

Choosing cost-efficiency in low-volume labs

Anne Ford

Cost-efficiency plays a leading role in any instrumentation decision. But in a low-volume laboratory, it takes center stage. "The small instruments by design have a higher cost per test than the machines designed for large throughput," says Jim Miller, general manager of Hemagen's clinical chemistry analyzer systems division. "And there's just so much you can do with the cost of the test."

Without economy of scale on their side, low-volume laboratories must figure out how to cut costs elsewhere without sacrificing accuracy or speed. The chemistry analyzers in this month's lineup—designed for the low-volume lab—offer features aimed to do just that.

The technologist and technician shortage means that these analyzers must require minimal hands-on time. "Even if you find a system that's extremely inexpensive to purchase, if it takes a lot of tech time to operate it, it doesn't result in cost savings for the lab," says Christine Forst, marketing product manager for clinical chemistry at Ortho-Clinical Diagnostics. It's helpful, too, if the system is user-friendly enough that it doesn't have to be operated by a medical technologist. Ortho-Clinical's Vitros DT 60-II system is "very robust—it can handle varying skill levels," she says.

Miller says that Hemagen's Analyst benchtop chemistry system is designed to reduce labor costs through its ease-of-use features. Instructions on the analyzer use symbols rather than words. "You push a symbol on the unit and it adds the sample, and you match that symbol to the symbol on the test, so that it adds the right sample and diluent to the right part of the test," he says. "'Go' looks like your index finger; 'stop' is a big X. It's very non-operator-dependent." Toward the same goal, Nova Biomedical's Stat Profile Critical Care XPress has a touch-screen, says Ron Newby, director of marketing, "so you can order the panels without doing a lot of programming."

Reagent kit size is another financial hot spot for low-volume labs. In these settings, buying in bulk usually doesn't reduce costs—instead, it often means that labs waste money by discarding expired reagents. To address this problem, says Kathy Iozzino, senior marketing manager at Alfa Wassermann, her company offers smaller reagent quantities for its Ace clinical chemistry system. "Our reagent kit sizes contain volumes which are appropriate for a physician's office laboratory," she says. "You're not forced to buy reagent kits with 1,000 tests at a time."

In instrument size, too, smaller is often better. By freeing up valuable floor space, smaller instruments can make lab operations more efficient and cost-effective. Though small, Abaxis' Picco-

Chemistry analyzers (for low-volume laboratories)

lo chemistry and electrolyte analyzer, says marketing director Ron Blasig, “can provide comparable panels to that of a core lab. During a presentation to Emory University Hospitals laboratory staff some time ago, I placed this little Piccolo on their big instrument and said, ‘This will do everything that does.’” Toni Perkins, marketing product manager at Dade Behring, adds that her company’s instrument, the Dimension Xpand, which “has a broad test menu of the most often ordered methods,” is attractive to physician office labs as well as hospitals “because of its small footprint.”

With its Synchron CX5 Pro analyzer, says product marketing manager Dan Siegenthaler, Beckman Coulter addresses another cost factor for labs: instrument maintenance and repair. The CX5 has remote diagnostic capabilities, so if a lab makes a maintenance request, he says, the company can “dial in through a modem and bring back what’s on the system to our computer, and we can actually operate the instrument and do different test functions. Often we can help fix problems right away over the phone.”

A more advanced remote diagnostics function is available now on Beckman Coulter’s higher-volume analyzers, but the company hopes to feature it on its low-volume analyzers in the future. The advanced function “monitors the vital signs of the instrument—pressures, voltages, temperatures—24 hours a day, seven days a week, and transmits the data every seven seconds through the Internet to a server at our facility,” says Siegenthaler. “If a parameter goes outside a certain set range, it triggers an alarm and sends an e-mail to the service manager, alerting him to the existence of a potential problem before it even results in instrument downtime.”

Meanwhile, Roche product manager Todd Atkinson thinks the next few years will find small labs focusing on instrument consolidation as a cost-saving measure. “They may have one or two people operating three or four instruments,” he says. “If they can consolidate and eliminate some of those extra instruments, they can tie up less time and fewer operators.” Roche’s Cobas Integra 400 Plus features more than 130 assays, 32 open channels, and four ISEs.

CAP TODAY’s lineup of chemistry analyzers for low-volume labs includes, in addition to those mentioned here, Abbott Laboratories’ i-Stat Portable and i-Stat 1; ACT Diagnostics’ Pronto Evolution; Alfa Wassermann’s Nextc; Analox Instruments’ GM7; Awareness Technology’s ChemWell; Beckman Coulter’s Synchron CX4 Pro; Clinical Data’s ATAC 6000, ATAC 8000, and AGII; Nova’s Nova 16; and Roche’s Hitachi 912 and Coba Mira Plus CC. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities. □

Anne Ford is CAP TODAY senior editor.

Part 1 of 11	Abaxis Inc. Ron Blasig ronblasig@abaxis.com 3240 Whipple Rd. Union City, CA 94587 800-822-2947 www.abaxis.com
See accompanying comments on page 32	
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Piccolo/1995 \$17,000 500/300 U.S./U.S./U.S. self-contained disc with multitest reag. panel
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	disc loaded directly into instrument/benchtop 9.5 x 6 x 11.5/1 sq ft
Tests available on instrument in U.S.	ALP, ALT, AST, GGT, amylase, albumin, total protein, bilirubin total, BUN, creatinine, calcium, cholesterol, glucose, uric acid, sodium, creatine kinase, potassium, TCO ₂ , chloride, cholesterol, HDL ratio, HDL, LDL, triglycerides-VLDL
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development User-defined methods implemented for what analytes	phosphorus, direct bilirubin — none magnesium, direct bilirubin none
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for ea. spec./No. 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 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 NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspirate & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high, low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown/Startup programmable	enzymatic/n/a n/a yes/4–14 analytes (chemistries) for 11 different chemistries/electrical profiles; reagent self-contained with each disc no 26 14 0/n/a 4–14/self-contained disc with reagents 4–12 6 mos/12 mos/n/a yes yes n/a \$0.84/n/a/n/a <15/1/14 reconstitutes onboard no/n/a no/n/a ~100 µL no/no no/n/a none no no/n/a yes/— no yes n/a n/a/yes/yes yes yes/yes yes/no n/a/n/a yes yes/yes self-calibrated onboard/disc/—/— yes/yes
Stat time to completion of all analytes, throughput per hr. 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 aspirate 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	15 min, 4 specimens 15 min, 4 specimens 15 min, 4 specimens (total bilirubin only, no phosphorus.) n/a automatic QC onboard/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface	onboard/no
Interfaces up and running in active user sites with	3
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 & results How labs get LOINC codes for reagent kits	no yes yes no —
Lab can control analyzer remotely Interface available (or will be) to automated specimen handling system	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 operator training available Annual service contract cost (24 h/7 d)	no/yes/yes 24-hr loaner/yes 3 yrs/— daily: none; weekly: none; monthly: none n/a/yes yes/yes 1-yr warranty, extended warranty—\$1,200
Distinguishing features	compact chemistry system using a few drops of whole blood, serum, or plasma provides turnaround of results at point of care, including hands-on time, in 15 minutes

Chemistry analyzers (for low-volume laboratories)

Part 2 of 11	Abbott Laboratories Joey Baugh joey.baugh@abbott.com 4A Crosby Dr. Bedford, MA 01730 781-276-6000 www.abbott.com	Abbott Laboratories Joey Baugh joey.baugh@abbott.com 4A Crosby Dr. Bedford, MA 01730 781-276-6000 www.abbott.com
See accompanying comments on page 32		
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	i-Stat Portable Clinical Analyzer/1995 \$7,900 12,000/4,000 U.S./U.S./Canada n/a/self-contained single-use cartridges-packages-slides	i-Stat 1/2000 \$9,500 1,500/500 U.S./U.S./Canada —/self-contained single-use cartridges-packages-slides
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	n/a/handheld-portable 8.26 x 2.52 x 2.05/n/a	n/a/handheld 23.48 x 7.68 x 7.24 cm/—
Tests available on instrument in U.S.	sodium, potassium, chloride, ionized calcium, BUN, glucose, creatinine, lactate, Hct, pH, pCO ₂ , pO ₂ , ACT _c , Calculated: Hb, TCO ₂ , HCO ₃ , BEecf, anion gap, SO ₂ , PT	sodium, potassium, chloride, ionized calcium, BUN, glucose, creatinine, lactate, Hct, pH, pCO ₂ , pO ₂ , ACT _c , Calculated: Hb, TCO ₂ , HCO ₃ , BEecf, anion gap, SO ₂ , PT
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development User-defined methods implemented for what analytes	none ACT _k none none/APTT, CK-MB, myoglobin, troponin none	none ACT _k none none/APTT, CK-MB, myoglobin, troponin none
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for ea. spec./No. 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 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/n/a 10 yes/1–7 yes 11 up to 16 n/a/n/a 1 cartridge at a time, each up to 7 tests 14 days at room temp./no no n/a n/a \$3–\$9/n/a/n/a approx. 2 min for any cartridge type depends on component no/n/a no/n/a 40 µL no/no no/n/a none no no/n/a no/no	potentiometry/— 10 yes/up to 16 yes 11 up to 16 n/a/n/a n/a/1 cartridge at a time, each up to 16 tests —/14 days/no no n/a n/a \$3–\$9/—/— 2 min/1/up to 16 — no no 40 µL no/no no/n/a none no no/no yes, patient, operator, identification (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/—
Reagent bar-code reading capability Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspirate & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced/Increased to rerun out-of-linear-range high, low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown/Startup programmable	n/a n/a no no/yes/yes yes yes/yes no/no no/no yes yes/no each test/each test/n/a/n/a to start, insert cartridge/automatically powers down	yes yes n/a n/a/yes/yes yes yes/yes no/no no/no yes yes/no each test/each test/—/— yes/yes
Stat time to completion of all analytes, throughput per hr. 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 aspirate 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, n/a 2 min, n/a n/a, n/a n/a 24 hrs, longest interval: each new lot/yes yes/yes yes	2 min, n/a 2 min, n/a n/a, — n/a shortest interval: 24 hrs; longest interval: each new lot/yes yes/yes yes
Data management capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with 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 & results How labs get LOINC codes for reagent kits	optional add-on (\$23,000 including LIS interface, SW manufacturer: Abbott/Sybase)/yes (additive cost) all systems yes (broadcast download & host query) yes yes yes —	optional add-on (\$45,000 including LIS interface, SW manufacturer: Abbott/Sybase)/yes all systems yes (broadcast download & host query) yes yes yes —
Lab can control analyzer remotely Interface available (or will be) to automated specimen handling system	no n/a	yes n/a
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 operator training available. Annual service contract cost (24 h/7 d)	yes/yes/yes replacement/yes not determined daily: none; weekly: none; monthly: none n/a/n/a yes (depends on need)/yes \$300	yes/yes/yes replacement/yes not determined/24 hrs daily: none; weekly: none; monthly: none n/a/n/a —/yes \$420
Distinguishing features	handheld portable analyzer	handheld portable analyzer

Chemistry analyzers (for low-volume laboratories)

Part 3 of 11	ACT Diagnostics LLC Robert Goewert rgoewert@actdiagnostics.com 4100 Avenida De La Plata Oceanside, CA 92056 760-631-8190 www.actdiagnostics.com	Alfa Wassermann Inc. info@alfawassermannus.com 4 Henderson Dr. West Caldwell, NJ 07006 800-220-4488 alfawassermannus.com
See accompanying comments on page 32		
Name of instrument/First year sold in U.S. List price 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	Pronto Evolution/2001 \$26,500 25/800 Italy/Italy/U.S. continuous random access/open reagent system ring/benchtop 15 x 24 x 20/3.3 sq ft	Ace Clinical Chemistry System/1993 \$64,900 1,000+ /600+ U.S./U.S./U.S. batch, random access, discrete, cont. random access, stat/closed reag. system with open reag. system channels ring with segments (15–30 samples/seg.)/benchtop 15.75 x 27.25 x 22.50 (analyzer only)/8 sq ft (full system)
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development User-defined methods implemented for what analytes	open system, chemistries, DAUs, TDMs, lipids, proteins none none none —/— alcohol, (hs)CRP, fructosamine, transferrin, IgA, IgM, IgG, ampheta- mine, barbituate, benzodiazepine, THC, cocaine, PCP, HDL, LDL, HbA1c, TDM	albumin, bilirubin direct & total, calcium, creatinine, glucose, in. phosphorus, iron, magnesium, total protein, BUN, uric acid, ALP, ALT, amylase, AST, CK, gamma-GT, LDH, cholesterol, HDL chol., LDL chol., triglycerides, sodium, potassium, chloride, CO ₂ , digoxin, T ₄ , T-uptake, HbA1c none none special proteins none/serum proteins acetaminophen, alcohol, cortisol, CRP, CK-MB, folate, fructosamine, lipase, salicylate, transferrin, B ₁₂ , amphetamine, barbiturate, benzodiazepine, THC, cocaine, opiate, PCP
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for ea. spec./No. 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 NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. 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/Increased to rerun out-of-linear- range high, low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	photometry/immunoturbidometric 0 no no 15 10 30/15 15/125 —/30 days/yes (10–14°C) yes requires operator prehandling, preparation yes \$0.05–0.15/\$2.50/\$2.50 120/58/250 liquid no no 3 µL no/no no/0.5 n/a yes/≤50 µL yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes no no yes no/no/no yes no/no yes/yes yes/no no no/yes no/daily/weekly/weekly no/no	photometry, potentiometry/CEDIA, turbidimetric, homogeneous, EIA 3 no/n/a no 43 200 18/18 40/100–150 tests per bottle 120 hrs/30 days/yes (10–14°C) yes yes yes \$0.16/\$3.50/\$3.50 150/150/450 liquid yes/248 no/n/a 3 µL yes/no no/n/a — yes/≤50 µL yes/yes yes, as sample is being aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes yes no yes yes/yes/no yes no/no yes/yes yes/no yes no/yes 3 hrs/30 days/45 days with 48 hr updates/TBD n/a/n/a
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, 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	6 min, 50 specimens (no Na or K) 6 min, 20 specimens (no Na or K) 6 min, 16 specimens 3–5 min user defined/yes yes/no user defined	3.5 min, 32 specimens <6 min, 25 specimens 9 min, 21 specimens immediate response, as soon as 10 sec daily/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with 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 (broadcast download) no no no no —	onboard/no Schuyler House, Antek, LabDaq, others yes (broadcast download) yes yes yes —
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 280 days/4 hrs daily: 5 min; weekly: 15 min; monthly: 1 hr no/no 2 days on site, 2 days at vendor offices/no ask vendor	no/yes/yes <24 hrs/yes —/<1 hr daily: 3 min; weekly: 30 min; monthly: 30 min yes (includes audit trail of who replaced parts)/no 4 days at vendor offices/yes ask vendor
Distinguishing features	open reagent system; software is extremely user friendly; primary tube sampling; benchtop; low maintenance	easy-to-use, multitasking software; closed-tube sampling

Chemistry analyzers (for low-volume laboratories)

Part 4 of 11	Alfa Wassermann Inc. info@alfawassermannus.com 4 Henderson Dr. West Caldwell, NJ 07006 800-220-4488 alfawassermannus.com	Analox Instruments U.S.A. Inc. Martin Widdowson P.O. Box 208 Lunenburg, MA 01462 978-582-9368 www.analox.com
See accompanying comments on page 32		
Name of instrument/First year sold in U.S. List price 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	Nexct Clinical Chemistry System/1998 \$37,400 200+/200+ U.S./U.S./U.S. batch, random access, discrete, cont. random access, stat/closed reag. system with open reag. system channels ring with segments (15–30 samples/seg.)/benchtop 15.75 x 27.25 x 22.50 (analyzer only)/4.5 sq ft (full system)	GM7/1985 \$12,900 —/— U.K./U.K./U.K. discrete/open reagent system —/benchtop 12 x 12 x 12/1 sq ft
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for 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, bilirubin direct & total, calcium, creatinine, glucose, in. phosphorus, iron, magnesium, total protein, BUN, uric acid, ALP, ALT, amylase, AST, CK, gamma-GT, LDH, cholesterol, HDL chol., LDL chol., triglycerides, CO ₂ , HbA1c none none none none/none acetaminophen, alcohol, CRP, CK-MB, folate, fructosamine, lipase, salicylate, transferrin, B ₁₂	glucose, lactate, cholesterol, urea — — — ethanol, methanol, uric acid, creatinine, acetoacetate, β-hydroxybutyrate, lactose, sucrose, ammonia, glutamine, glycerol, triglyceride, pyruvate/none —
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for ea. spec./No. 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 NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. 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/Increased to rerun out-of-linear-range high, low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	photometry/CEDIA, turbidimetric, homogeneous, EIA 0 (optional ISE interface) no/n/a no 20 200 9/9 20/40–60 tests per bottle 120 hrs/30 days/no yes yes yes \$0.23/TBD/TBD 30/150/58 liquid yes/58 no/n/a 3 µL yes/no no/n/a — yes/≤50 µL yes/yes yes, as sample is being aspirated (2 of 5 interl., Codabar, codes 39 & 128)/yes yes no yes yes/yes/no yes no/no yes/yes yes/no yes no/yes n/a/30 days/TBD/TBD no/no	oxygen electrode/— — no yes 1 1 2/1 1/100–300 24 hrs/1 day/no no requires operator prehandling, preparation yes \$0.1–\$1/—/— n/a/—/— liquid no/— no/— 2.5 µL no/— no — no no/no no/— — — no no/yes/— yes not required/not required not required/no —/— yes no/not required —/1 hr/—/— no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , 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	3.5 min (with offline ISE), 55 specimens (with offline ISE) <6 min (with offline ISE), 40 specimens (with offline ISE) 9 min, 21 specimens immediate response, as soon as 10 sec daily/yes yes/yes yes	—, — 20 sec, — —, — 1 min shortest interval: 4 hrs; longest: daily/yes yes/no yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	onboard/no
Interfaces up and running in active user sites with	LabDaq, Schuyler House, Antek, others	—
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	yes (broadcast download) yes yes yes —	no yes no no n/a
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 —/≤1 hr daily: 2 min; weekly: 1 min; monthly: 30 min yes (includes audit trail of who replaced parts)/no 4 days at vendor offices/yes ask vendor	no/—/— n/a/— —/— daily: 1 min; weekly: 1 min; monthly: 10 min no/— 1 day on site/no \$500
Distinguishing features	easy-to-use, multitasking software; closed-tube sampling	large test menu; small sample size; cost per test; 20-second analysis time

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

Chemistry analyzers (for low-volume laboratories)

<i>Part 5 of 11</i>	Awareness Technology Inc. C. Schneider info@awaretech.com P.O. Box 1679 Palm City, FL 34991 772-283-6540 www.awaretech.com	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com
<i>See accompanying comments on page 32</i>		
Name of instrument/First year sold in U.S. List price 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	ChemWell/1999 \$25,000 4/270 U.S./U.S./open system batch, random access/open reagent system rack/benchtop 16 x 34 x 20/—	Synchron CX4 Pro/2001 \$162,400 —/— U.S./U.S./U.S. & Ireland continuous random access/open reagent system sectors, centrifugable/floor-standing 69 x 27 x 30/5.6 sq ft
Tests available on instrument in U.S.	unlimited, open system; Pointe Scientific reagents have been FDA cleared and given CLIA moderate complexity and include: ALT, albumin, amylase, AST, bilirubin direct & total, calcium, cholesterol enzymatic, CK, CK-MB, creatinine, GGT, glucose (hexokinase), glucose (oxidase), iron/TIBC, lactate dehydrogenase, LDL cholesterol, magnesium, inorganic phosphorus, total protein, triglyceride, urea (BUN), uric acid	alb, ALP, ALT, amylase, AST, BUN, calc., CO ₂ , chloride, cholest., CK-MB, creatinine, dir. bilirubin, GGT, glucose, HDLD, iron/TIBC, lipase, LD, LDLD, magnesium, phosphorus, potassium, sodium, total protein, total bilirubin, triglyceride, triglyceride glycerol blanked, urea, uric acid; esoteric chemistries: ammonia, cholinesterase, hemoglobin A1c, lactate, micro-albumin, prealbumin, salicylate; drugs of abuse testing; therapeutic drug monitoring; proteins: anti-streptolysin O, IgA, IgM, IgG, rheumatoid factor, transferrin; thyroids: thyroxine, T-up, P-amylase
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development User-defined methods implemented for what analytes	none none unlimited, open system any colorimetric (340–700 nm), open system/n/a all colorimetric end points and kinetic assays; open systems	none none none none/none UIBC
Methods supported/Immunoassay methods	photometry/EIA-microplate format	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay
No. of direct ion selective electrode channels • Must load separate reag. pack for ea. spec./No. 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	n/a no no up to 27 unlimited unlimited/up to 27 27/assay dependent n/a/n/a/no yes reagent dependent yes assay dependent not limited/96/not limited liquid chemistry system yes/96 yes/weekly 2 µL no/no no/<1 L 60 no no/no yes, by handheld scanner as tubes are loaded onto instrument/no no no yes yes/yes/no yes no/no yes/yes yes/no yes yes/yes n/a/user defined/user defined/user defined yes/yes photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay 0 no no 24 50 96/24 24/2,400–9,600 (100–900 tests per container) 168 hr/30 days/yes (2–8°C) yes yes yes assay dependent 400/63/1,512 liquid no/n/a yes/permanent–2-yr warranty (80 stored on instrument) 3 µL yes/no yes/7 L 70 yes/40 µL 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/no yes/no yes no/yes n/a/up to 90 days/60 days/14 days none required	
Reagent bar-code reading capability Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. 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/Increased to rerun out-of-linear-range high, low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	no no yes yes/yes/no yes no/no yes/yes yes/no yes yes/yes n/a/user defined/user defined/user defined yes/yes	yes yes yes yes/yes/yes yes yes/yes yes/no yes/no yes no/yes n/a/up to 90 days/60 days/14 days none required
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , 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	sodium and potassium not available sodium and potassium not available 5.5 min, 28 15 sec user defined/yes yes/yes yes, if LIS is enabled	n/a, n/a n/a, n/a 10 min, 32 specimens 45 sec 24 hr/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard (Awareness Technology Inc.)/no	onboard & optional add-on (SW mfr: Beckman Coulter DL2000)/yes (addt'l cost)
Interfaces up and running in active user sites with	n/a	Cerner, Misys, Meditech, Citation, MedLab, CHC, SMS, McKesson, Labquest, CCA, VA-Mumps, others
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	yes yes yes yes n/a	yes (broadcast download & host query) yes yes no —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no 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 48 hrs in U.S./— not specified/— daily: <10 min; weekly: <30 min; monthly: <1 hr no/— 2 days on site, 3 days at vendor offices/yes \$4,000	yes/yes/no metro: same day; rural: same or next day/yes —/— daily: 5 min; weekly: 15 min; monthly: 20 min no/no 1 day on site, 5 days at vendor offices/no —
Distinguishing features	ChemWell can also be programmed to perform ELISA assays in the microwell format; optional reagent refrigeration unit is available	serum indices; centrifugable sectors; clot detection; bar-coded calibrators and controls; host query; reagent load while running; ready-to-use liquid reagents; Peltier thermal ring; pulsed xenon light source; polychromatic correction; semipermanent glass cuvettes; DL2000 Sample Manager

SURVEY OF INSTRUMENTS	42 / CAP TODAY		June 2003
	Chemistry analyzers (for low-volume laboratories)		
	Part 6 of 11	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com	Clinical Data Inc. 2 Thurber Blvd. Smithfield, RI 02917 800-345-2822 www.clda.com
	See accompanying comments on page 32		
	Name of instrument/First year sold in U.S. List price 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	Synchron CX5 Pro/2001 \$193,500 —/— U.S./U.S./U.S. & Ireland continuous random access/open reagent system sectors, centrifugable/floor-standing 69 x 61 x 30/12.7 sq ft	ATAC 6000 Chemistry System/1990 — —/— —/—/— discrete/open reagent system sample wheel/benchtop 21 x 23 x 18.5/~3 sq ft
	Tests available on instrument in U.S.	alb, ALP, ALT, amylase, AST, BUN, calc., CO ₂ , chloride, cholest., CK-MB, creatinine, dir. bilirubin, GGT, glucose, HDLD, iron/TIBC, lipase, LD, LDLD, magnesium, phosphorus, potassium, sodium, total protein, total bilirubin, triglyceride, triglyceride glycerol blanked, urea, uric acid; esoteric chemistries: ammonia, cholinesterase, hemoglobin A1c, lactate, micro-albumin, prealbumin, salicylate; drugs of abuse testing; therapeutic drug monitoring; proteins: anti-streptolysin O, IgA, IgM, IgG, rheumatoid factor, transferrin; thyroids: thyroxine, T-up, P-amylase	albumin, ALP, Apo A, Apo B, amylase, bilirubin direct & total, BUN, CO ₂ , calcium, cholesterol, CPK, creatinine, fructosamine, GGT, glucose, AST, ALT, HDL, iron-total, phos., LDH, magnesium, total protein, triglycerides, uric acid, sodium, potassium, chloride-ISE
	Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development User-defined methods implemented for what analytes	none none none none/none UIBC	none none none none/none none
	Methods supported/Immunoassay methods	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay	photometry, potentiometry/n/a
	No. of direct ion selective electrode channels • Must load separate reag. pack for ea. spec./No. 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	5 (indirect) no no 29 50 100/29 29/2,900–69,600 (100–2,400 tests per container) 168 hr/30 days/yes (2–8°C) yes yes yes assay dependent 400/63/1,827 liquid no/n/a yes/permanent–2-yr warranty (80 stored on instrument) 3 µL yes/no yes/7 L 70 yes/40 µL 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/no yes/no yes no/yes 24 hr/up to 90 days/60 days/14 days none required	3 no/n/a no 16 16 48/16 16/30 6 hrs/2 days/no no no, requires operator prehandling, preparation no —/—/— —/—/96 liquid yes/96 no/n/a 2 µL no/no no/— — no no/no no no/no no/no no/no no no/no 4 hrs/daily/n/a/n/a no/—
	Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , 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, 75 specimens 8 min, 75 specimens 10 min, 32 specimens 45 sec 24 hr/yes yes/yes yes	—, — —, — —, — — 2 levels daily/yes yes/yes yes
	Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with 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 (SW mfr: Beckman Coulter DL2000)/yes (addt'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, SMS, McKesson, Labquest, CCA, VA-Mumps, others yes (broadcast download & host query) yes yes no n/a	onboard/yes (addt'l cost) Fletcher-Flora yes (host query) yes yes no —
	Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no yes	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/no metro: same day; rural: same or next day/yes —/— daily: 5 min; weekly: 15 min; monthly: 20 min no/no 1 day on site, 5 days at vendor offices/no —	no/no/no within 24 hrs/yes —/— daily: 5 min; weekly: 15 min; monthly: 15 min no/— 5 days on site/no —
	Distinguishing features	serum indices; centrifugable sectors; clot detection; bar-coded calibrators and controls; host query; reagent load while running; ready-to-use liquid reagents; Peltier thermal ring; ISE system; pulsed xenon light source; polychromatic correction; semipermanent glass cuvettes; DL2000 Sample Manager	batch mode with broad test menu; high level of flexibility and performance; includes LIS

Chemistry analyzers (for low-volume laboratories)

Part 7 of 11	Clinical Data Inc. 2 Thurber Blvd. Smithfield, RI 02917 800-345-2822 www.clda.com	Clinical Data Inc. 2 Thurber Blvd. Smithfield, RI 02917 800-345-2822 www.clda.com
See accompanying comments on page 32		
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	ATAC 8000 Random Access Chemistry System/1995 — —/— —/—/— continuous random access/open reagent system	AGII Chemistry System (w/ISE)/1998 contact manufacturer 39/225 U.S./U.K./U.S. batch, random access/open reagent system
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	sample wheel/benchtop 19.5 x 39 x 20.5/5.5 sq ft	wheel/benchtop 24 x 24 x 14/4 sq ft
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for 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, ALP, amylase, Apo A1, Apo B, bilirubin direct & total, BUN, calcium, cholesterol, CPK, CK-MB, creatinine, fructosamine, glycohemoglobin, GGT, glucose, AST, ALT, direct HDL, direct LDL, total iron, TIBC, LDH, magnesium, microalbumin, phosphorus, total protein, triglycerides, uric acid [CO ₂ , chloride, potassium, sodium—ISE] none HbA1c none none/none none	albumin, alk. phos., ALT, AST, amylase, total/direct bilirubin, BUN, calcium, cholesterol, creatinine, CO ₂ , CK/CPK, CRP, GGTP, HDL cholesterol, total iron, LDH, LDL direct, magnesium, phosphorus, total protein, triglycerides, uric acid; w/ISE: sodium, potassium, chloride n/a n/a open system n/a/thyroid (T ₃ , T ₄ , T-uptake, TSH), auto HDL n/a
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for ea. spec./No. 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 NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. 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/Increased to rerun out-of-linear-range high, low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	photometry, potentiometry/n/a 4 no/n/a no 40 40 320/40 40/150 5 days/12 days/yes yes yes yes —/—/— 240+/50/1,200 liquid no/n/a yes/5 yrs 2 µL yes/no no/n/a — no yes/no no/— no — yes yes/yes/no yes —/— yes/yes yes/yes yes no/yes 4 hrs/14 days/n/a/n/a no/no	photometry/n/a 4 with ISE modules no yes 16 16 unlimited/16 16/average 600–1,000 per kit 2 hrs/7 days/no yes requires operator prehandling, preparation yes —/—/— 10 min/38/38 either liquid or powder no yes/after 10 uses 2 µL yes/no no/0.25 L ~35 no no/no no/— no no no/no/no no no/no no/no no no/no ISE separate unit/n/a/n/a/n/a no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , 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	60 sec, 60 specimens 6 min, 45 specimens 7 min, 36 patients with specified panel 20 sec 2 levels daily/yes yes/yes yes	30 sec, 180 13 min, 50 15 min, 35 <30 sec shortest interval: each rotor; longest: 1 8-hr shift/yes n/a/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with 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 (add'l cost) Fletcher-Flora yes (broadcast download & host query) yes yes yes no —	onboard/no (additional) LabDaq, LabPak yes yes yes —
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 within 24 hrs/yes —/— daily: none; weekly: 15 min; monthly: 30 min yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices, 5 days on site/yes —	no/no/no 24–48 hrs/no once every 27 months/2 hrs daily: 5 min; weekly: 5 min; monthly: 30 min no/no 3 days at vendor offices/yes Cap service agreement—no service fee if not needed, no more than \$4,200 per year with reagent agreement
Distinguishing features	475 tests per hour of general chemistry and ISE; reusable glass cuvettes, ensuring low reagent cost; onboard refrigeration; includes LIS	cost per test; Cap service agreement, long-term mean time between failures; reusable rotors; user friendly; true Windows-based software; software very flexible; onboard QC; load and analyze at the same time; economical; small footprint; open system

Chemistry analyzers (for low-volume laboratories)

Part 8 of 11	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 800-242-3233 www.dadebehring.com	Hemagen Diagnostics Inc. sales@hemagen.com 9033 Red Branch Rd. Columbia, MD 21045 800-Hemagen www.hemagen.com
See accompanying comments on page 32		
Name of instrument/First year sold in U.S. List price 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 Integrated Chemistry System/2001 \$173,500 431/— U.S./U.S./U.S. continuous random access/self-contained multi-use cartridges- pakages-slides & open reagent system sample segments/floor-standing 45 x 31 x 51/—	Analyst Benchtop Chemistry System/1986 \$5,500–\$9,900 —/— France-U.S./U.S./U.S. batch/self-contained single-use cartridges-packages-slides, rotors —/benchtop 8.5 x 25 x 13/2.25 sq ft
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development User-defined methods implemented for what analytes	general chemistries, including no-pretreatment HDL & LDL, enzymes, electrolytes, endocrinology, immunology including hsCRP, heterogeneous immunoassays (see distinguishing features), specialty, therapeutic drug monitoring, & toxicology — — — —/procaïnamide, quinidine, lidocaine, triiodothyronine, n-acetylprocaïnamide, tacrolimus, microalbumin —	ALP, GGT, GPT, Got, BUN, glucose, calcium, cholesterol, triglyc- erides, amylase, uric acid, total bilirubin, total protein, HDL-chol. none none none none/— none
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for ea. spec./No. 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 NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. 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/Increased to rerun out-of-linear- range high, low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	photometry, potentiometry, turbidimetric assays/Petinia, Emit, Acma, mag. part. sep. 3 no no 47 190 10/10 47/average 80–120 72 hrs/30 days/yes (2–8°C) yes yes yes n/a can be hrs/60/>1,000 liquid & reconstituted onboard yes/12,000 no/— 2 µL yes/no yes/2 L <70 yes/10–20 µL 5, 7, 10 mL/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 no/no yes/yes yes/yes yes no/yes 2 hrs (auto)/90 days/60 days/60 days —/—	photometry/n/a n/a yes/14 per rotor per patient no — 14 —/— 14/14 —/—/no — yes no —/—/— 10/1/14 dry no (uses rotors) no/n/a 10 µL & 80 µL no/no no/n/a — no no/no no yes — no no/no/no no no/no no/no no/no no no/— n/a/60 days/n/a/n/a no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., 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 4 min, 62 8 min, 42 60 sec steady state, 2 min from standby daily/yes yes/— yes	—, — 10 min, 6 specimens (glucose, urea, creatinine) 10 min, 6 specimens — —/— no/no —
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with 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 interfaces available for all major LIS vendors yes (broadcast download & host query) yes yes no —	—/yes (included in price) in development — — — — —
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)	yes/yes/yes situation dependent/yes —/— daily: 5 min; weekly: n/a; monthly: 20 min yes/no 5 days on site, 4 days at vendor offices/no \$21,000	no/yes/yes most troubleshooting via phone/yes 14–16 mos/— daily: 2 min; weekly: 15 min; monthly: 30 min no/— 1 day on site/yes \$650
Distinguishing features	Dimension Xpand is first and only to combine comprehensive chemistry and stat immunoassay testing on a single, compact platform for the lower-volume setting; no sample splitting; hetero- geneous immunoassay tests include ferritin, free thyroxine, HCG, mass CK-MB, myoglobin, TSH, total and free PSA, and troponin I	uses only 90 µL of sample & requires less than 60 seconds of prep work; minimal maintenance required; offered with sodium, potassium, and chloride ISE units

Chemistry analyzers (for low-volume laboratories)

Part 9 of 11	Nova Biomedical Corp. Jennifer Adams info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com	Nova Biomedical Corp. Nova Sales Department 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com
See accompanying comments on page 32		
Name of instrument/First year sold in U.S. List price 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 \$25,000–\$59,000 —/— U.S./U.S./U.S. discrete/self-contained multi-use cartridges	Nova 16/1995 \$22,500–\$25,500 —/— U.S./U.S./U.S. batch, random access/self-contained multiuse cartridges
Sample handling system/Model type	sample automatically drawn from syringe, capillary, or open tube/benchtop	40-position tray, stat sampling directly from sample container/benchtop
Dimensions in inches (H x W x D)/Instrument footprint	17.2 x 17.3 x 22.3/2.7 sq ft	20.5 x 19.2 x 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, ionized magnesium, glucose, BUN, creatinine, lactate, deoxyhemoglobin, oxyhemoglobin, methemoglobin, carboxyhemoglobin	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 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	none none none none none	none none none none/none none
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for ea. spec./No. 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 NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. 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/Increased to rerun out-of-linear-range high, low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	potentiometry (ISE), optical, reflectance/n/a 12 no/n/a no 19 19 0/n/a 19/200–500 samples (2,600–6,500 tests), depending on lab 45 days/45 days/no n/a requires operator prehandling, preparation n/a \$.06–\$.28 per test (cost varies with volume); bundled instr. reag. maint. cost per result \$.07–\$.31 per test (5-yr reagent rental)/n/a/n/a n/a/n/a/n/a ISE no/n/a no/n/a 50 µL no (optional)/no no/n/a minimal no/n/a 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 min/30–120 min/n/a/n/a yes/yes	potentiometry/n/a 8 no/n/a no 8 8 0/n/a 8/(@ 8,000 tests/mo): 2,700 tests 21 days/21 days/no n/a no, requires prehandling (remove clip from sealed bag & mix) n/a standard chemistries: @25 sam/d: \$0.40 (8-test panel); bundled instr., reag., maint. cost per result: \$0.92 (8-test panel)/—/— 60 per tray/40 per tray/280 per tray n/a no/n/a n/a/n/a 385 µL no/no no/n/a minimal n/a yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes alternate method n/a yes no/yes/yes yes no/no yes/yes no/no yes yes/n/a 2 hrs/2 hrs/n/a/n/a n/a/n/a
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , 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	65 sec, 19–42, depending on use mode 142 sec, 19–22, depending on use mode n/a, n/a <2 sec 8 hrs/yes yes/yes yes	90 sec, 39 specimens 90 sec, 39 specimens n/a 9 sec CLIA minimum/yes no/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no	onboard & optional add-on (\$9,225, SW mftr: Nova)/no
Interfaces up and running in active user sites with	n/a	most LIS vendors including Cerner, Sunquest, HBO, Soft, others
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	yes yes yes no n/a	yes yes no no —
Lab can control analyzer remotely Interface avail. (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 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 business hrs/yes n/a/n/a daily: none; weekly: <5 min; monthly: <15 min yes (includes audit trail of who replaced parts)/yes 1 day on site/yes \$3,750–\$7,685	no/yes/yes <8 business hrs/yes —/— daily: <2 min; weekly: <5 min; monthly: <5 min no/no 2 days on site/yes call for pricing
Distinguishing features	comprehensive 19-test critical care profile including ionized magnesium, BUN, and creatinine; color touch screen; 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	only whole blood analyzer for creatinine & TCO ₂ available; can analyze whole blood, serum, plasma, urine, CSF, and dialysate

Chemistry analyzers (for low-volume laboratories)

Part 10 of 11	Ortho-Clinical Diagnostics Distributor Sales Support Center 1001 U.S. Highway 202 Raritan, NJ 08869 800-457-7848 orthoclinical.com	Roche Diagnostics Corp. Todd Atkinson todd.atkinson@roche.com 9115 Hague Rd. Indianapolis, IN 46256 317-521-4564 www.roche.com
See accompanying comments on page 32		
Name of instrument/First year sold in U.S. List price No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type	Vitros DT60-II Analyzer/1993 — 15,000 units worldwide U.S./U.S./U.S. batch, random access, discrete/self-contained single-use cartridges-packages-slides —/benchtop	Cobas Integra 400 Plus/1999 \$175,000 >2,000/2,000 Switzerland/Switzerland/U.S. & Germany continuous random access/self-contained multi-use cassettes
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	—/benchtop 6.75 x 18.75 x 13.75/1.8 sq ft	rack/benchtop 30 x 53 x 26/9.6 sq ft
Tests available on instrument in U.S.	ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN-urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH, theophylline, CO ₂ , sodium, potassium, chloride, urine creatinine, CK-MB	α -1-acid glycoprot., α -1-antitryp., apo A1 & B, antistrepto.-O, AT III, complement C3c & C4, cerul., CRP latex, ferr., hapt., IgA/G/M, myo., prealb., RF, transferr., amph., barb., benz., coca., ethanol, LSD, meth., methaq., opia., PCP, PPX, S barb., S benz., THC, ACPP, ALP, ALT, α -amy. pancreatic, AP, AST, cholinest. & Che-D, CK-MB, γ -glutamyltrans., LDH, lipase, alb., bil direct & total, Ca., chol., CO ₂ , creat. jaffe, creat. enzymatic, 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., phery., prim., proc., quin., sali., theo., tobra., valp. acid, vanc., T ₄ , T-up, D-dimer, soluble transferrin receptor, cyclosporine, total amylase, total CK, free phenytoin, free VPA, microalbumin
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development User-defined methods implemented for what analytes	none none none none/none none	none none lipoprotein A none/homocysteine, lipoprotein A caffeine
Methods supported/Immunoassay methods	potentiometry, dry slide technology/n/a	photometry, potentiometry, fluorescence polarization/turbidimetric, latex particle enhanced
No. of direct ion selective electrode channels • Must load separate reag. pack for ea. spec./No. 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 NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. 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/Increased to rerun out-of-linear-range high, low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable	4 yes/1 yes n/a 1 none n/a/n/a n/a/n/a/no no no n/a n/a/n/a/n/a n/a/n/a/n/a dry no/n/a no/n/a 10 μ L no/no no/none — n/a no/no no/— yes — n/a n/a/yes/yes yes —/— no/no no/no no/no no no/yes 6 mos/6 mos/6 mos/n/a no/no	4 no/1 no 36 tests plus applications for urine & CSF up to 999 0/0 36/50–800 tests, cassettes 2 weeks/8–12 weeks/yes (12°C) yes yes no —/—/— 176/90/1,808 liquid yes/1,500 no/n/a 1 μ L no/no no/2 L 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, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , 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	100 tests 100 tests 100 tests none every 24 hrs/no no/no —	369 tests 369 tests 250 tests none 24 hrs/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface Interfaces up and running in active user sites with 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	—/no — no yes yes — —	onboard/yes (addt'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)	no/yes/yes —/yes — daily: 5 min; weekly: 5 min; monthly: none no/no 1 day on site/— —	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	disposable tips eliminate sample carryover; random access testing so chemistries can be run in any order, with no reag. prep.; indiv. packaged test slides elim. waste and facilitate rapid analysis; dry slide technology minimizes the effects of common interferences to provide precise, accurate results; wide ranges allow for fewer dilutions and repeats	unique reagent cassette eliminates reagent preparation; menu consolidates testing, including direct LDL, whole blood, HbA1c, and lithium

Chemistry analyzers (for low-volume laboratories)

Part 11 of 11	Roche Diagnostics Corp. Todd Atkinson todd.atkinson@roche.com 9115 Hague Rd. Indianapolis, IN 46256 317-521-4564 www.roche.com	Roche Diagnostics Corp. 9115 Hague Rd. Indianapolis, IN 46256 800-428-5074 www.roche.com
See accompanying comments on page 32		
Name of instrument/First year sold in U.S. List price 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	Roche Hitachi 912/1997 \$159,000 >1,100 Japan-U.S./Japan-U.S./U.S.-Germany continuous random access/open reagent system disk/floor-standing 46 x 40 x 30/8.3 sq ft	Cobas Mira Plus CC/1992 \$50,000 2,500/12,500 Switzerland/Switzerland/Germany-U.S. random access/open reagent system rack/benchtop 26 x 29 x 23/4.63 sq ft
Tests available on instrument in U.S.	alb., ALP, ALT, ammonia, amy. total & panc., AST, bili. total & direct, BUN, Ca, cholest., cholinest., CK, CO ₂ , fruct., GGT, glu., HDL direct, iron, lact., LD, LD-1, LDL direct, lipase, Mg, phos., TIBC (calc.), NAPA, procainamide, TP, trig., T ₄ , T-up, UIBC, UA, Na, K, Cl, α-1-antitryp., ASLO, B-2-microgl., C3c, C4, ceru., CRP, ferr., fol., hapt., HbA1c, IgA/E/G/M, microalb., myo., prealb., RF, transferrin, B ₁₂ , carb., dig., gent., pheno., pheny., salicy., theo., tobra., valp. acid, alcohol, amph., barb., benz., coca., methad., opia., PCP, propoxy., THC; also CSF and urine chemistries, D-dimer, sol. transfer. recept., microalb., creat. jaffe, creat. enzym., (hs)CRP, LDH, TPU-c, acetaminophen, ACT P-5-P, AST P-5-P, CRP, (hs)latex, Apo A1, Apo B	ACP, alb., alk. phos., ALT, amy., amm., Apo A1 & B, AST, bili. direct & total, BUN, Ca., chol., CK, CO ₂ , crea., alcohol, iron TIBC, GGT, HDL direct, HDL, glu., LDH, LDL direct, Mg, phosphorus, TP, triglycerides, UA, fruct., HbA1c, amph., barb., benz., THC, coca., methad., methaq., opia., PCP, propoxy., dig., acetamin., salic, Na, K, Cl by ISE
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	none none kappa/lambda light chains, %CDT, α-1-glycoprotein, α-1-microgl., cyclos., lipoprotein A	none none none
Research-use-only assays/Tests in development User-defined methods implemented for what analytes	none/homocysteine none	none/information to be released at test launch none
Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for ea. spec./No. 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	photometry, potentiometry/turbidimetric, latex particle enhanced, CEDIA 3 no/n/a no 35 tests plus applications for urine & CSF 68 65/65 35/100–500 —/30 days/yes (2–12°C) yes yes no —/—/— 408/70/2,450 liquid no/n/a yes/monthly (120 stored on instrument) 2 µL no/yes yes/30 L ≤65 yes/— 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/no (not necessary due to sampling method) yes yes/yes yes/yes yes/yes yes yes/yes 24 hrs/lot change (every 6 mos)/3–5 days/56 days yes/— photometry, potentiometry/n/a 3 no/n/a no max. 30 104 + profiles & ratios 104 + profiles & ratios/max. 30 max. 30/40–50 6–8 hrs/30 days/yes (10–14°C below ambient) yes yes, but requires some operator prehandling, preparation no —/—/— max. 120 min/90/depends on test vol. liquid yes/— no/n/a 1 µL no/no no/4 L daily ≤62 no yes/no yes, as soon as tubes loaded & start key activated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes no — no no/yes/no yes no/no yes/yes yes/yes yes yes/yes every hr/30–60 days/—/n/a no/no	
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Album., 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	3.5 min, 180 specimens 5.5 min, 90 specimens 10.5 min, 60 specimens 30 sec 24 hrs/yes yes/yes yes	4 min, 15 specimens 7 min, 9 specimens 7.5 min, 8 specimens none 8 hrs, longest interval: daily/yes yes/no yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/yes (add'tl cost)	onboard & optional add-on (\$5,000, SW mfr: Antek, Fletcher Flora)/no
Interfaces up and running in active user sites with	all major LIS vendors	—
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	yes (host query) yes yes no —	yes yes yes — —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no yes (CLAS)	yes (limited) 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 —/yes —/— daily: —; weekly: —; monthly: — yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes —	no/—/— 24 hrs/yes 4 mos/2 hrs daily: 10 min; weekly: 10 min; monthly: 5 min no/no 4 days at vendor offices/no approx. \$9,000
Distinguishing features	sophisticated software with easy stat function provides instant stat selection; Roche Hitachi open system dependability and throughput	level detection of the sample and reagent; entire system is user friendly