

## Chemistry analyzers (for low-volume laboratories)

Part 1 of 13	Abaxis Inc. Rick Betts rickbetts@abaxis.com 3240 Whipple Rd., Union City, CA 94587 800-822-2947 www.abaxis.com	Abbott Point of Care Glen Tinevez glen.tinevez@abbott.com 104 Windsor Center Dr., East Windsor, NJ 08520 800-827-7828 www.abbottpointofcare.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2008 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	Piccolo Xpress/2006 \$18,000/— 2,500/4,000 U.S./U.S./U.S. self-contained disk with multi-test reagent panel disk loaded directly into instrument/benchtop 12.75 x 6 x 8/1 sq. ft.	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.
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	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 — — none — none	tropinin I, CK-MB, lactate, BUN, creatinine, glucose, ionized calcium, sodium, potassium, chloride, hematocrit, pH, PCO2, PO2, TCO2, ACTc, ACTk, PT/INR; hemoglobin, HCO3, BEcf, SO2, anion gap, BNP — — — — —
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of diff. 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/Max. 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	enzymatic/— — no, self-contained discs with multi-test reagent panel/up to 14 tests per disc with 13 available discs no CLIA waived CMP has 14 analytes 14 0/— self-contained reagent discs have from 2 to 14 tests per disc — yes yes — \$0.57/—/— approximately 12/1/14 reconstitutes onboard no/— no/— requires 80 to 100 µL of whole blood, serum, or plasma no/no no/— none no no/— yes/—	potentiometry, amperometric, conductometric/— 10 yes/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, shortly before sample is aspirated, by handheld scanner as tubes are loaded, at the bedside (2 of 5 interleaved, Codabar, 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 aspir. & 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 calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes — —/yes/yes yes yes/yes yes/no —/— yes yes/yes self-calibrated onboard/disk/—/— yes/yes	yes yes — —/yes/yes yes no/no no/no no/no none no/— no/no yes no/yes each test/each test/—/— yes/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. 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	10–12 min, 2–14 tests 10–12 min, 2–14 tests 10–12 min, 2–14 tests — automatic QC onboard/yes yes/yes yes	2 min, — 2 min, — — none shortest interval: 24 hr; longest interval: each new lot or reagent/yes yes/yes yes
Data mgmt. 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 chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	onboard/no hundreds of LIS' and EMR systems yes yes yes no —	optional add-on (<\$30,000, SW mfr: Abbott Point of Care)/yes (add'l cost) all systems yes (broadcast download & host query) yes yes yes customized on site
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no —	yes —
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/yes/yes 24-hr loaner/yes 3 years/— daily: none; weekly: none; monthly: none —/yes yes/yes 1-year warranty, extended warranty—\$1,200	yes/yes/yes replacement within 24 hr/yes not determined/replacement within 24 hr daily: none; weekly: none; monthly: none — —/yes \$750
Distinguishing features (supplied by company)	provides comprehensive CLIA-waived menu of tests; 13 available discs (9 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	handheld portable analyzer; unit use system can perform chemistry, blood gas, cardiac marker, and coagulation tests on two drops of whole blood or plasma

## Chemistry analyzers (for low-volume laboratories)

Part 2 of 13	Alfa Wassermann Diagnostic Technologies LLC Julie Famulare jfamulare@alfawassermannus.com 4 Henderson Dr., West Caldwell, NJ 07006 800-220-4488 www.alfawassermannus.com	Alfa Wassermann Diagnostic Technologies LLC Lauren DiPrima LDiPrima@alfawassermannus.com 4 Henderson Dr., West Caldwell, NJ 07006 800-220-4488 www.alfawassermannus.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2008 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 & closed reagent system with open reagent system channel ring with up to 5 segments (15 samples per segment)/benchtop ACE: 15.75 × 27.25 × 22.50; ACE Alera: 23 × 27.5 × 22.5/4.3 sq. ft.	Alfa S40/2008 \$23,000/— —/ Japan/Japan/Japan batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages-slides single patient rack with multiple sample types/benchtop 17.6 × 21.1 × 23.4/3 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 <sub>2</sub> , T <sub>4</sub> , T-uptake, HbA1c, lipase, direct TIBC, ferritin, homocysteine, Lp(a), microalbumin, apo A1, apo B, transferrin	albumin, alkaline phosphatase, alanine aminotransferase, amylase, aspartate aminotransferase, total bilirubin, blood urea nitrogen, calcium, carbon dioxide, creatine kinase, creatinine, C-reactive protein, gamma-glutamyl transferase, glucose, inorganic phosphorus, direct low-density lipoprotein, total protein, uric acid
Tests cleared but not clinically released	none	—
Tests not available in U.S. but submitted for FDA 510(k) clearance	none	cholesterol, hemoglobin A1c, high-density lipoprotein cholesterol, lactate dehydrogenase, triglycerides
Tests not available in U.S. but available in other countries	UIBC	DIG, THEO
Research-use-only assays/Tests in development	—/—	—/magnesium, direct bilirubin, Cl, Na, K
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/homogeneous EIA	photometry
No. of direct ion selective electrode channels	3	0
• Must load separate reagent pack for each specimen/No. of diff. assays in pack	no/—	no/—
• Separate reagent pack for each test run	no	yes
No. of different measured assays onboard simultaneously	40	0
No. of different assays programmed, calibrated at once	200	40
No. of user-definable (open) channels/No. active simultaneously	15/15	0/0
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	40/30–250 tests per bottle	40/1 test per container set
Shortest/Median onboard reagent stability/Refrigerated onboard	5 days/30 days/yes (10° to 14°C)	—/—/no
Multiple reagent configurations supported	yes	no
Reagent container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reagent used	yes	no
Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes	\$0.16/—/\$3.50	\$0.95–\$3.50 (bundled instrument/reagent/maintenance cost per reportable result: \$1.05–\$3.60)/—/—
Walkaway capacity in minutes/No. of specimens/No. of tests-assays	75/75/248	20/1/11
System is liquid, dry, or reconstituted onboard	liquid	liquid
Uses disposable cuvettes/Max. No. stored	yes/248	yes/included in test cartridge
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum sample volume aspirated precisely at one time	3 µL	3 µL
Supplied with UPS (backup power)/Requires floor drain	yes/no	no/no
Requires dedicated water system/Water consumption in L per hour	no/—	no/0.4
Noise generated in decibels	55	25
Dedicated pediatric sample cup/Dead volume	no/—	yes/20 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	—
Reagent bar-code reading capability	yes, proprietary dot coding	yes
Bar-code placement per CLSI standard Auto2A	no	no
Onboard test auto inventory (determines volume in container)	yes	no
Measures No. of tests remaining/Short sample detection/Clot detection	yes/yes/no	—/yes/no
Automatic detection of adequate reagent for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	—	no/no
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/no	—
Autocalibration or autocalibration alert	yes	—
Calibrants stored onboard/Multipoint calibration supported	no/yes	—/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	3 hr/30 days/45 days with 48 hr updates/—	—/reagent cartridges are factory-calibrated/—/—
Automatic shutdown/Startup programmable	—	no/no
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TC02	4 min, 35 specimens	—
• Sodium, potassium, chloride, TC02, glucose, urea, creatinine	7 min, 20 specimens	—
• Album., direct & total bili., AST, ALT, ALP	10 min, 12 specimens	15 min/4 specimens
Typical time delay from ordering stat test to aspir. of sample	immediate response, as soon as 10 seconds	30 seconds
How often QC required/Onboard SW capability to review QC	daily/yes	daily/no
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	no/—
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	optional add-on (various manufacturers)/no
Lab information systems with which interfaces up and running in active user sites	Schuyler House, Antek, LabPak, Apex, others	Apex
Bidirectional interface capability	yes (broadcast download)	no
Test results transmitted to LIS as soon as chem. time complete	yes, when requisition is done	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Lab can control analyzer remotely	no	no
Interface avail. (or will be) to automated specimen handling system	no	no
Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component	no/yes/yes	no/no/no
On-site time of svc. engineer/Onboard error codes for troubleshooting	24 hr/yes	will use depot repair/yes
Mean time between failures/To repair failures	2 per yr/1 hr	less than one per year/<24 hrs
Average time to complete maintenance by lab personnel	daily: 15 min; weekly: 30 min; monthly: 60 min	daily: <5 min; weekly: <10 min; monthly: <10 min
Onboard maintenance records/Maint. training demo module	yes/no	no/no
Training provided with purchase/Advanced oper. training avail.	4.5 days at manufacturer's facility/yes	1 day on site/yes
Annual service contract cost (24 h/7 d)	varies, several programs available	\$1,800 year
Distinguishing features (supplied by company)	easy-to-use multitasking software; closed-tube sampling; stat interrupt capability; extensive test menu; onboard sample and reagent refrigeration; onboard reagent inventory management; liquid, ready-to-use reagents; integrated ISE module; dedicated field service organization; self-contained analyzer; no external water source or waste drainage	self-contained reagent cartridge/optical cuvette system with all test parameters encoded on 2D bar code; large test menu; true operator walkaway time



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Part 4 of 13	<b>Beckman Coulter Inc.</b> 200 South Kraemer Blvd., P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com	<b>The Binding Site</b> Maureen Zetlmeisl info@thebindingsite.com 5889 Oberlin Drive, Suite 101, San Diego, CA 92121 800-633-4484 www.thebindingsite.com
<b>Name of instrument/First year sold in U.S.</b> <b>List price/No. of analyzers sold in 2008</b> <b>No. units in clinical use in U.S./Outside U.S.</b> <b>Country where designed/Manufactured/Where reagents mftd.</b> <b>Operational type/Reagent type</b> <b>Sample handling system/Model type</b> <b>Dimensions in inches (H x W x D)/Instrument footprint</b>	<b>AU480 Clinical System/2009</b> —/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 47.5 x 57.1 x 30/18.1 sq. ft. (includes PC stand)	<b>SPAPlus (Serum Protein Analyzer)/2007</b> —/— —/— Japan/Japan/United Kingdom batch, random access, discrete/self-contained multi-aliquot barcoded cartridges two sample carousels that can each hold 45 samples: 30 primary tubes + 10 non-bar-coded sample cups + 5 stat/benchtop 20.5 x 31.5 x 25.2/14 sq. ft.
<b>Tests available on instrument in U.S.</b>  <b>Tests cleared but not clinically released</b> <b>Tests not available in U.S. but submitted for FDA 510(k) clearance</b> <b>Tests not available in U.S. but available in other countries</b> <b>Research-use-only assays/Tests in development</b>  <b>User-defined methods implemented for what analytes</b>	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: $\alpha$ 1-acid glycoprotein, a1-antitrypsin, anti-streptolysin O, apolipoprotein A1, apolipoprotein B, $\beta$ 2-microglobulin, C3 complement, C4 complement, ceruloplasmin, C-reactive protein, D-dimer, more; TDM: acetaminophen, amikacin, caffeine, carbamazepine, digoxin, disopyramide, ethosuximide, gentamicin, lidocaine, more; DAT: alcohol, amphetamine, barbiturate, benzodiazepine, cannabinoid 20, more — — — —/HbA1c (fully automated) total open system, unlimited	serum free kappa, serum free lambda, cystatin C, IgG, IgG1, IgG2, IgG3, IgG4, IgA, IgM, beta-2-microglobulin  — — — tetanus toxoid/IgD, C3/C4, IgA subclasses, CH50, hevyLite IgG, hevyLite IgA, hevyLite IgM —
<b>Methods supported/Immunoassay methods</b>  <b>No. of direct ion selective electrode channels</b> <b>• Must load separate reagent pack for each specimen/No. of diff. assays in pack</b> <b>• Separate reagent pack for each test run</b> <b>No. of different measured assays onboard simultaneously</b> <b>No. of different assays programmed, calibrated at once</b> <b>No. of user-definable (open) channels/No. active simultaneously</b> <b>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</b> <b>Shortest/Median onboard reagent stability/Refrigerated onboard</b> <b>Multiple reagent configurations supported</b> <b>Reagent container placed directly on system for use</b> <b>Instrument has same capabilities when 3rd-party reagent used</b> <b>Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes</b> <b>Walkaway capacity in minutes/No. of specimens/No. of tests-assays</b> <b>System is liquid, dry, or reconstituted onboard</b> <b>Uses disposable cuvettes/Max. No. stored</b> <b>Uses washable cuvettes/Replacement frequency</b> <b>Minimum sample volume aspirated precisely at one time</b> <b>Supplied with UPS (backup power)/Requires floor drain</b> <b>Requires dedicated water system/Water consumption in L per hour</b> <b>Noise generated in decibels</b> <b>Dedicated pediatric sample cup/Dead volume</b> <b>Primary tube sampling/Pierces caps on primary tubes</b> <b>Sample bar-code reading capability/Autodiscrimination</b>  <b>Reagent bar-code reading capability</b> <b>Bar-code placement per CLSI standard Auto2A</b> <b>Onboard test auto inventory (determines volume in container)</b> <b>Measures No. of tests remaining/Short sample detection/Clot detection</b> <b>Automatic detection of adequate reagent for aspir. &amp; analysis</b> <b>Hemolysis/Turbidity detection-quantitation</b> <b>Dilution of patient samples onboard/Automatic rerun capability</b> <b>Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results</b> <b>Autocalibration or autocalibration alert</b> <b>Calibrants stored onboard/Multipoint calibration supported</b> <b>Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse</b> <b>Automatic shutdown/Startup programmable</b>	photometry, potentiometry (ion selective electrode), homogenous EIA, turbidimetry, latex agglutination/— 3 electrodes, indirect method no/— no 63 63 60/all up to 60 different assays/50 to 1,500 (per vial) 336 hours/30 days/yes (4° to 12°C) yes yes yes — 1 hour/80/variety, depends on bottle size liquid chemistry system no/— yes/permanent 1 $\mu$ L no/yes yes/20 <60 yes/30 $\mu$ L 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 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	turbidimetry/— — no/— no 24 — —/77 24/100 720 hours/30 days/yes (9° to 12°C) yes yes no — ~60/45/6 liquid no/60 yes/OD threshold (0.33) 3 $\mu$ L yes/no no/3.5 — no/— yes/no yes, on sample transport, shortly before sample is aspirated (Codebar, codes 39 & 128)/— yes yes no yes/yes/no yes no/no yes/yes yes/yes yes no/yes — no/no
<b>Stat time to completion of all analytes, throughput per hr. for:</b> <b>• Sodium, potassium, chloride, TC02</b> <b>• Sodium, potassium, chloride, TC02, glucose, urea, creatinine</b> <b>• Album., direct &amp; total bili., AST, ALT, ALP</b> <b>Typical time delay from ordering stat test to aspir. of sample</b> <b>How often QC required/Onboard SW capability to review QC</b> <b>Onboard real-time QC/Support multiple QC lot Nos. per analyte</b> <b>QC results transferred automatically to LIS</b>	7 min, 42 seconds to print, 200 specimens 9 min, 25 seconds to print, 80 specimens 9 min, 43 seconds to print, 50 specimens minimum: 9 seconds from when sampling commences user defined/yes yes/yes yes	— — — — —/yes yes/no yes
<b>Data mgmt. capability/Instrument vendor supplies LIS interface</b> <b>Interfaces up and running in active user sites with</b> <b>Bidirectional interface capability</b> <b>Test results transmitted to LIS as soon as chem. time complete</b> <b>LIS interface operates simultaneously with running assays</b> <b>Uses LOINC to transmit orders &amp; results</b> <b>How labs get LOINC codes for reagent kits</b>	no/no, additional — yes, host query yes yes yes yes Web site, package insert, reagent lot and bottle info sent through interface	no (optional add-on in Europe)/yes (additional cost) Cerner, Sunquest, Data Innovations, CyberLab yes yes yes no —
<b>Lab can control analyzer remotely</b> <b>Interface avail. (or will be) to automated specimen handling system</b>	yes no	no yes
<b>Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component</b> <b>On-site time of svc. engineer/Onboard error codes for troubleshooting</b> <b>Mean time between failures/To repair failures</b> <b>Average time to complete maintenance by lab personnel</b> <b>Onboard maintenance records/Maint. training demo module</b> <b>Training provided with purchase/Advanced oper. training avail.</b> <b>Annual service contract cost (24 h/7 d)</b>	yes/yes/yes —/yes new instrument, info not available daily: 10 min; weekly: 59 min; monthly: 45 min yes/yes 5 days at vendor offices/yes contract dependent	no/no/no 24 hrs/yes 360 days/24 hrs daily: 9 min; weekly: 20 min no/no 5 days, installation and on-site training —
<b>Distinguishing features (supplied by company)</b>	reliable system; standardized reagents/consumables across AU family ensures high productivity and efficiency; improved GUI, Windows XP OS with touchscreen simplifies training and operation	low maintenance; prozone detection; autodilution, combination of air-mixing system, dual-compartment reaction cuvettes, and a hot water wash make it effective for The Binding Site latex assays

## Chemistry analyzers (for low-volume laboratories)

Part 5 of 13	Carolina Liquid Chemistries Patricia A. Shugart    contactsales@carolinachemistries.com 391 Technology Way, Suite 2, Winston Salem, NC 27101 877-722-8910    www.carolinachemistries.com	Horiba Medical Chuck Rebisz    Chuck.Rebisz@horiba.com 34 Bunsen Dr., Irvine, CA 92618 888-903-5001    www.horiba-abx.com/us
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2008 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	BioLis 24i/2008 \$60,000/— >200/3,000 Japan/Japan/USA batch, random access, continuous random access/open reagent system	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 25 × 40 × 28 in/7.7 sq. ft.
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	sample ring/benchtop 20 × 31 × 25/5 sq. ft.	— —
Tests available on instrument in U.S.	100	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
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	Lp-PLA2 vitamin D —	— — Alpha 1 antitrypsin, C3, C4, ceruloplasmin, orosomucoid, heparin, kappa chains, lambda chains
Research-use-only assays/Tests in development User-defined methods implemented for what analytes	—/vitamin D —	—/TDMs, DAUs alcohol, apolipoprotein A1, apolipoprotein B, beta 2, microglobulin, ferritin, fructosamine, glyco mark, haptoglobin, Hgb A1c, homocysteine, HS CRP, IgA, IgG, IgM, pre albumin, rheumatoid factor, TIBC, transferrin, UIBC
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of diff. 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/Max. 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/— 3 no/— no 39 39 39/39 39/3 × 300 7 days/14 days/yes (2° to 8°C) yes yes yes — 4 hrs/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 yes yes yes yes/yes/yes yes yes/yes yes/yes yes/yes no yes/yes 24 hrs/14 days/14 days/14 days yes/yes	photometry, potentiometry (ion selective electrode), turbidimetric/— 3 no/— no 55 55 15/15 55/100 to 400 8 hours/30 days/yes (15° to 32°C) yes yes yes — 2 hrs/60/— liquid yes/432 no/— 2 µL no/no no/0.5 average <66 no/— yes/no yes/no yes/yes yes yes yes/yes/yes yes yes/yes yes/yes yes yes/yes 2 hrs/14 days/—/— no/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 aspir. & 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 calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes yes yes/yes/yes yes yes/yes yes/yes yes/yes no yes/yes 24 hrs/14 days/14 days/14 days yes/yes	yes yes yes yes/yes/yes yes yes/yes yes/yes yes yes yes/yes 2 hrs/14 days/—/— no/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. 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	12 min, 160 specimens 1 hr, 60 specimens 14 min, 240 specimens 5 min 8–24 hrs/yes yes/yes yes	<5 min, — 7.5 min, 35 specimens <11 min, 23 specimens 1–2 min 8 hrs/yes yes/yes yes
Data mgmt. 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 chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	onboard/yes (additional cost) Fletcher Flora, Lab Track, and several other common systems yes (broadcast download, host query) yes yes — —	onboard/no Antek, Fletcher Flora, Mediatech, Orchard, Schuyler House, Sunquest, Technidata yes yes yes no —
Lab can control analyzer remotely Interface avail. (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 svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/yes/yes 24 hrs/yes — daily: visual; weekly: 20 min; monthly: visual inspections <5 min yes (includes audit trail)/no 5 days on site/yes —	yes/yes/yes <24 hrs/yes —/ <24 hrs daily: 5 min; weekly: 5 min; monthly: 15 min yes/yes 4 days at corporate office in California/yes —
Distinguishing features (supplied by company)	use of a water system eliminates the need to purchase, ship, and store cubes of water; HbA1c can be performed directly onboard with results equivalent to HPLC, no need to purchase a separate HbA1c analyzer; small size and large menu, 39 onboard chemistries; can run general and special chemistries, from CMPs to D-dimer, cystatin C, insulin, and more	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



## Chemistry analyzers (for low-volume laboratories)

Part 7 of 13	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 2008 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Stat Profile Critical Care Xpress/2002 —/— —/— U.S./U.S./U.S. discrete/self-contained multi-use cartridges	Stat Profile pH0x series/1998 —/— —/— U.S./U.S./U.S. discrete/self-contained multi-use cartridges-packages-slides
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	sample automatically drawn from syringe, capillary, or open tube/bencht 17.2 × 17.3 × 22.3/2.7 sq. ft.	sample automatically drawn from syringe, capillary, or open tube/bencht 15 × 15 × 18/1.9 sq. ft.
Tests available on instrument in U.S.	pH, PCO <sub>2</sub> , PO <sub>2</sub> , SO <sub>2</sub> %, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, ionized Mg, glucose, BUN, creatinine, lactate, bilirubin, deoxyhemoglobin, oxyhemoglobin, methemoglobin, carboxyhemoglobin	pH, PCO <sub>2</sub> , PO <sub>2</sub> , SO <sub>2</sub> %, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, glucose, lactate
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	potentiometry (ISE), optical, reflectance/—	potentiometry (ISE), optical, reflectance/—
No. of direct ion selective electrode channels	12	5
• 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	20	11
No. of different assays programmed, calibrated at once	20	11
No. of user-definable (open) channels/No. active simultaneously	0/—	0/—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	20/200–500 samples (2,600–6,500 tests), depending on lab	11/varies by analyzer and laboratory use pattern
Shortest/Median onboard reagent stability/Refrigerated onboard	45 days/45 days/no	45 days/45 days/no
Multiple reagent configurations supported	—	—
Reagent container placed directly on system for use	requires operator prehandling, preparation	requires operator prehandling, preparation
Instrument has same capabilities when 3rd-party reagent used	—	—
Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes	cost varies with volume/—/—	cost varies with volume/—/—
Walkaway capacity in minutes/No. of specimens/No. of tests-assays	—	—
System is liquid, dry, or reconstituted onboard	ISE	ISE
Uses disposable cuvettes/Max. No. stored	no/—	no/—
Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum sample volume aspirated precisely at one time	60 µL	45 µL
Supplied with UPS (backup power)/Requires floor drain	no (optional)/no	no (optional)/no
Requires dedicated water system/Water consumption in L per hour	no/—	no/—
Noise generated in decibels	minimal	minimal
Dedicated pediatric sample cup/Dead volume	no/—	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes (optional), by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes	yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	yes
Bar-code placement per CLSI standard Auto2A	no	no
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/yes
Automatic detection of adequate reagent for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes (on co-oximeter module)/yes (on co-oximeter module)	yes*/yes*
Dilution of patient samples onboard/Automatic rerun capability	yes (on co-oximeter module)/no	yes*/no
Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	no/no	no/no
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	30–120 min/30–120 min/—/—	30–120 min/30–120 min/—/—
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
• Sodium, potassium, chloride, TC02	50 sec, 26-36, depending on use mode	50 sec, 44
• Sodium, potassium, chloride, TC02, glucose, urea, creatinine	123 sec, 21-24, depending on use mode	—, —
• Album., direct & total bili., AST, ALT, ALP	—, —	—, —
Typical time delay from ordering stat test to aspir. of sample	<2 sec	<2 sec
How often QC required/Onboard SW capability to review QC	8 hrs/yes	8 hrs (CLIA)/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	no/no
Lab information systems with which interfaces up and running in active user sites	—	virtually all
Bidirectional interface capability	yes	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	no
How labs get LOINC codes for reagent kits	—	—
Lab can control analyzer remotely	yes	yes
Interface avail. (or will be) to automated specimen handling system	no	no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	yes/yes/yes	yes/yes/yes
On-site time of svc. engineer/Onboard error codes for troubleshooting	<8 business hr/yes	<8 business hr/yes
Mean time between failures/To repair failures	—	—
Average time to complete maintenance by lab personnel	daily: none; weekly: <5 min; monthly: <15 min	daily: none; weekly: <5 min; monthly: <15 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	yes/yes
Training provided with purchase/Advanced oper. training avail.	yes/yes	yes/yes
Annual service contract cost (24 h/7 d)	call for pricing	call for pricing
Distinguishing features (supplied by company)	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	onboard quality control; liquid calibration eliminates gas tanks; remote control; remote review; space-saving design

\*on co-oximeter module

## Chemistry analyzers (for low-volume laboratories)

Part 8 of 13	Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com	Ortho-Clinical Diagnostics Sales Support 1001 U.S. Highway 202, Raritan, NJ 08869 800-828-6316 www.orthoclinical.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2008 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Nova 16/1995 —/— —/— U.S./U.S./U.S. batch, random access/self-contained multiuse cartridges	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
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	40-position tray, stat sampling directly from sample container/benchttop 20.5 × 19.2 × 20.7/2.75 sq. ft.	—/benchttop 6.75 × 18.75 × 13.75/1.8 sq. ft. (DT 60 II)
Tests available on instrument in U.S.	sodium, potassium, chloride, total CO <sub>2</sub> , glucose, BUN, creatinine, Hct	ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN-urea, glucose, Mg, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH, theophylline, CO <sub>2</sub> , sodium, potassium, chloride, urine creatinine, CK-MB
Tests cleared but not clinically released	—	none
Tests not available in U.S. but submitted for FDA 510(k) clearance	—	none
Tests not available in U.S. but available in other countries	—	none
Research-use-only assays/Tests in development	—	none/none
User-defined methods implemented for what analytes	—	none
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of diff. 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/Max. 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	potentiometry/— 8 no/— no 8 8 0/— 8/(@ 8,000 tests/mo): 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 hr/2 hr/—/— —	potentiometry, colorimetric, enzymatic/— 4 yes/1 yes one per module (DT 60 II, DTE II, DTSC II) 1 none — —/—/—no no no — — — — dry no/— no/— 10 µL no/no no/no — — no/no no/yes reagent lot changes no/no
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 aspir. & 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 calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes — yes no/yes/yes yes no/no yes/yes no/no — yes yes/— 2 hr/2 hr/—/— —	yes — — — no/no no/no no no/yes reagent lot changes no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. 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	52 sec, 69 specimens 85 sec, 45 specimens —, — 9 sec CLIA minimum/yes no/yes yes	15 tests 75 tests 20 tests none every 24 hrs/no no/no yes
Data mgmt. 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 chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	onboard & optional add-on (\$9,225, SW mfr: Nova)/no most LIS vendors including Cerner, Misys, McKesson, Soft, others yes yes no no —	—/no — no yes yes — —
Lab can control analyzer remotely Interface avail. (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 svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/yes/yes <8 business hr/yes — daily: <2 min; weekly: <5 min; monthly: <5 min no/no yes/yes call for pricing	no/yes/yes —/yes — daily: 5 min; weekly: 5 min; monthly: none no/no yes/— —
Distinguishing features (supplied by company)	whole blood analyzer for creatinine & TC02; can analyze whole blood, serum, plasma, urine, CSF, and dialysate	disposable tips eliminate sample carryover; random access testing so chemistries can be run in any order, with no reagent prep.; indiv. packaged test slides elim. waste and facilitate rapid analysis; dry-slide technology minimizes the effects of interferences to provide accurate results



## Chemistry analyzers (for low-volume laboratories)

Part 10 of 13	Randox Laboratories marketing@randox.com 4065 Oceanside Blvd., Ste. Q, Oceanside, CA 92056 760-639-1500 www.randox.com	Roche Diagnostics Corp. Jim Dodds jim.dodds@roche.com 9115 Hague Road, Indianapolis, IN 46256 317-521-4723 www.roche-diagnostics.us
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2008 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	Rx Daytona/2005 — >1,000 units worldwide Japan/Japan/U.K. random access, discrete/self-contained multi-use cartridges-packages-slides removable ring/benchtop 30.2 x 24.8 x 20.2 sq. ft./—	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.
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	*acid phos., alb., aldolase, ALT, ammonia, alk. phos., AST (GOT), amylase, panc. amylase, bilirubin (direct/total), calcium, total CO <sub>2</sub> , cholesterol, HDL-C, LDL-C, CK-NAC, CK-MB, complement C3/C4, copper, CRP, HS CRP, FR CRP, creatinine, ferritin, fructosamine, glucose, GGT, HbA1c, IgA, IgE, IgG, IgM, LDH, lipase, lithium, ASO, lipoprotein(a), ApoA1, ApoB, microalb., magnes., myoglobin, sodium, prealbumin, phosphorus, potas., RF, iron, phenobarbital, phenytoin, digoxin, digitoxin, theophylline, gentamicin, valp. acid, carbamazepine, transferrin, TIBC, total protein, triglycerides, uric acid, BUN/urea, urinary protein, zinc, ISE Na, others — — cystatin C, S LDL, amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine metabolite, opiates, EDDP, ecstasy, ethanol, methadone *acetic acid, Apo E, Apo CIII, Apo CII, ApoAII, alpha-1-antitryp, alpha-1-acid glycoprotein, bile acids, butyryl choline., others/— acetaminophen, drugs of abuse, salicylate cyclosporine, alcohol, glycerol-3-phosphate, oxidase, phospholipids, maltose, T4, T-uptake	NT-proBNP, troponin I, myoglobin, CK-MB — — — — — —
Methods supported/Immunoassay methods  No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of diff. 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/Max. 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 aspir. & 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 calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	photometry, potentiometry (ISE), immunoturbidimetry, latex-enhanced immunoturbidimetry/— 3 Na+, K+, CL— no/50 to 2,205 no 30 60 —/60 27/71 to 1,053 8 hrs/30 days/yes (8° to 15°C) yes yes yes — —/40/— liquid no/45 yes/5 years 2 µL no/no yes/7.5 daily 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 no/yes daily/28 days/7 days/— no/yes	—/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 min/up to 6/up to 4 per specimen dry no/— no/— 75 µL no/no no/— 69 at 1 meter no/— no/no upon executing run assay mode/yes yes — no/yes/yes no no/no no/no no/no yes —/— — no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO <sub>2</sub> • Sodium, potassium, chloride, TCO <sub>2</sub> , glucose, urea, creatinine • Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. 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	10 min, 20 sec, — 11 min, 20 sec, — 11 min, 40 sec, — 60 sec shortest: daily; longest: at customer discretion/yes yes/yes yes	— — — — per local requirements/yes yes/yes yes
Data mgmt. 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 chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	onboard/no — yes (host query) yes yes no —	optional add-on/no — no yes yes no —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	— no	no no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/yes/yes — within 24 hr/yes —/— daily: 5 min; weekly: 15 min no/no 3 days on site/yes —	no/yes/yes —/yes —/overnight replacement daily: a few min; weekly: a few min; monthly: a few min no/no 1 day on site/no multi-year warranty provided
Distinguishing features (supplied by company)	comprehensive clinical and research test menu, benchtop, low water consumption, automatic start, multi-speed mixing, Windows software  *Contact company for complete list	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

## Chemistry analyzers (for low-volume laboratories)

Part 11 of 13	Roche Diagnostics Corp. Adam Sterle adam.sterle@roche.com 9115 Hague Rd., Indianapolis, IN 46256 317-521-4804 www.roche.com	Roche Diagnostics Corp. Adam Sterle adam.sterle@roche.com 9115 Hague Rd., Indianapolis, IN 46256 317-521-3099 www.roche-diagnostics.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2008 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	cobas c311/2009 \$125,000/— >20/>200 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.	Cobas Integra 400 Plus/1999 \$175,000/— 550/>2,000 Switzerland/Switzerland/U.S. & Germany continuous random access/self-contained multi-use cassettes rack/benchtop 30 x 53 x 26/9.6 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	acetaminophen, $\alpha$ 1-acid glycoprotein, alanine aminotransferase, alanine aminotransferase (with P-5-P), albumin, alkaline phosphatase, amikacin ammonia, $\alpha$ -amylase, $\alpha$ -amylase pancreatic, antistreptolysin O, $\alpha$ 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, C-reactive protein high sensitive, calcium, cannabinoids, carbamazepine, cholesterol, cholinesterase, CK-MB, cocaine, complement C3c, complement C4, creatine kinase, creatinine, creatinine jaffee, cystatin C, others triglycerides GB, EDDP, oxycodone, ceruloplasmin, lidocaine microalbumin, amphetamines — —/ albumin/BCP, 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 —	* $\alpha$ -1-acid glycoprot., $\alpha$ -1-antitryp., apo A1 & B, antistrepto.-O, comp. C3c & C4, cerul., CRP latex, CRP (hs), 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, $\alpha$ -amy. pancreatic, AP, AST, cholinest., CK-MB, $\gamma$ -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, others none none lipoprotein A none/none —
Methods supported/Immunoassay methods  No. of direct ion selective electrode channels • Must load separate reag. pack for each specimen/No. of diff. assays in pack • Separate reag. 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 reag. containers onboard at once/Tests per container set Shortest/Median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Reag. 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/Max. 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 reag. for aspir. & 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 calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	photometry, potentiometry 3 no/— — 45 >130 10/10 up to 42 (+3 ISE)/100–800 120 hours/84 days/yes (5° to 15°C) yes yes yes varies/varies/varies 173/108/45 liquid no/66 yes/monthly 1 $\mu$ L yes/yes yes/12 <65 yes/50 $\mu$ 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 hrs/lot/lot/lot yes/yes	photometry, potentiometry, fluorescence polarization/turbidimetric, latex particle enhanced 4 no/1 no 36 tests plus applications for urine & CSF up to 999 0/0 36/50–800 tests, cassettes 2 weeks/8 to 12 weeks/yes (12°C) yes yes yes — 176/90/1,808 liquid yes/1,500 no/— 1 $\mu$ L no/no no/2 maximum — yes/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes — yes yes/yes/yes — no/no yes/yes yes/yes yes yes/yes 5 hrs/once per lot/each lot & 12 weeks/each lot & 12 weeks yes/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. 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 min, 150 specimens 8 min, 38 specimens 11 min, 22 specimens <1 minute daily/yes yes/yes yes	369 tests 369 tests 250 tests none 24 hr/yes yes/yes yes
Data mgmt. 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 chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	onboard/no all major LIS providers yes (broadcast download & host query) yes yes yes Web site (MyLab Online)	onboard/yes (add'l cost) all major LIS vendors yes (broadcast download & host query) yes yes — —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	yes —
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes <8 hrs/yes 300 days/<2 hrs daily: 10 min; weekly: 5 min; monthly: 15 min yes (includes audit trail of who replaced parts)/no 2 days on site; 5 days at vendor offices/yes varies	yes/yes/yes —/yes — daily: none; weekly: 5 min; monthly: none yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes —
Distinguishing features (supplied by company)	convenience and stability of cobas c pack reagents, standardized operator interface and reagents with other cobas chemistry platforms, Hitachi reliability	unique reagent cassette eliminates reagent preparation; menu consolidates testing, including direct LDL, whole blood, HbA1c, and lithium *Contact company for complete list

## Chemistry analyzers (for low-volume laboratories)

Part 12 of 13	Roche Diagnostics Corp. Ken Dean kendea@roche.com 9115 Hague Rd., Indianapolis, IN 46256 317-521-7538 www.poc.roche.com	SDI Biomed Inc. Robert Silverberg rs@sdibiomed.com 23679 Calabasas Road, #241, Calabasas, CA, 91302 818-349-4464 www.sdibiomed.com
Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2008 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	cobas c111/2007 \$49,000/>80 >100/>2,000 Switzerland/Switzerland/Germany continuous random access/multi-use reagent bottles rack/benchtop 18.9 x 28.4 x 21.7/4.3 sq. ft.	SDI CA 480 Clinical Chemistry System/2004 \$85,000/— >50/>600 Europe/Europe/United States random access/self-contained single-use cartridges-packages-slides wheel, with 4 independent segments/benchtop 40.5 x 25.4 x 17.7/7.2 sq. ft.
Tests available on instrument in U.S.	albumin, ALT, ALP, ammonia, amylase (total), amylase (pancreatic), AST, bicarbonate, D-bilirubin, T-bilirubin, BUN, calcium, chloride, cholesterol, CK, CK-MB, creatinine Jaffe, creatinine plus, hsCRP, ethanol, CRP, GGT, glucose, HbA1c, HDL cholesterol, iron, lactate, LDH, LDL cholesterol, lipase, magnesium, microalbumin, phosphate, potassium, sodium, total protein, triglycerides, uric acid	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 User-defined methods implemented for what analytes	— D-dimer — —/homocysteine —	— — — none/drugs of abuse none
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/Max. 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 3 no no 17 112 0/— 17/50-100 5 days/28 days/yes yes yes no — 60/8/60 liquid yes/60 no/— 2 µL no/no no/.3 standby: 44.4, running: 51.2 no/— yes/no yes, by handheld scanner as tubes are loaded onto instrument (interleaved 2 of 7, EAN, UPC, Codabar, codes 3 of 9, code 28)/yes yes — yes yes/yes/no (ISE only) yes no/no yes/no yes/yes yes no/yes 24 hrs (main calibration)/lot/—/— no/no	photometry, potentiometry/selected methodologies 3 no/— no 33 33 0/available on request 30/150 per container 14 days/30 days/yes (14°C) yes yes yes — 165/40/33 liquid no yes/analyzer uses permanent quartz cuvettes 3 µL yes/no no/1 — no/— yes/no yes/yes yes yes yes/yes/no yes no/no yes/yes yes/no yes yes/yes 30 minutes/once per week/once per week/once per week no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. 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 min, 100 specimens 11 min, 100 specimens 13 min, 100 specimens immediately upon completion of currently running test daily/yes no/yes yes	1.5 min, 60 specimens 6 min, 48 sec, 60 specimens 7 min, 12 sec, 50 specimens 3 min 8 hrs/yes yes/yes yes
Data mgmt. 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 chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits	onboard/no >20 yes (broadcast download, host query) yes yes no —	onboard/— Schylab, LabDaq, Fletcher Flora, Medcom yes yes yes no —
Lab can control analyzer remotely Interface avail. (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 svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/yes/no within 24 hrs/yes 216 days/1.5 hrs daily: 45 min; weekly: 15 min; monthly: 10 min no/no yes (5 days on site)/no \$4,500	yes/yes/yes yes, guaranteed within 24 hours/yes 10,000 hours/2 hours daily: 5 min.; weekly: 15 min.; monthly: 15 min. yes/no 4 days on site or 4 days at vendor offices/yes \$7,500
Distinguishing features (supplied by company)	compact size, truly automated, consistent results with larger cobas analyzers	permanent cuvettes, onboard jet wash/dry system, six minutes to first result, notebook-like operator interface, small footprint

## Chemistry analyzers (for low-volume laboratories)

Part 13 of 13	Siemens Healthcare Diagnostics Diane Bandy diane.m.bandy@siemens.com 1717 Deerfield Rd., Deerfield, IL 60015 302-631-9435 www.siemens.com	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 2008 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	Dimension Xpand Plus Integrated Chemistry System/2004 —/— —/— U.S./U.S./U.S. continuous random access/self-contained single-use & multi-use cartridges racks/floor-standing 45 x 51 x 31 (without monitor)/10.6 sq. ft.	Envoy 500 Chemistry Analyzer/2005 —/— 180/— Italy/Italy/U.S. random access/self-contained multi-use cartridges-packages-slides rotor/benchtop 27 x 40 x 23/6 sq. ft.
Tests available on instrument in U.S.	calcium, creatinine, direct bilirubin, enzymatic carbonate, enzymatic creatinine, iron, magnesium, phosphorus, total bilirubin, total iron-binding capacity, IBCT (no pre-treat), total protein, urea nitrogen, uric acid, carbon dioxide, chloride, potassium, sodium, acid phosphatase, alanine aminotransferase, alkaline phosphatase, amylase, aspartate, aminotransferase, creatine kinase, creatine kinase MB, isoenzyme, glutamyl transferase, lactic dehydrogenase, lipase, pseudocholinesterase, hemoglobin A1c, glucose (liquid), microalbumin, cardiac troponin I, low volume cardiac troponin, mass CK-MB, myoglobin, myeloperoxidase, NT-proBNP, low volume NT-proBNP, cardiophase hsCRP, cholesterol, automated HDL, cholesterol, automated LDL, others	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
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	— — — —/sirolimus, mycophenolic acid —	— — — — CRP wide range, hsCRP, digoxin, ferritin, fructosamine, lipase, phenobarbital, UIBC, glyoMark, 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 diff. 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/Max. 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	colorimetric, immunoturbidimetric, potentiometric, EMIT (homogeneous IA), ACMA (heterogeneous IA) 3 no/one no 47 190 10/10 47/15-360 72 hr/30 days/yes (2° to 8°C) yes yes yes — can be hrs/60/>1,000 liquid, no reagent prep required by operator yes/12,000 no/— 2 µL yes/no yes/up to 2 maximum <70 no/20 µL yes/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	photometry, potentiometry, turbidimetric 4 no/— no 40 40 500/40 40/150 80 hrs/21 days/yes (12° to 15°C) yes yes no — 240 min/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 barcode 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 min/21 days/—/— 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 aspir. & 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 calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes yes yes/yes/no yes yes/yes yes/yes yes/no yes yes(Na, K, Cl)/yes every 2 hrs, autocalibrate/—/60-90 days/30 days not required/—	yes no yes yes/yes/no yes no/no yes/yes yes/yes yes no/yes 4 min/21 days/—/— yes/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. 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 min, 62 specimens 4 min, 60 specimens 8 min, 40 specimens 60 sec steady state, 2 min from standby daily/yes yes/yes yes	3 min, 45 sec, 37 specimens 6 min, 10 sec, 45 specimens 9 min, 26 sec, 26 specimens >1 min 4-24 hrs yes/yes yes
Data mgmt. 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 chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & 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 & 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 avail. (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 svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes 2-8 hr/yes — daily: 5 min; weekly: 10 min; monthly: 15 min no/no 5 days on site, 4 days at vendor offices/no multiple types	yes/yes/yes within 24 hrs/yes — daily: 5 min; weekly: 10 min; monthly: 15 min 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