 seconds, — 30 seconds shortest: daily; longest: customer discretion/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites Bidirectional interface capability Test results transmitted to LIS as soon as chemistry time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	onboard/no — — yes yes no —	onboard/no — yes (host query) yes yes no —
Lab can control analyzer remotely Interface available (or will be) to automated specimen handling system	no no	no no
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component On-site time of service engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced oper. training available Annual service contract cost (24 h/7 d)	no/no/no depot service/yes —/— daily: 1 minute; monthly: 5 minutes no/no 1 day on site/no —	yes/yes/yes within 24 hours/yes 2 per 3 years/—within 8 working hours daily: 5 minutes; weekly: 15 minutes; monthly: 1 hour no/no 3 days on site/yes varies on level
Distinguishing features (supplied by company)	small analyzer ideal for stat labs, small POLs, ERs, and imaging centers; analyzer and reagent test strips are CLIA-waived; dry chemistry strips, effective stability, and shelf life; single test strips and panel strips available; customizable testing	benchtop analyzer offers consolidation of testing in an established compact platform; dedicated multi-speed paddle mixers allow optimum mixing for each assay; direct ISE module prevents pseudohyponatremia

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

Chemistry analyzers (for low-volume laboratories)

Part 10 of 12	Roche Diagnostics Corp. Jim Dodds jim.dodds@roche.com 9115 Hague Road, Indianapolis, IN 46256 317-521-4723 www.roche-diagnostics.us	Roche Diagnostics Corp. Adam Sterle adam.sterle@roche.com 9115 Hague Rd., Indianapolis, IN 46256 317-521-4804 www.roche.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	Cardiac 200/2009 —/— —/— Canada/Canada/Canada continuous random access/self-contained single-use cartridges-packages-slides transfer device 12 x 8 x 8/0.4 sq. ft.	cobas c311/2009 \$125,000/— >75/>500 Japan/Japan/Germany continuous random access/self-contained multi-use cartridges-packages-slides sample rotor/floor-standing 50 x 52 x 34/8.5 sq. ft.
Tests available on instrument in U.S.	NT-proBNP, troponin I, myoglobin, CK-MB	acetaminophen, α 1-acid glycoprotein, alanine aminotransferase, alanine aminotransferase (with P-5-P), albumin, alkaline phosphatase, amikacin, ammonia, α -amylase, α -amylase pancreatic, antistreptolysin O, α 1-antitrypsin apolipoprotein A-1, apolipoprotein A-1, apolipoprotein B, aspartate aminotransferase, aspartate aminotransferase (with P5P), barbiturates, benzodiazepines, bicarbonate, bilirubin (direct), bilirubin (total), BUN/urea, C-reactive protein, hsCRP, calcium, cannabinoids, carbamazepine, cholesterol, cholinesterase, CK-MB, cocaine, complement C3c, complement C4, creatine kinase, creatinine, others
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development	— — — —	— — — —/cholinesterase (acetyl), LSD, gentamicin, amphetamines (oral fluids), amp/methamp/MDMA combo (oral fluids), barbiturates (oral fluids), benzodiazepine (oral fluids), buprenorphine (oral fluids), cocaine (oral fluids), others
User-defined methods implemented for what analytes	—	—
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of different assays in pack • Separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates 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 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Maximum No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L 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	—/quantitative lateral flow immunochromatographic fluorescence assay — no/— no — 50 lot numbers 0/— up to 4/1 —/—/no no yes no —/—/available upon request 10–19 minutes/up to 6/up to 4 per specimen dry no/— no/— 75 μ L no/no no/— 69 no/— no/no upon executing run assay mode/yes	photometry, potentiometry no no/— — 45 >130 10/10 50/800 120 hours/84 days/yes (5°–15°C) yes yes yes varies/varies/varies 173/108/45 liquid no/66 yes/monthly 1 μ L yes/yes yes/12 <65 yes/50 μ L yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes yes/yes/yes yes yes/yes yes/yes yes/yes yes no/yes 24 hours/lot/lot/lot yes/yes
Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/ Clot detection Automatic detection of adequate reagent for aspiration and analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/ Drugs of abuse Automatic shutdown/Startup programmable	yes — no no/yes/yes no no/no no/no no/no yes —/— — no/no	yes yes yes yes/yes/yes yes yes/yes yes/yes yes/yes yes no/yes 24 hours/lot/lot/lot yes/yes
Stat time to completion of all analytes, throughput per hour for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Albumin, direct & 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 Nos. per analyte QC results transferred automatically to LIS	— — — — per local requirements/yes yes/yes yes	5 minutes, 150 specimens 8 minutes, 38 specimens 11 minutes, 22 specimens <1 minute daily/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites Bidirectional interface capability Test results transmitted to LIS as soon as chemistry time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	optional add-on/no — no yes yes no —	onboard/no all major LIS providers yes (broadcast download and host query) yes yes yes Web site (MyLab Online)
Lab can control analyzer remotely Interface available (or will be) to automated specimen handling system	no no	no no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of service engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced oper. training available Annual service contract cost (24 h/7 d)	no/yes/yes —/yes —/overnight replacement daily: a few minutes; weekly: a few minutes; monthly: a few minutes no/no 1 day on site/no multi-year warranty provided	yes/yes/yes <8 hours/yes 300 days/<2 hours daily: 10 minutes; weekly: 5 minutes; monthly: 15 minutes yes (includes audit trail of who replaced parts)/no 2 days on site; 5 days at vendor offices/yes varies
Distinguishing features (supplied by company)	internal standard corrects for a number of variable factors often encountered in POC testing with lateral flow immunochromatographic technologies; modularity of testing capacity with consolidation of multiple systems into one analyzer; lab-like performance of cardiac markers	convenience and stability of cobas c pack reagents, standardized operator interface and reagents with other cobas chemistry platforms, Hitachi reliability

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

Chemistry analyzers (for low-volume laboratories)

Part 11 of 12	Roche Diagnostics Corp. Adam Sterle adam.sterle@roche.com 9115 Hague Rd., Indianapolis, IN 46256 317-521-3099 www.roche-diagnostics.com	SDI Biomed Robert Silverberg rs@sdiomed.com 23679 Calabasas Road, #241, Calabasas, CA, 91302 818-349-4464 www.sdiomed.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	Cobas Integra 400 Plus/1999 \$145,000/— 550/>2,000 Switzerland/Switzerland/U.S. & Germany continuous random access/self-contained multi-use cassettes rack/benchtop 28.5 × 53 × 26/9.6 sq. ft.	SDI CA 480 Clinical Chemistry System/2004 \$65,000/— >50/>600 Europe/Europe/United States random access/self-contained single-use cartridges-packages-slides wheel, with 4 independent segments/benchtop 40.5 × 25.4 × 17.7/7.2 sq. ft.
Tests available on instrument in U.S.	* α -1-acid glycoprot., α -1-antitryp., apo A1 & B, antistrepto.-O, comp. C3c & C4, cerul., CRP latex, hsCRP, hapt., IgA/G/M, myo., prealb., RF, transferr., amph., barb., benz., coca., ethanol, LSD, meth., methaq., opia., PCP, PPX, S barb., S benz., THC, ACP, ALP, ALT, α -amy. pancreatic, AP, AST, cholinest., CK-MB, γ -glutamyltrans., LDH, lipase, alb., bil direct & total, Ca., chol., CO2, creat. jaffe, creat. enzy., fructosam., gluc., HbA1c, HDL direct, iron, lact., LDL direct, Mg, ammon., phos., TP, TPU-C, trig., UA, UIBC, urea, Na, K, Cl, Li, acet., amik., carb., dig., gent., lido., NAPA, pheno., pheny., prim., proc., quin., sali., theo., tobra., valp. acid, vanc., T4, T-up, D-dimer, MPA, Cys C, Cyclo, oxycodone, others	albumin, alkaline phosphatase, ALT, amylase, AST, CO2, direct bilirubin, total bilirubin, calcium, cholesterol, CK, creatinine, Gamma-GT, glucose-HK, D-HDL, iron, phosphorus, LDH-L, magnesium, total protein, triglycerides, urea nitrogen, uric acid, D-LDL, UCRP WR, fructosamine, ferritin, HbA1c
Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development	— — lipoprotein A adulterants (chromate, creatinine, nitrates, oxidant, pH, specific gravity), syphilis, homocysteine/—	— — — —/drugs of abuse
User-defined methods implemented for what analytes	—	none
Methods supported/Immunoassay methods	photometry, potentiometry, fluorescence polarization/turbidimetric, latex particle enhanced	photometry, potentiometry/selected methodologies
No. of direct ion selective electrode channels	4	3
• Must load separate reagent pack for each specimen/No. of different assays in pack	no/1	no/—
• Separate reagent pack for each test run	no	no
No. of different measured assays onboard simultaneously	36 tests plus applications for urine and CSF	33
No. of different assays programmed, calibrated at once	up to 999	33
No. of user-definable (open) channels/No. active simultaneously	10/10	0/—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	36/50–800 tests-cassette	30/150 per container
Shortest/Median onboard reagent stability/Refrigerated onboard	2 weeks/8–12 weeks/yes (12°C)	14 days/30 days/yes (14°C)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reagent used	yes	yes
Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes	varies/varies/varies	—
Walkaway capacity in minutes/No. of specimens/No. of tests-assays	176/90/1,808	165/40/33
System is liquid, dry, or reconstituted onboard	liquid	liquid
Uses disposable cuvettes/Maximum No. stored	yes/1,000	no
Uses washable cuvettes/Replacement frequency	no/—	yes/analyzer uses permanent quartz cuvettes
Minimum sample volume aspirated precisely at one time	2 μ L	3 μ L
Supplied with UPS (backup power)/Requires floor drain	yes/no	yes/no
Requires dedicated water system/Water consumption in L per hour	no/2 maximum	no/1
Noise generated in decibels	<61	—
Dedicated pediatric sample cup/Dead volume	yes/50 μ L	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	yes/yes
Reagent bar-code reading capability	yes	yes
Bar-code placement per CLSI standard Auto2A	yes	yes
Onboard test auto inventory (determines volume in container)	yes	yes
Measures No. of tests remaining/Short sample detection/Clot detection	yes/yes/yes	yes/yes/no
Automatic detection of adequate reagent for aspiration and analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	yes/yes	yes/no
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	5 hours/once per lot/each lot and 20–26 weeks/each lot and 3–6 weeks	30 minutes/once per week/once per week/once per week
Automatic shutdown/Startup programmable	yes/yes	no/no
Stat time to completion of all analytes, throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct & 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 Nos. per analyte QC results transferred automatically to LIS	5 minutes 8 minutes 11 minutes <1 minute 24 hours/yes yes/yes yes	1.5 minutes, 60 specimens 6 minutes, 48 sec, 60 specimens 7 minutes, 12 sec, 50 specimens 3 minutes 8 hours/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites Bidirectional interface capability Test results transmitted to LIS as soon as chemistry time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	onboard/yes (additional cost) all major LIS vendors yes (broadcast download and host query) yes yes — —	onboard/— SchuyLab, LabDaq, Fletcher Flora, Medcom yes yes yes no —
Lab can control analyzer remotely Interface available (or will be) to automated specimen handling system	yes no	no no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of service engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced oper. training available Annual service contract cost (24 h/7 d)	yes/yes/yes —/yes — daily: none; weekly: 5 minutes; monthly: none yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes —	yes/yes/yes yes, guaranteed within 24 hours/yes 10,000 hours/2 hours daily: 5 minutes; weekly: 15 minutes; monthly: 15 minutes yes/no 4 days on site or 4 days at vendor offices/yes \$7,500
Distinguishing features (supplied by company)	unique reagent cassette eliminates reagent preparation; menu consolidates testing, including direct LDL, whole blood, HbA1c, and lithium	permanent cuvettes, onboard jet wash/dry system, six minutes to first result, notebook-like operator interface, small footprint

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

Chemistry analyzers (for low-volume laboratories)

Part 12 of 12	Siemens Healthcare Diagnostics Jason Ong jason.f.ong@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 800-242-3233 www.usa.siemens.com/diagnostics	Vital Diagnostics USsales@vitaldiagnostics.com 27 Wellington Road, Lincoln, RI 02865 800-345-2822 www.vitaldiagnostics.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2009 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Dimension Xpand Plus Integrated Chemistry System/2004 —/— —/— U.S./U.S./U.S. batch, random access, continuous random access/self-contained single-use and multi-use cartridges racks/floor-standing 45 × 51 × 31 (without monitor)/10.6 sq. ft.	Envoy 500 Chemistry Analyzer/2005 —/— 240/— Italy/Italy/Australia random access/self-contained multi-use cartridges-packages-slides
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	rotor/benchtop 27 × 40 × 23/6 sq. ft.	
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for FDA 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development User-defined methods implemented for what analytes	thyronine uptake, total T4/thyroxine, triiodothyronine, cardiac troponin I, ferritin, free PSA, free T4/thyroxine, human chorionic gonadotropin hormone, mass CK-MB, myoglobin, NT-pro BNP, thyroid stimulating hormone, total PSA CardioPhase hsCRP, complement C3, complement C4, C-reactive protein, C-reactive protein extended range, IgA, IgG, IgM, transferrin, cyclosporine extended range, hemoglobin A1c, carbamazepine, cyclosporine, digoxin, digitoxin, gentamicin, lidocaine, lithium, N-acetylprocainamide, phenobarbital, phenytoin, procainamide, tacrolimus, theophylline, tobramycin, vancomycin, valproic acid, acetaminophen, ethyl alcohol, others — — — —/mycophenolic acid —	general chemistry, albumin, bilirubin, direct, bilirubin, total, calcium, creatinine, glucose, iron, total, magnesium, phosphorus, protein, total, urea nitrogen (BUN), uric acid, enzyme, alanine aminoTransferase (ALT), alkaline phosphatase, amylase, aspartate transaminase (AST), creatine phosphokinase (CPK), gamma glutamyl transferase (GGT), lactate dehydrogenase (LDH), lipid, direct LDL, triglycerides, direct HDL, cholesterol, electrolyte, carbon dioxide, chloride, potassium, sodium, special chemistries, direct hemoglobin A1c — — — — CRP wide range, hsCRP, digoxin, ferritin, fructosamine, lipase, phenobarbital, UIBC, glycoMark, cystatin C, valproic acid, carbamazepine, IgA, IgG, IgM, ethanol
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of different assays in pack • Separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates 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 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Maximum No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L 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 Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/ Clot detection Automatic detection of adequate reagent for aspiration and analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/ Drugs of abuse Automatic shutdown/Startup programmable	photometry, potentiometry (ISE)/colorimetric, immunoturbidimetric, potentiometric, EMIT (homogeneous IA), ACMA (heterogeneous IA) 3 no/— no 47 >90 10/10 47/72–1,440 72 hours/30 days/yes (2°–8°C) yes yes yes — can be hours/60/>1,000 liquid, reconstitutes onboard yes/12,000 no/— 2 µL yes/no yes/up to 2 maximum <70 no/20 µL yes/no on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes yes yes yes/yes/no yes yes/yes yes/yes yes/no yes yes/yes every 2 hours, autocalibrate/—/60–90 days/30 days no/no	photometry, potentiometry, turbidimetric 4 no/— no 40 40 500/40 40/150 80 hours/21 days/yes (12°–15°C) yes yes no — 240/52 specimens/> 1,000 liquid no yes/never 1 µL yes/no no/2 >60 no/— yes/no sample loaded on the analyzer by internal bar-code scanner (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/no yes no yes yes/yes/no yes no/no yes/yes yes/yes yes no/yes 4 minutes/21 days/—/— yes/yes
Stat time to completion of all analytes, throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct & 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 Nos. per analyte QC results transferred automatically to LIS	2 minutes, 62 specimens 4 minutes, 60 specimens 8 minutes, 40 specimens 60 second steady state, 2 minutes from standby daily/yes yes/yes yes	3 minutes, 45 seconds, 37 specimens 6 minutes, 10 seconds, 45 specimens 9 minutes, 26 seconds, 26 specimens >1 minute 4–24 hours yes/yes yes
Data management capability/Instrument vendor supplies LIS interface Lab information systems with which interfaces up and running in active user sites Bidirectional interface capability Test results transmitted to LIS as soon as chemistry time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results How labs get LOINC codes for reagent kits	optional add-on/yes (additional cost) interfaces available for all major LIS vendors yes (broadcast download and host query) yes yes no —	no/no Antek, Fletcher Flora, Orchard, Skyler Lab, Data Innovations, Sunquest broadcast download yes yes no —
Lab can control analyzer remotely Interface available (or will be) to automated specimen handling system	no no	no no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of service engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced oper. training available Annual service contract cost (24 h/7 d)	yes/yes/yes 2–8 hours/yes — daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes no/no 5 days on site, 4 days at vendor offices/no multiple types	yes/yes/yes within 24 hours/yes — daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes yes/no 5 days on site/yes \$8,995 (M-F, 8 am–8 pm)
Distinguishing features (supplied by company)	integrated chem., specialty, and immunoassay workstation; back-up system for other Dimension systems; niche testing platform for no pre-treat immuno-suppressive drug testing; no reagent prep.; minimal operator maintenance	C02 performed as an electrolyte; four-parameter onboard dry ISE; 570 tests per hour; reusable glass cuvettes; small footprint

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