

Latest chemistry wish lists in low-volume labs

Anne Ford

The paperless workplace might be a mythical beast, but the "less paper" workplace—well, that sounds a little more realistic, doesn't it?

Peter Karkantis, Abbott point-of-care marketing director, thinks so. His company's PrecisionWeb data-management system for point-of-care testing in the hospital lets users "eliminate passing around faxes, interoffice mail, and so on," he says. "You access information anywhere at any time within the hospital network environment. You're talking nurses, pathologists, laboratory, point-of-care—all at the same time

from their own desktop PCs." Hospital demand is high for this service, he says. "And other vendors are talking about moving into the point-of-care Web arena. The whole industry is talking about Web-based data management." Are you salivating on your printouts yet?

But that's just one of several marketplace developments that pop up in a discussion of chemistry analyzers for low-volume laboratories, which are profiled on the following pages. Breadth of menu is a common customer concern. Nova Biomedical aims to address that need with its Stat Profile Critical Care Xpress, which, says

marketing director Ron Newby, "combines up to 19 measured tests."

Meanwhile, Dan Siegenthaler, Beckman Coulter marketing product manager, says expandability has become an important feature to physician office labs in particular. "If they don't have a chemistry analyzer, then typically the doctor sends these tests out to other labs and pays a high price," he says. "When they form group practices, they come to a certain critical mass where it's more cost-effective to test them in-house. And therefore it's important that they have the flexibility to add additional tests and generate additional

revenue—which helps them justify having a clinical chemistry analyzer." Handy how that works out.

Ron Blasig, Abaxis director of marketing for the Piccolo system, chimes in. "I've even heard of rural areas with outpatient clinics where they were paying a taxicab to ferry" testing to other laboratories, he says. He knows, too, of even urban labs "literally having to courier a sample to the main hospital laboratory." Putting a small—but expandable—instrument on site relieves that problem. Who wants to shell out money to chauffeur samples around?

"Consolidation" is another industry buzzword. Toni Perkins, Dade Behring marketing product manager, says, "We're seeing a continuation of the same trend—customers needing to consolidate instruments to help address the labor shortage and its effect on productivity." Todd Atkinson, Roche product manager for stand-alone systems, concurs. "Customers are demanding solutions that are going to allow them to further consolidate and improve their overall efficiencies," he says.

Clinical Data marketing project manager Mark Moran says the popularity of one of the features his company offers illustrates the marketplace's focus on consolidation. "Our four-parameter dry ISE is integrated with our Selectra chemistry systems," he says. "You don't have to split patient samples or buy a separate ISE analyzer. Our customers really love that aspect of our analyzer."

Later this year, Abbott plans to roll out a feature designed to simplify and consolidate a different laboratory process—competency management. "The way the training is done today, it's all manual," Karkantis says. "You have to bring people into classes, and it's a very elaborate process. We are developing Web-based automated systems, so if somebody doing POC isn't following certain rules, the system will be smart enough to push out to those individuals the right training packages for them to learn and review." Why will labs find this attractive? "It's very hard to have a consistent training process," he says. "Usually the POC coordinator is tasked to do all this—and they're overwhelmed."

CAP TODAY's lineup of chemistry analyzers for low-volume laboratories includes products from the companies listed above and from Alfa Wassermann, ACT Diagnostics, Analox Instruments, Hemagen Diagnostics, and Ortho-Clinical Diagnostics. 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.

Chemistry analyzers (for low-volume laboratories)

Part 1 of 11	<p>Abaxis Inc. Ron Blasig ronblasig@abaxis.com 3240 Whipple Rd. Union City, CA 94587 800-822-2947 www.abaxis.com</p>	<p>Abbott Laboratories Joey Baugh joey.baugh@abbott.com 104 Windsor Center Dr. East Windsor, NJ 08520 800-827-7828 www.istat.com</p>
<p>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</p>	<p>Piccolo/1995 \$17,900 500/300 U.S./U.S./U.S. self-contained disc with multitest reag. panel</p>	<p>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</p>
<p>Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint</p>	<p>disc loaded directly into instrument/benchtop 9.5 x 6 x 11.5/1 sq ft</p>	<p>n/a/handheld-portable 8.26 x 2.52 x 2.05/n/a</p>
<p>Tests available on instrument in U.S.</p>	<p>ALP, ALT, AST, GGT, amylase, albumin, total protein, bilirubin total, BUN, creatinine, calcium, cholesterol, glucose, uric acid, sodium, creatine kinase, potassium, TCO₂, chloride, cholesterol, HDL ratio, HDL, LDL, triglycerides-VLDL, phosphorus, direct bilirubin, magnesium</p>	<p>sodium, potassium, chloride, ionized calcium, BUN, glucose, creatinine, lactate, Hct, pH, pCO₂, pO₂, ACT_c, Calculated: Hb, TCO₂, HCO₃, BE_{ecf}, anion gap, SO₂, PT/INR, ACT_k</p>
<p>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</p>	<p>— — none — none</p>	<p>none none none none/APTT, CK-MB none</p>
<p>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 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. 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</p>	<p>enzymatic/n/a n/a yes/4–14 analytes (chemistries) for 11 diff. chem./ elec. profiles; reagent self-contained with each disk no 26 14 0/n/a 4–14/self-contained disk with reagents 4–12 6 months/12 months/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/disk/—/— yes/yes</p>	<p>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 no/no yes yes/no each test/each test/n/a/n/a to start, insert cartridge/automatically powers down</p>
<p>Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO₂ • Sodium, potassium, chloride, TCO₂, glucose, urea, creatinine • Albumin, 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</p>	<p>15 min, 4 specimens 15 min, 4 specimens 15 min, 4 specimens (total bilirubin only, no phos.) n/a automatic QC onboard/yes yes/yes yes</p>	<p>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</p>
<p>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</p>	<p>onboard/no 3 no yes yes no —</p>	<p>optional add-on (\$23,000 including LIS interface, SW mfr: Abbott/Sybase)/yes (add'l cost) all systems yes (broadcast download & host query) yes yes yes —</p>
<p>Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system</p>	<p>no no</p>	<p>no n/a</p>
<p>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)</p>	<p>no/yes/yes 24-hr loaner/yes 3 years/— daily: none; weekly: none; monthly: none n/a/yes yes/yes 1-year warranty, extended warranty—\$1,200</p>	<p>yes/yes/yes replacement/yes not determined daily: none; weekly: none; monthly: none n/a/n/a yes (depends on need)/yes \$300</p>
<p>Distinguishing features</p>	<p>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</p>	<p>handheld portable analyzer</p>

Chemistry analyzers (for low-volume laboratories)

Part 2 of 11	<p>Abbott Laboratories Joey Baugh joey.baugh@abbott.com 104 Windsor Center Dr. East Windsor, NJ 08520 800-827-7828 www.istat.com</p>	<p>ACT Diagnostics LLC Robert Goewert rgoewert@actdiagnostics.com 4100 Avenida De La Plata Oceanside, CA 92056 760-631-8190 www.actdiagnostics.com</p>
<i>See accompanying article on page 44</i>		
<p>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</p>	<p>i-Stat 1/2000 \$9,500 1,500/500 U.S./U.S./Canada —/self-contained single-use cartridges-packages-slides</p>	<p>Pronto Evolution/2001 \$26,500 25/800 Italy/Italy/U.S. continuous random access/open reagent system</p>
<p>Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint</p>	<p>n/a/handheld 23.48 x 7.68 x 7.24 cm/—</p>	<p>ring/benchtop 15 x 24 x 20/3.3 sq ft</p>
<p>Tests available on instrument in U.S.</p>	<p>sodium, potassium, chloride, ionized calcium, BUN, glucose, creatinine, lactate, Hct, pH, pCO₂, pO₂, ACT_v, Calculated: Hb, TCO₂, HCO₃, BE_{ecf}, anion gap, SO₂, PT/INR, ACT_k, cTnl</p>	<p>open system, chemistries, DAUs, TDMs, lipids, proteins</p>
<p>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</p>	<p>none none none none/APTT, CK-MB none</p>	<p>none none none —/— alcohol, (hs)CRP, fructosamine, transferrin, IgA, IgM, IgG, amphetamine, barbiturate, benzodiazepine, THC, cocaine, PCP, HDL, LDL, HbA1c, TDM</p>
<p>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</p>	<p>potentiometry/— 10 up to 16</p>	<p>photometry/immunoturbidimetric 0 no</p>
<p>• 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</p>	<p>yes 11 up to 16 n/a/n/a n/a/1 cartridge at a time, each up to 16 tests</p>	<p>no 15 10 30/15 15/125</p>
<p>reg. 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</p>	<p>—/14 days/no no n/a n/a \$3–\$9/—/—</p>	<p>—/30 days/yes (10–14°C) yes requires operator prehandling, preparation yes \$0.05–0.15/\$2.50/\$2.50</p>
<p>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</p>	<p>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)/— yes yes n/a n/a/yes/yes yes yes/yes no/no no/no no yes/no each test/each test/—/— yes/yes</p>	<p>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 no no/yes no/daily/weekly/weekly no/no</p>
<p>Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO₂ • Sodium, potassium, chloride, TCO₂, glucose, urea, creatinine • Albumin, 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</p>	<p>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</p>	<p>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</p>
<p>Data mgmt. capability/Instrument vendor supplies LIS interface</p>	<p>optional add-on (\$45,000 including LIS interface, SW mfr: Abbott/Sybase)/yes all systems</p>	<p>onboard/no —</p>
<p>Interfaces up and running in active user sites with</p>		
<p>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</p>	<p>yes (broadcast download & host query) yes yes yes —</p>	<p>yes (broadcast download) no no no —</p>
<p>Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system</p>	<p>yes n/a</p>	<p>no no</p>
<p>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)</p>	<p>yes/yes/yes replacement/yes not determined/24 hrs daily: 5 min; weekly: 15 min; monthly: none n/a/n/a —/yes \$420</p>	<p>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</p>
<p>Distinguishing features</p>	<p>handheld portable analyzer</p>	<p>open reagent system; software is extremely user friendly; primary tube sampling; benchtop; low maintenance</p>

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

Chemistry analyzers (for low-volume laboratories)

Part 3 of 11	<p>Alfa Wassermann Diagnostic Technologies LLC info@alfawassermannus.com 4 Henderson Dr. West Caldwell, NJ 07006 800-220-4488 alfawassermannus.com</p>	<p>Analog Instruments U.S.A. Inc. Martin Widdowson P.O. Box 208 Lunenburg, MA 01462 978-582-9368 www.analox.com</p>
<i>See accompanying article on page 44</i>		
<p>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</p>	<p>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 reagent system with open reagent system channels ring with segments (15–30 samples/seg.)/benchtop</p>	<p>GM7/1985 \$13,500 —/— U.K./U.K./U.K. discrete/open reagent system</p>
<p>Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint</p>	<p>15.75 x 27.25 x 22.50 (analyzer only)/8 sq ft (full system)</p>	<p>—/benchtop 12 x 12 x 12/1 sq ft</p>
<p>Tests available on instrument in U.S.</p>	<p>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, CO₂, digoxin, T₄, T-uptake, HbA1c, hsCRP, digoxin</p>	<p>glucose, lactate, cholesterol, urea</p>
<p>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</p>	<p>none none none special proteins none/serum proteins</p>	<p>— — — alcohol, uric acid, creatinine, acetoacetate, β-hydroxybutyrate, ammonia, glutamine, glycerol, triglyceride, pyruvate/none —</p>
<p>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</p>	<p>photometry, potentiometry/CEDIA, turbidimetric, homogeneous, EIA 3 no/n/a</p>	<p>oxygen electrode/— no —</p>
<p>• 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</p>	<p>no 40 200 18/18 40/100–150 tests per bottle</p>	<p>yes 1 2/1 1/100–300</p>
<p>reg. 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</p>	<p>120 hrs/30 days/yes (10–14°C) yes yes yes \$0.16/\$3.50/\$3.50</p>	<p>24 hrs/1 day/no requires operator prehandling, preparation yes \$0.1–\$1/—/—</p>
<p>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</p>	<p>150/150/450 liquid yes/248 no/n/a 3 µL yes/no no/n/a 55 no/existing sample cup 50 µL dead volume yes/yes yes, as sample is being aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes</p>	<p>n/a/—/— liquid no/— no/— 2.5 µL no/— no no/no no/— yes no/yes yes, as sample is being aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes</p>
<p>Reagent bar-code reading capability Bar-code placement per NCCLS 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</p>	<p>yes yes n/a n/a/yes/yes yes yes/yes no/no yes/yes no/no yes yes/no each test/each test/—/— yes/yes</p>	<p>no no yes no/no/no yes no/no yes/yes yes/no no/daily/weekly/weekly no/no</p>
<p>Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO₂ • Sodium, potassium, chloride, TCO₂, glucose, urea, creatinine • Albumin, 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</p>	<p>4.2 min, 30 specimens 5.8 min, 25 specimens 12.6 min, 17 specimens immediate response, as soon as 10 sec daily/yes yes/yes yes</p>	<p>— 20 sec, — 1 min shortest interval: 4 hrs; longest: daily/yes yes/no yes</p>
<p>Data mgmt. capability/Instrument vendor supplies LIS interface</p>	<p>onboard/no Schuyler House, Antek, LabDaq, others</p>	<p>onboard/no —</p>
<p>Interfaces up and running in active user sites with</p>		
<p>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</p>	<p>yes (broadcast download) yes yes yes —</p>	<p>no yes no no n/a</p>
<p>Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system</p>	<p>no no</p>	<p>no no</p>
<p>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)</p>	<p>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</p>	<p>no/—/— n/a/— —/— daily: 1 min; weekly: 1 min; monthly: 10 min no/— 1 day on site/no \$500</p>
<p>Distinguishing features</p>	<p>easy-to-use, multitasking software; closed-tube sampling; stat interrupt capability; extensive test menu; onboard sample and reagent refrigeration; onboard reagent inventory management</p>	<p>large test menu; small sample size; cost per test; 20-second analysis time</p>

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Chemistry analyzers (for low-volume laboratories)

Part 4 of 11	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.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 article on page 44</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	Synchron CX3 Delta/1995 \$72,300 —/— 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	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 47 x 30/9.8 sq ft
Tests available on instrument in U.S.	sodium, potassium, chloride, CO ₂ , calcium, creatinine, BUN, glucose, total protein	alb, ALP, ALT, amylase, AST, BUN, calc., CO ₂ , chloride, cholest., CK-MB, creatinine, dir. bilirubin, GGT, glucose, HDL, iron/TIBC, lipase, LD, LDL, magnesium, phosphorus, potassium, sodium, total protein, total bilirubin, triglyceride, triglyceride glycerol blanked, urea, uric acid; esoteric chemistries: ammonia, cholinesterase, hemoglobin A1c, lactate, microalbumin, 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, C-reactive protein, creatine kinase
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 UIBC, cyclosporine
Methods supported/Immunoassay methods	photometry, potentiometry/turbidimetric, direct turbidimetric, particle-enhanced turbidimetric, enzyme immunoassay	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay
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 NCCLS 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	4 no no 9 9 0 9/400–2,400 tests per container 168 hrs/30 days/yes (2–8°C) yes yes yes assay dependent 400/63/1,827 liquid no/n/a yes/permanent–2-yr warranty 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 24 hr/n/a/n/a/n/a none required	n/a no no 24 50 96/24 24/2,400–9,600 (100–900 tests per container) 168 hrs/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
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 8 min, 75 n/a, n/a 45 sec 24 hrs/yes yes/yes yes	n/a, n/a n/a, n/a 10 min, 32 specimens 45 sec 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	onboard & optional add-on (SW mfr: Beckman Coulter DL2000)/yes (add'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, SMS, McKesson, Labquest, CCA, VA-Mumps, others yes (broadcast download & host query) yes yes no —	onboard & optional add-on (SW mfr: Beckman Coulter DL2000)/yes (add'l cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, SMS, McKesson, Labquest, CCA, VA-Mumps, others 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/no metro: same day; rural: same or next day/yes n/a/n/a daily: 5 min; weekly: 15 min; monthly: 20 min no/no 1 day on site, 5 days at vendor offices/no n/a	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	fast stat chemistry analyzer; centrifugable sectors; bar-coded calibrations and controls; host query; reagent load while running; ready-to-use liquid reagents; ISE system; pulsed xenon light source; available DL2000 Sample Manager	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; available DL2000 Sample Manager

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

Chemistry analyzers (for low-volume laboratories)

Part 5 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
<i>See accompanying article on page 44</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	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	Vitalab Selectra XL/2004 — 70/70 Netherlands/Netherlands/U.S. random access/bottles rotor/floor-standing 45 x 46 x 30/12 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, HDL, iron/TIBC, lipase, LD, LDL, magnesium, phosphorus, potassium, sodium, total protein, total bilirubin, triglyceride, triglyceride glycerol blanked, urea, uric acid; esoteric chemistries: ammonia, cholinesterase, hemoglobin A1c, lactate, microalbumin, 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, C-reactive protein, creatine kinase	ALT, alkaline phosphatase, albumin, amylase, aspartate transaminase, direct & total bilirubin, calcium, CO ₂ , chloride, cholesterol, CPK, creatinine, digoxin, direct HDL & LDL, GGT, glucose, total iron, LDH, magnesium, phenobarbital, phenytoin, phosphorus, potassium, total protein, sodium, theophylline, triglycerides, BUN, uric acid, HbA1c
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, cyclosporine	— — — none/hsCRP —
Methods supported/Immunoassay methods	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay	photometry, potentiometry (ISE)/immunoturbidimetric
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 NCCLS 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	5 (indirect) 4 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) 1 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 hrs/up to 90 days/60 days/14 days none required	4 no no 40 40 6/40 70 72 hr/7 days/yes (12°C below ambient) yes yes yes —/—/— 240/80/2,400 liquid no yes/10,000 tests 1 µL yes/no no/~0.8 L — yes/~20 µL yes/no yes, as sample is being aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/— no yes yes yes/yes/yes —/— yes/yes yes/no yes/no yes no/yes 4 hrs/1–14 days/—/— 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	52 sec, 75 specimens 8 min, 75 specimens 10 min, 32 specimens 45 sec 24 hrs/yes yes/yes yes	8 min, — 10 min, — 10 min, — 6 min 4 hrs/daily no/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 (additional cost) Cerner, Misys, Meditech, Citation, MedLab, CHC, SMS, McKesson, Labquest, CCA, VA-Mumps, others yes (broadcast download & host query) yes yes no n/a	optional add-on/yes (additional cost) — yes yes yes — —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	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/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/yes/yes within 24 hrs/yes 6 months/4 hrs daily: 10 min; weekly: 20 min; monthly: 60 min no/yes 5 days on site/yes n/a
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; available DL2000 Sample Manager	onboard wash system; 4 parameter dry ISE with CO ₂ ; reusable cuvette rotor; 2–30 µL sample size; ready-to-use liquid reagents

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

Chemistry analyzers (for low-volume laboratories)

Part 6 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 article on page 44		
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	Vitalab Selectra E/— — 7/5,000 Netherlands/Netherlands/U.S. random access/self-contained multi-use cartridges-packages-slides	ATAC 8000 Random Access Chemistry System/1995 — 800/n/a Italy/Italy/U.S. continuous random access/open reagent system
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	rotor/benchtop 19 x 45 x 22/8 sq. ft.	sample wheel/benchtop 19.5 x 39 x 20.5/5.5 sq ft
Tests available on instrument in U.S.	ALT, alkaline phosphatase, albumin, amylase, aspartate transaminase, bilirubin direct & total, calcium, CO ₂ , chloride, cholesterol, CPK, creatinine, digoxin, direct HDL & LDL, GGT, glucose, total iron, LDL, magnesium, phenobarbital, phenytoin, phosphorus, potassium, total protein, sodium, theophylline, triglycerides, BUN, uric acid, HbA1c	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], hsCRP
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/hsCRP —	none HbA1c none none/none 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 Reagent bar-code reading capability Bar-code placement per NCCLS 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)/immunoturbidimetric 4 no no 26 — 6/26 31/— 72 hrs/7 days/yes (12°C below ambient) yes yes yes —/—/— 120/50/~1,500 liquid no yes/~10,000 tests 1 µL yes/no no/~0.5 L — yes/20 µL yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128) no yes yes yes/yes/yes no/no yes/yes yes/no yes yes/— 4 hrs/7 days/—/— yes/yes	photometry, potentiometry/n/a 4 no/n/a 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
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	8 min, — 10 min, — 10 min, — 6 min 4 hrs/daily yes/yes —	60 sec, 60 specimens 6 min, 45 specimens 7 min, 36 patients with specified panel 20 sec 2 levels daily/yes yes/yes yes
Data mgmt. capability/Instrument vendor supplies LIS interface	optional add-on/yes (additional cost)	onboard/yes (additional cost)
Interfaces up and running in active user sites with	—	Fletcher-Flora
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 (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 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 6 months/4 hrs daily: 10 min; weekly: 20 min; monthly: 60 min no/yes 5 days on site/yes n/a	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 —
Distinguishing features	reusable cuvette; dry ISE with CO ₂ ; 2–30 µL sample size; onboard wash system; ready-to-use liquid reagents	475 tests per hour of general chemistry and ISE; reusable glass cuvettes, ensuring low reagent cost; onboard refrigeration; includes LIS; onboard wash laboratory information system; four parameter dry ISE with CO ₂ ; ready-to-use liquid reagents

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

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	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 800-242-3233 www.dadebehring.com
See accompanying article on page 44		
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	AGII Chemistry System (w/ISE)/1998 — 39/225 U.S./U.K./U.S. batch, random access/open reagent system	Dimension Xpand Integrated Chemistry System/2001 \$182,000 >800/— U.S./U.S./U.S. continuous random access/self-contained multi-use cartridges-packages-slides & open reagent system sample segments/floor-standing 45 x 31 x 51/—
Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint	wheel/benchtop 24 x 24 x 14/4 sq ft	
Tests available on instrument in U.S.	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	general chemistries, including no-pretreatment HDL & LDL, enzymes, electrolytes, endocrinology, immunology including hsCRP, heterogeneous immunoassays (see distinguishing features), specialty, therapeutic drug monitoring, & toxicology
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	n/a n/a open system n/a/thyroid (T ₃ , T ₄ , T-uptake, TSH), auto HDL	— — — —/NT-proBNP, quinidine, n-acetylprocainamide, tacrolimus, microalbumin —
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 NCCLS 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/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 yes no/yes ISE separate unit/n/a/n/a/n/a no/no	photometry, potentiometry, turbidimetric assays/Petinia, Emit, Acmia, 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 & reconstitutes 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 yes 2 hrs (auto)/90 days/60 days/60 days —/—
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	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	2 min, 62 4 min, 62 8 min, 42 60 sec steady state, 2 min from standby daily/yes yes/— yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/no (add'l cost)	onboard/no
Interfaces up and running in active user sites with	LabDaq, LabPak	interfaces available for 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 yes yes — —	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)	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	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 \$24,750
Distinguishing features	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	Dimension Xpand system 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; heterogeneous immunoassay tests include ferritin, free thyroxine, HCG, mass CK-MB, myoglobin, TSH, total and free PSA, and troponin I

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Chemistry analyzers (for low-volume laboratories)

Part 8 of 11	Hemagen Diagnostics Inc. Zafar Khan zkhan@hemagen.com 9033 Red Branch Rd. Columbia, MD 21045 443-367-5500 www.hemagen.com	Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com
<i>See accompanying article on page 44</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	Analyst Benchtop Chemistry System/1986 \$6,900 —/— France/U.S./U.S. batch/self-contained single-use cartridges-packages-slides	Stat Profile Critical Care Xpress/2002 \$25,000–\$59,000 —/— U.S./U.S./U.S. discrete/self-contained multi-use cartridges
Sample handling system/Model type	rotors/benchtop	sample automatically drawn from syringe, capillary, or open tube/benchtop
Dimensions in inches (H x W x D)/Instrument footprint	8.5 x 25 x 13/2.25 sq ft	17.2 x 17.3 x 22.3/2.7 sq ft
Tests available on instrument in U.S.	ALP, GGT, GPT, GOT, BUN, glucose, calcium, cholesterol, triglycerides, amylase, uric acid, total bilirubin, total protein, HDL cholesterol	pH, PCO ₂ , PO ₂ , SO ₂ %, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, ionized magnesium, glucose, BUN, creatinine, lactate, deoxyhemoglobin, oxyhemoglobin, methemoglobin, carboxyhemoglobin
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
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/— — yes/14 no — 14 —/— 14/14 —/—/— n/a 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 yes no/no no/no no/no no no/— —/60 days/—/— no/no	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 \$0.66–\$0.28 per test (cost varies with volume); bundled instr. reagent maint. cost per result \$0.07–\$0.31 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
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 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, 6 specimens 10 min, 6 specimens — —/— no/no —	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
Data mgmt. capability/Instrument vendor supplies LIS interface	no/yes (included in price)	onboard/no
Interfaces up and running in active user sites with	in development	n/a
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 — — — —	yes yes yes no n/a
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	— —	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)	no/yes/yes —/yes — — no/no 1 day on site/yes \$650 per year	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
Distinguishing features	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	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

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Chemistry analyzers (for low-volume laboratories)

Part 9 of 11	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
<i>See accompanying article on page 44</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	Stat Profile pHx Series/1998 \$12,000–\$32,000 —/— U.S./U.S./U.S. discrete/self-contained multi-use cartridges-packages-slides sample automatically drawn from syringe, capillary, or open tube/benchtop	Nova 16/1995 \$22,500–\$25,500 —/— U.S./U.S./U.S. batch, random access/self-contained multiuse cartridges 40-position tray, stat sampling directly from sample container/bench-top
Dimensions in inches (H x W x D)/Instrument footprint	15 x 15 x 18/1.9 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, glucose, lactate	sodium, potassium, chloride, total CO ₂ , glucose, BUN, creatinine, Hct
Tests cleared but not clinically released Tests not available in U.S. but submitted for 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 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 (ISE), optical, reflectance/n/a 5 no/n/a no 11 11 0/n/a 11/varies by analyzer and laboratory use pattern 45 days/45 days/no n/a requires operator prehandling, preparation n/a varies by model/n/a/n/a n/a/n/a/n/a ISE no/n/a no/n/a 45 µL no (optional)/no no/n/a minimal no/n/a yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes yes yes/yes yes/yes/yes yes yes*/yes* yes*/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., reagent, 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/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 • Albumin, 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, 40 n/a, n/a n/a, n/a <2 sec 8 hrs (CLIA)/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	no/no	onboard & optional add-on (\$9,225, SW mfr: Nova)/no
Interfaces up and running in active user sites with	virtually all	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 (broadcast download & host query) 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/yes 1 day on site/yes varies by analyzer configuration & geographic location; discounts for multiple-year contract or 5-year reagent rental or lease	no/yes/yes <8 business hrs/yes n/a/n/a daily: <2 min; weekly: <5 min; monthly: <5 min no/no 2 days on site/yes call for pricing
Distinguishing features	onboard quality control; liquid calibration eliminates gas tanks; remote control; remote review; space saving design	only whole blood analyzer for creatinine & TCO ₂ available; can analyze whole blood, serum, plasma, urine, CSF, and dialysate
<i>* on co-oximeter module</i>		

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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
<i>See accompanying article on page 44</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	Vitros DT60-II Analyzer/1993 — 15,000 units worldwide U.S./U.S./U.S. batch, random access, discrete/self-contained single-use car- tridges-packages-slides —/benchtop 6.75 x 18.75 x 13.75/1.8 sq ft	Cobas Integra 400 Plus/1999 \$175,000 >2,000/2,000 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.	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., methaqa., 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., pheny., 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, microal- bumin none none lipoprotein A none/homocysteine, lipoprotein A caffeine
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 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 NCCLS 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	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 6 months/6 months/6 months/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, 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	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 (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)	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

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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 article on page 44		
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, β -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, aceta-minophen, 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., methaqa., opia., PCP, propoxy., dig., acetamin., salic, Na, K, Cl by ISE
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	kappa/lambda light chains, %CDT, α -1-glycoprotein, α -1-microgl., cyclos., lipoprotein A	none
Research-use-only assays/Tests in development	none/homocysteine	none/information to be released at test launch
User-defined methods implemented for what analytes	none	none
Methods supported/Immunoassay methods	photometry, potentiometry/turbidimetric, latex particle enhanced, CEDIA	photometry, potentiometry/n/a
No. of direct ion selective electrode channels	3	3
• Must load separate reagent pack for each specimen/No. of diff. assays in pack	no/n/a	no/n/a
• Separate reagent pack for each test run	no	no
No. of different measured assays onboard simultaneously	35 tests plus applications for urine & CSF	max. 30
No. of different assays programmed, calibrated at once	68	104 + profiles & ratios
No. of user-definable (open) channels/No. active simultaneously	65/65	104 + profiles & ratios/max. 30
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	35/100-500	max. 30/40-50
Shortest/Median onboard reagent stability/Refrigerated onboard	—/30 days/yes (2-12°C)	6-8 hrs/30 days/yes (10-14°C below ambient)
Multiple reagent configurations supported	yes	yes
Reagent container placed directly on system for use	yes	yes, but requires some operator prehandling, preparation
Instrument has same capabilities when 3rd-party reagent used	no	no
Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes	—/—/—	—/—/—
Walkaway capacity in minutes/No. of specimens/No. of tests-assays	408/70/2,450	max. 120 min/90/depends on test vol.
System is liquid, dry, or reconstituted onboard	liquid	liquid
Uses disposable cuvettes/Max. No. stored	no/n/a	yes/—
Uses washable cuvettes/Replacement frequency	yes/monthly (120 stored on instrument)	no/n/a
Minimum sample volume aspirated precisely at one time	2 μ L	1 μ L
Supplied with UPS (backup power)/Requires floor drain	no/yes	no/no
Requires dedicated water system/Water consumption in L per hour	yes/30 L	no/4 L daily
Noise generated in decibels	\leq 65	\leq 62
Dedicated pediatric sample cup/Dead volume	yes/—	no
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes	yes, as soon as tubes loaded & start key activated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes
Reagent bar-code reading capability	yes	no
Bar-code placement per NCCLS standard Auto2A	yes	—
Onboard test auto inventory (determines volume in container)	yes	no
Measures No. of tests remaining/Short sample detection/Clot detection	yes/yes/no (not necessary due to sampling method)	no/yes/no
Automatic detection of adequate reagent for aspir. & analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/yes	yes/yes
Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	yes/yes	yes/yes
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/yes
Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse	24 hrs/lot change (every 6 months)/3-5 days/56 days	every hr/30-60 days/—/n/a
Automatic shutdown/Startup programmable	yes/—	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 • Albumin, direct & total bili., AST, ALT, ALP	3.5 min, 180 specimens 5.5 min, 90 specimens 10.5 min, 60 specimens	4 min, 15 specimens 7 min, 9 specimens 7.5 min, 8 specimens
Typical time delay from ordering stat test to aspir. of sample	30 sec	none
How often QC required/Onboard SW capability to review QC	24 hrs/yes	8 hrs, longest interval: daily/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/no
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/Instrument vendor supplies LIS interface	onboard/yes (add'l 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	yes (host query)	yes
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	—
How labs get LOINC codes for reagent kits	—	—
Lab can control analyzer remotely	no	yes (limited)
Interface avail. (or will be) to automated specimen handling system	yes (CLAS)	no
Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component	no/yes/yes	no/—/—
On-site time of svc. engineer/Onboard error codes for troubleshooting	—/yes	24 hrs/yes
Mean time between failures/To repair failures	—/—	4 months/2 hrs
Average time to complete maintenance by lab personnel	daily: —; weekly: —; monthly: —	daily: 10 min; weekly: 10 min; monthly: 5 min
Onboard maintenance records/Maint. training demo module	yes (includes audit trail of who replaced parts)/yes	no/no
Training provided with purchase/Advanced oper. training avail.	5 days at vendor offices/yes	4 days at vendor offices/no
Annual service contract cost (24 hr/7 d)	—	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