

Chemistry analyzers (for low-volume labs)

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| Part 1 of 9 | Abaxis Inc. Ron Blasig ronblasig@abaxis.com 3240 Whipple Rd. Union City, CA 94587 800-822-2947 www.abaxis.com |
| Name of instrument/First year sold in U.S. | Piccolo/1995 |
| List price/No. of analyzers sold in 2005 | \$18,000/— |
| No. units in clinical use in U.S./Outside U.S. | 1,500/1,500 |
| Country where designed/Manufactured/Where reagents mftd. | U.S./U.S./U.S. |
| Operational type/Reagent type | self-contained disk with multi-test reagent panel |
| Sample handling system/Model type | disk loaded directly into instrument/benchtop |
| Dimensions in inches (H x W x D)/Instrument footprint | 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, phosphorus, direct bilirubin, magnesium, LD |
| 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 |
| Research-use-only assays/Tests in development | — |
| User-defined methods implemented for what analytes | none |
| Methods supported/Immunoassay methods | enzymatic/n/a |
| No. of direct ion selective electrode channels | n/a |
| • Must load separate reagent pack for each specimen/No. of diff. assays in pack | yes/4–14 analytes (chemistries) for 12 diff. chem./elec. profiles; reagent self-contained with each disk |
| • Separate reagent pack for each test run | no |
| No. of different measured assays onboard simultaneously | 26 |
| No. of different assays programmed, calibrated at once | 14 |
| No. of user-definable (open) channels/No. active simultaneously | 0/n/a |
| No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set | 4–14/self-contained disk with reagents 4–12 |
| Shortest/Median onboard reagent stability/Refrigerated onboard | 6 months/12 months/n/a |
| Multiple reagent configurations supported | yes |
| Reagent container placed directly on system for use | yes |
| Instrument has same capabilities when 3rd-party reagent used | n/a |
| Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes | \$0.64/n/a/n/a |
| Walkaway capacity in minutes/No. of specimens/No. of tests-assays | <15/1/14 |
| System is liquid, dry, or reconstituted onboard | reconstitutes onboard |
| Uses disposable cuvettes/Max. No. stored | no/n/a |
| Uses washable cuvettes/Replacement frequency | no/n/a |
| Minimum sample volume aspirated precisely at one time | ~100 µL |
| Supplied with UPS (backup power)/Requires floor drain | no/no |
| Requires dedicated water system/Water consumption in L per hour | no/n/a |
| Noise generated in decibels | none |
| Dedicated pediatric sample cup/Dead volume | no |
| Primary tube sampling/Pierces caps on primary tubes | no/n/a |
| Sample bar-code reading capability/Autodiscrimination | yes/— |
| Reagent bar-code reading capability | yes |
| Bar-code placement per CLSI standard Auto2A | yes |
| Onboard test auto inventory (determines volume in container) | n/a |
| Measures No. of tests remaining/Short sample detection/Clot detection | n/a/yes/yes |
| Automatic detection of adequate reagent for aspir. & analysis | yes |
| Hemolysis/Turbidity detection-quantitation | yes/yes |
| Dilution of patient samples onboard/Automatic rerun capability | yes/no |
| Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results | n/a/n/a |
| Autocalibration or autocalibration alert | yes |
| Calibrants stored onboard/Multipoint calibration supported | yes/yes |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | self-calibrated onboard/disk/—/— |
| Automatic shutdown/Startup programmable | yes/yes |
| Stat time to completion of all analytes, throughput per hr. for: | |
| • Sodium, potassium, chloride, TCO ₂ | 15 min, 4 specimens |
| • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine | 15 min, 4 specimens |
| • Albumin, direct & total bili., AST, ALT, ALP | 15 min, 4 specimens |
| Typical time delay from ordering stat test to aspir. of sample | n/a |
| How often QC required/Onboard SW capability to review QC | automatic QC onboard/yes |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | yes/yes |
| QC results transferred automatically to LIS | yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard/no |
| Interfaces up and running in active user sites with | 15 |
| Bidirectional interface capability | no |
| Test results transmitted to LIS as soon as chem. time complete | yes |
| LIS interface operates simultaneously with running assays | yes |
| Uses LOINC to transmit orders & results | no |
| How labs get LOINC codes for reagent kits | — |
| Lab can control analyzer remotely | no |
| Interface avail. (or will be) to automated specimen handling system | n/a |
| Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component | no/yes/yes |
| On-site time of svc. engineer/Onboard error codes for troubleshooting | 24-hr loaner/yes |
| Mean time between failures/To repair failures | 3 years/— |
| Average time to complete maintenance by lab personnel | daily: none; weekly: none; monthly: none |
| Onboard maintenance records/Maint. training demo module | n/a/yes |
| Training provided with purchase/Advanced oper. training avail. | yes/yes |
| Annual service contract cost (24 h/7 d) | 1-year warranty, extended warranty—\$1,200 |
| Distinguishing features (supplied by company) | 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 |

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

Survey editor: Raymond Aller, MD

Menu and other enhancements underway

Anne Ford

As any parent who's ever tried to make dinner with a toddler, a teenager, and the family dog around knows, productivity often declines in direct inverse proportion to the number of entities on hand (or underfoot). That principle could hold true in the laboratory, too.

"The trend in the small-volume marketplace continues to be focused on reducing the total number of analyzers while improving efficiencies in the laboratory," says Dade Behring's Joseph Meola, marketing manager of chemistry/immunochemistry systems.

In other words, if you want to maximize, minimize.

This month's instrumentation survey covers chemistry analyzers for the low-volume laboratory. Like their larger cousins in last month's survey of mid- to high-volume chemistry analyzers, many of these instruments perform immunochemistry testing as well. But integration isn't the only card up manufacturers' collective sleeve; some of them have enhanced (or are planning to enhance) their instruments with other new capabilities, too.

Here's the rundown:

✓ To its Piccolo instrument, Abaxis has added a basic metabolic panel plus, which includes the eight BMP analytes plus Mg and LD; marketing director Ron Blasig says the panel was "designed specifically for oncologists."

✓ Nova Biomedical plans to add total bilirubin to its Nova Stat Profile Critical Care Xpress analyzer "in the very near future," says marketing communications manager Harlan Polishook. Also known as the CCX, the analyzer measures chemistries and electrolytes such as glucose, BUN, creatinine, sodium, potassium, and chloride. It can also calculate and report TCO₂.

✓ Forthcoming from Hemagen Diagnostics later this year: a benchtop analyzer that, says James J. Miller, general manager in the company's automated clinical chemistries systems division, "will offer state-of-the-art features with our proven rotor technology and our legendary accuracy."

✓ In the last quarter of 2006, Dade Behring will introduce QCC PowerPak, "an efficiency enhancement package that brings exciting new calibration, QC, and data storage features to the Dimension Xpand Plus, a second-generation integrated chemistry/immunochemistry system," says Meola. James Meenan, Dade Behring's marketing manager for chemistry/immunochemistry methods, adds: "Low-volume NT-proBNP, Ecstasy, extended-range cyclosporine, and CardioPhase hsCRP have just been introduced on the Dimension Xpand Plus system. In addition, Dade Behring plans to expand its immunosuppressive drug menu."

✓ Finally, Beckman Coulter anticipates expanding its UniCel line, which comprises the DxC 600 and DxC 800 chemistry systems and the DxC 600i integrated workstation, into the low-volume laboratory market. Dave Heibel, director of product management marketing for chemistry and protein systems, says the UniCel analyzers "are designed to meet different testing volume requirements within a network. All systems, whether high-volume or low-volume, offer the same complete menu."

CAP TODAY's survey of chemistry analyzers for the low-volume laboratory includes systems from the manufacturers cited above and from Abbott Point of Care, Alfa Wassermann, Clinical Data, Ortho-Clinical Diagnostics, Randox Laboratories, Roche Diagnostics, and Thermo Electron Corp. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities.

Anne Ford is a writer in Chicago.

SURVEY OF INSTRUMENTS

Chemistry analyzers (for low-volume laboratories)

| | | |
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| <p>Part 2 of 9</p> <p><i>See accompanying article on page 19</i></p> | <p>Abbott Point of Care Glen Tinevez glen.tinevez@abbott.com 104 Windsor Center Dr. East Windsor, NJ 08520 800-827-7828 www.abbottpointofcare.com</p> | <p>Alfa Wassermann Diagnostic Technologies LLC info@alfawassermannus.com 4 Henderson Dr. West Caldwell, NJ 07006 800-220-4488 www.alfawassermannus.com</p> |
| <p>Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2005 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 Analyzer/2000 \$8,761/— 30,000+ worldwide U.S./U.S./Canada —/self-contained single-use cartridges packages-slides</p> | <p>ACE/1993; ACE Alera Clinical Chemistry System/2004 \$69,995/— 1,000+/600+ U.S./U.S./U.S. batch, random access, discrete, cont. random access, stat/closed reagent system with open reagent system channel ring with up to 5 segments (15 samples/seg.)/benchtop ACE: 15.75 x 27.25 x 22.50; ACE Alera: 18 x 27.5 x 22.5/4.3 sq ft</p> |
| <p>Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint</p> | <p>n/a/handheld 9.25 x 3.0 x 2.85/< 1 sq ft</p> | <p>ACE: 15.75 x 27.25 x 22.50; ACE Alera: 18 x 27.5 x 22.5/4.3 sq ft</p> |
| <p>Tests available on instrument in U.S.</p> | <p>tropinin I, CK-MB, lactate, BUN, creatinine, glucose, ionized calcium, sodium, potassium, chloride, hematocrit, pH, PCO₂, PO₂, TCO₂, ACTc, ACTk, PT/INR; calculated: hemoglobin, HCO₃, BEecf, SO₂, anion gap</p> | <p>albumin, gamma GT, bilirubin direct & total, calcium, creatinine, glucose, in. phosphorus, total iron, magnesium, total protein, BUN, uric acid, amylase, AST (GOT), alkaline phosphatase, ALT (GPT), CK, LDH, cholesterol, HDL-C, LDL-C, triglycerides, sodium, potassium, chloride, CO₂, digoxin, T4, T-uptake, HbA1c, hsCRP</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>n/a BNP n/a n/a/n/a n/a</p> | <p>none none UIBC none/lipase, homocysteine, Lp(a), microalbumin, ApoAI, Apo B, TIBC open channel bottles are available for user-derived or third party reagents</p> |
| <p>Methods supported/Immunoassay methods</p> | <p>potentiometry, amperometric, conductometric/—</p> | <p>photometry, potentiometry, turbidimetric/homogeneous EIA</p> |
| <p>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</p> | <p>10 yes/up to 13 yes n/a 18 200 n/a/n/a n/a/unit use n/a/14 days/no no n/a n/a based on volume/n/a/based on volume 2 min/1/up to 18 — no/— no/— 16 µL no/no no/n/a none no/n/a no/no yes, shortly before sample is aspirated, by handheld scanner as tubes are loaded, at the bedside (2 of 5 interleaved, Codabar, codes 39 & 128)/yes</p> | <p>3 no/n/a no 40 200 15/15 40/100–150 tests per bottle 120 hr/30 days/yes (10–14°C) yes yes yes \$0.16/\$3.50/\$3.50 75/75/248 liquid yes/248 no/n/a 3 µL yes/no no/n/a 55 no/n/a yes/yes yes, as sample is being aspirated (2 of 5 interleaved, Codabar, code 39, code 128 set B & C)/yes</p> |
| <p>Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/ Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable</p> | <p>yes yes n/a n/a/yes/yes yes no/no no/no no/no yes no/yes each test/each test/—/— yes/yes</p> | <p>yes, proprietary dot coding no yes yes/yes/no yes bichromatic correction for both yes/yes yes/no yes no/yes 3 hr/30 days/45 days with 48 hr updates/n/a n/a/n/a</p> |
| <p>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</p> | <p>2 min, n/a 2 min, n/a n/a, n/a none shortest interval: 24 hr; longest interval: each new lot or reagent/yes yes/yes yes</p> | <p>4 min, 35 specimens 8 min, 20 specimens 12 min, 12 specimens immediate response, as soon as 10 sec daily/yes yes/yes yes</p> |
| <p>Data mgmt. capability/Instrument vendor supplies LIS interface</p> | <p>optional add-on (<\$30,000, SW mfr: Abbott Point of Care)/yes (add'l cost)</p> | <p>onboard/no</p> |
| <p>Interfaces up and running in active user sites with</p> | <p>all systems</p> | <p>Schuyler House, Antek, LabPak, others</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 customized on site</p> | <p>yes (broadcast download) yes, when requisition is done yes no n/a</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 within 24 hr/yes not determined/replacement within 24 hr daily: none; weekly: none; monthly: none n/a/n/a —/yes \$750</p> | <p>no/yes/yes 24 hr/yes 2 per yr/1 hr daily: 15 min; weekly: 45 min; monthly: 60 min yes/no 4.5 days at manufacturer's facility/yes varies, several programs available</p> |
| <p>Distinguishing features (supplied by company)</p> | <p>handheld portable analyzer, unit use system can perform chemistry, blood gas, cardiac marker, and coagulation tests on two drops of whole blood or plasma</p> | <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> |

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

Chemistry analyzers (for low-volume laboratories)

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| Part 3 of 9 | 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 19</i> | | |
| Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2005 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, HDLD, iron/TIBC, lipase, LD, LDLD, Mg, 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, 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, homocysteine, lithium |
| Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen/No. of diff. assays in pack • Separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set Shortest/Median onboard reagent stability/Refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination | photometry, potentiometry/turbidimetric, direct turbidimetric, particle-enhanced turbidimetric, enzyme immunoassay 4 no no 9 9 0 9/400–2,400 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 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 | photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay n/a 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 |
| 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 hr/yes yes/yes yes | 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 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, Mediatech, Citation, MedLab, CHC, Siemens, 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, Mediatech, Citation, MedLab, CHC, Siemens, 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 (supplied by company) | 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 |

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Chemistry analyzers (for low-volume laboratories)

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|---|---|---|
| Part 4 of 9 | 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 article on page 19 | | |
| Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2005 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 E/— —/— 7/5,000 Netherlands/Netherlands/U.S. random access/self-contained multi-use cartridges-packages-slides rotor/benchtop 19 x 45 x 22/8 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, Mg, 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, C-reactive protein, creatine kinase | 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 |
| Tests cleared but not clinically released | none | — |
| Tests not available in U.S. but submitted for 510(k) clearance | none | — |
| Tests not available in U.S. but available in other countries | none | — |
| Research-use-only assays/Tests in development | none/none | none/hsCRP |
| User-defined methods implemented for what analytes | UIBC, cyclosporine, homocysteine, lithium | — |
| 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 | 5 (indirect) | 4 |
| • Must load separate reagent pack for each specimen/No. of diff. assays in pack | no | no |
| • Separate reagent pack for each test run | no | no |
| No. of different measured assays onboard simultaneously | 29 | 26 |
| No. of different assays programmed, calibrated at once | 50 | — |
| No. of user-definable (open) channels/No. active simultaneously | 100/29 | 6/26 |
| No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set | 29/2,900-69,600 (100-2,400 tests per container) | 31/— |
| Shortest/Median onboard reagent stability/Refrigerated onboard | 168 hr/30 days/yes (2-8°C) | 72 hr/7 days/yes (12°C below ambient) |
| Multiple reagent configurations supported | yes | yes |
| Reagent container placed directly on system for use | yes | yes |
| Instrument has same capabilities when 3rd-party reagent used | yes | yes |
| Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes | assay dependent | —/—/— |
| Walkaway capacity in minutes/No. of specimens/No. of tests-assays | 400/63/1,827 | 120/50/~1,500 |
| System is liquid, dry, or reconstituted onboard | liquid | liquid |
| Uses disposable cuvettes/Max. No. stored | no/n/a | no |
| Uses washable cuvettes/Replacement frequency | yes/permanent-2-yr warranty (80 stored on instrument) | yes/~10,000 tests |
| Minimum sample volume aspirated precisely at one time | 3 µL | 1 µL |
| Supplied with UPS (backup power)/Requires floor drain | yes/no | yes/no |
| Requires dedicated water system/Water consumption in L per hour | yes/7 L | no/~0.5 L |
| Noise generated in decibels | 70 | — |
| Dedicated pediatric sample cup/Dead volume | yes/40 µL | yes/20 µL |
| 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, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/— |
| Reagent bar-code reading capability | yes | no |
| Bar-code placement per CLSI standard Auto2A | yes | yes |
| Onboard test auto inventory (determines volume in container) | yes | yes |
| Measures No. of tests remaining/Short sample detection/Clot detection | yes/yes/yes | yes/yes/yes |
| Automatic detection of adequate reagent for aspir. & analysis | yes | — |
| Hemolysis/Turbidity detection-quantitation | yes/yes | no/no |
| Dilution of patient samples onboard/Automatic rerun capability | yes/no | yes/yes |
| Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results | yes/no | yes/no |
| Autocalibration or autocalibration alert | yes | yes |
| Calibrants stored onboard/Multipoint calibration supported | no/yes | yes/— |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | 24 hr/up to 90 days/60 days/14 days | 4 hr/7 days/—/— |
| Automatic shutdown/Startup programmable | none required | yes/yes |
| Stat time to completion of all analytes, throughput per hr. for: | | |
| • Sodium, potassium, chloride, TCO ₂ | 52 sec, 75 specimens | 8 min, — |
| • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine | 8 min, 75 specimens | 10 min, — |
| • Album., direct & total bili., AST, ALT, ALP | 10 min, 32 specimens | 10 min, — |
| Typical time delay from ordering stat test to aspir. of sample | 45 sec | 6 min |
| How often QC required/Onboard SW capability to review QC | 24 hr/yes | 4 hr/daily |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | yes/yes | yes/yes |
| QC results transferred automatically to LIS | yes | — |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard & optional add-on (SW mfr: Beckman Coulter DL2000)/yes (add'l cost) | optional add-on/yes (add'l cost) |
| Interfaces up and running in active user sites with | Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, McKesson, Labquest, CCA, VA-Mumps, others | — |
| Bidirectional interface capability | yes (broadcast download & 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 | n/a | — |
| Lab can control analyzer remotely | no | no |
| Interface avail. (or will be) to automated specimen handling system | yes | no |
| Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component | yes/yes/no | no/yes/yes |
| On-site time of svc. engineer/Onboard error codes for troubleshooting | metro: same day; rural: same or next day/yes | within 24 hr/yes |
| Mean time between failures/To repair failures | —/— | 6 months/4 hr |
| Average time to complete maintenance by lab personnel | daily: 5 min; weekly: 15 min; monthly: 20 min | daily: 10 min; weekly: 20 min; monthly: 60 min |
| Onboard maintenance records/Maint. training demo module | no/no | no/yes |
| Training provided with purchase/Advanced oper. training avail. | 1 day on site, 5 days at vendor offices/no | 5 days on site/yes |
| Annual service contract cost (24 h/7 d) | — | n/a |
| Distinguishing features (supplied by company) | 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 | reusable cuvette; dry ISE with CO ₂ ; 2-30 µL sample size; onboard wash system; ready-to-use liquid reagents |

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

Chemistry analyzers (for low-volume laboratories)

| | | |
|---|---|--|
| Part 5 of 9 | Dade Behring Inc. 1717 Deerfield Rd. Deerfield, IL 60015 800-242-3233 www.dadebehring.com | Hemagen Diagnostics Inc. sales@hemagen.com 9033 Red Branch Rd. Columbia, MD 21045 443-367-5500 www.hemagen.com |
| <i>See accompanying article on page 19</i> | | |
| Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type | Dimension Xpand Plus Integrated Chemistry System/2004 —/— 1,200/800 U.S./U.S./U.S. continuous random access/self-contained single-use & multi-use cartridges | Analyst Benchtop Chemistry System/1986 \$6,900/— —/— France/U.S./U.S. batch/self-contained single-use cartridges-packages-slides |
| Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | racks/floor-standing 45 x 51 x 31 (without monitor)/10.6 sq ft | rotors/benchtop 8.5 x 25 x 13/2.25 sq ft |
| Tests available on instrument in U.S. | ser. acetamino., acid phos., alb., alk. phos., ALT, ammonia, amylase, AST, automated HDL & LDL, C3 compl., C4, calc., carbamaz., CO ₂ , chlor., cholesterol, CRP, creat. kin., creatinine, CK-MB isoenzyme, digitoxin, digoxin, ethyl alcohol, gentamicin, GGT, glucose, HbA1c, IgA/G/M, iron, lactic acid, LDH, lidoc., lipase, lith., magnes., microalb., n-acetylprocain., NT-pro BNP, phenobart., pheny., phosphorus, potas., prealbum., procainam., pseudocholesterol, ser. salicyl., sod., ser. TCA, theophyl., thyronine uptake, TIBC, tobramycin, tot. protein, tPSA, tot. T4/thyroxine, transferrin, triglycerides, urea nitrog., uric acid, urine amphet. Screen, urine barbitura. screen, benzodiazepine., cannabinoids, cocaine metabolite, methadone, opiates, phencyclidine, TBIL, DBIL, cyclosporine, ferritin, fPSA, free T4/thyroxine, hCG, myoglobin, TSH, triiodothyronine, trop. I, urine/CSF protein, valporic acid, vancomycin | ALP, GGT, GPT, GOT, BUN, glucose, calcium, cholesterol, creatinine, triglycerides, amylase, uric acid, total bilirubin, total protein, HDL cholesterol |
| 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 | — — — —/sirolimus, tacrolimus, serum barb., serum benzodiazep., serum TCA, myeloperox., urine ecstasy, urine propoxy., CSEA, mycophenolic acid | none none none none/— |
| User-defined methods implemented for what analytes | — | none |
| Methods supported/Immunoassay methods | photometry, potentiometry, turbidimetric assays/Petinia, Emit, Acmia, mag. part. sep. | photometry/— |
| 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 | 3 no no | — yes/14 no |
| No. of different measured assays onboard simultaneously | 47 | — |
| No. of different assays programmed, calibrated at once | 190 | 14 |
| No. of user-definable (open) channels/No. active simultaneously | 10/10 | —/— |
| No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set | 47/15-360 | 14/14 |
| Shortest/Median onboard reagent stability/Refrigerated onboard | 72 hr/30 days/yes (2-8°C) | —/—/— |
| Multiple reagent configurations supported | yes | — |
| Reagent container placed directly on system for use | yes | yes |
| Instrument has same capabilities when 3rd-party reagent used | yes | no |
| Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes | — | —/—/— |
| Walkaway capacity in minutes/No. of specimens/No. of tests-assays | can be hrs/60/>1,000 | 10/1/14 |
| System is liquid, dry, or reconstituted onboard | liquid, no reagent prep required by operator | dry |
| Uses disposable cuvettes/Max. No. stored | yes/12,000 | no (uses rotors) |
| Uses washable cuvettes/Replacement frequency | no/— | no/n/a |
| Minimum sample volume aspirated precisely at one time | 2 µL | 10 µL & 80 µL |
| Supplied with UPS (backup power)/Requires floor drain | yes/no | no/no |
| Requires dedicated water system/Water consumption in L per hour | yes/up to 2 µL | no/none |
| Noise generated in decibels | <70 | — |
| Dedicated pediatric sample cup/Dead volume | yes/10-20 µL | no |
| Primary tube sampling/Pierces caps on primary tubes | yes/no | no/no |
| Sample bar-code reading capability/Autodiscrimination | yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes | no/— |
| Reagent bar-code reading capability | yes | yes |
| Bar-code placement per CLSI standard Auto2A | yes | — |
| Onboard test auto inventory (determines volume in container) | yes | no |
| Measures No. of tests remaining/Short sample detection/Clot detection | yes/yes/yes | no/no/no |
| Automatic detection of adequate reagent for aspir. & analysis | yes | no |
| Hemolysis/Turbidity detection-quantitation | yes/yes | no/no |
| Dilution of patient samples onboard/Automatic rerun capability | yes/yes | no/no |
| Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results | yes/yes | no/no |
| Autocalibration or autocalibration alert | yes | no |
| Calibrants stored onboard/Multipoint calibration supported | yes (Na, K, Cl)/yes | no/— |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | —/up to 90 days/—/— | —/60 days/—/— |
| Automatic shutdown/Startup programmable | not required | 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 | 2 min, 62 4 min, 62 8 min, 62 | —, — 10 min, 6 specimens 10 min, 6 specimens |
| Typical time delay from ordering stat test to aspir. of sample | 60 sec steady state, 2 min from standby | — |
| How often QC required/Onboard SW capability to review QC | daily/yes | —/— |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | yes/yes | no/no |
| QC results transferred automatically to LIS | yes | — |
| Data mgmt. capability/Instrument vendor supplies LIS interface | optional add-on/yes (additional cost) | no/yes (included in price) |
| Interfaces up and running in active user sites with | interfaces available for all major LIS vendors | in development |
| Bidirectional interface capability | yes (broadcast download & host query) | no |
| Test results transmitted to LIS as soon as chem. time complete | yes | — |
| LIS interface operates simultaneously with running assays | yes | — |
| Uses LOINC to transmit orders & results | no | — |
| How labs get LOINC codes for reagent kits | — | — |
| Lab can control analyzer remotely | no | — |
| Interface avail. (or will be) to automated specimen handling system | no | — |
| Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component | yes/yes/yes | no/yes/yes |
| On-site time of svc. engineer/Onboard error codes for troubleshooting | 2-8 hr/yes | —/yes |
| Mean time between failures/To repair failures | —/— | — |
| Average time to complete maintenance by lab personnel | daily: 5 min; weekly: 10 min; monthly: 15 min | — |
| Onboard maintenance records/Maint. training demo module | yes/no | no/no |
| Training provided with purchase/Advanced oper. training avail. | 5 days on site, 4 days at vendor offices/no | 1 day on site/yes |
| Annual service contract cost (24 h/7 d) | multiple types | \$650 per year |
| Distinguishing features (supplied by company) | consolidated low-volume workstation that integrates immunoassays onboard with other chemistries; allows single platform to meet over 95 percent of testing needs; eliminates sample splitting, aliquotting | 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 |

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

Chemistry analyzers (for low-volume laboratories)

| Part 6 of 9 <i>See accompanying article on page 19</i> | Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com | Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com |
|---|--|--|
| Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2005 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/n/a —/— U.S./U.S./U.S. discrete/self-contained multi-use cartridges | Stat Profile pH0x Series/1998 \$12,000–\$32,000/n/a —/— U.S./U.S./U.S. discrete/self-contained multi-use cartridges-packages-slides |
| Sample handling system/Model type | sample automatically drawn from syringe, capillary, or open tube/benchtop | sample automatically drawn from syringe, capillary, or open tube/benchtop |
| Dimensions in inches (H x W x D)/Instrument footprint | 17.2 x 17.3 x 22.3/2.7 sq ft | 15 x 15 x 18/1.9 sq ft |
| Tests available on instrument in U.S. | pH, PCO ₂ , PO ₂ , SO ₂ %, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, ionized Mg, glucose, BUN, creatinine, lactate, deoxyhemoglobin, oxyhemoglobin, methemoglobin, carboxyhemoglobin | pH, PCO ₂ , PO ₂ , SO ₂ %, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, glucose, lactate |
| 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 Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/ Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable | 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 \$0.06–\$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 60 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 (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 no 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 |
| 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 | 50 sec, 26–36, depending on use mode 123 sec, 21–24, depending on use mode n/a, n/a <2 sec 8 hr/yes yes/yes yes | 50 sec, 44 n/a, n/a n/a, n/a <2 sec 8 hr (CLIA)/yes yes/yes yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard/no | no/no |
| Interfaces up and running in active user sites with | n/a | virtually all |
| 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 (broadcast download & host query) yes yes no n/a |
| 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 hr/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 | yes/yes/yes <8 business hr/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 |
| Distinguishing features (supplied by company) | comprehensive 19-test critical care profile, including ionized Mg, 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 | onboard quality control; liquid calibration eliminates gas tanks; remote control; remote review; space saving design |

* on co-oximeter module

Chemistry analyzers (for low-volume laboratories)

| | | |
|---|---|--|
| Part 7 of 9 | Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com | Ortho-Clinical Diagnostics Sales Support 1001 U.S. Highway 202 Raritan, NJ 08869 800-828-6316 www.orthoclinical.com |
| <i>See accompanying article on page 19</i> | | |
| Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type | Nova 16/1995 \$22,500-\$25,500/n/a —/— U.S./U.S./U.S. batch, random access/self-contained multiuse cartridges | VITROS DT 60 II Chemistry System (DT 60 II, DTE, DTSC)/1993 —/— 15,000 units worldwide U.S./U.S./U.S. batch, random access, discrete/self-contained single-use cartridges-packages-slides |
| Sample handling system/Model type | 40-position tray, stat sampling directly from sample container/benchtop | —/benchtop |
| Dimensions in inches (H x W x D)/Instrument footprint | 20.5 x 19.2 x 20.7/2.75 sq ft | 6.75 x 18.75 x 13.75/1.8 sq ft (DT 60 II) |
| Tests available on instrument in U.S. | sodium, potassium, chloride, total CO ₂ , glucose, BUN, creatinine, Hct | ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN-urea, glucose, Mg, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH, theophylline, CO ₂ , sodium, potassium, chloride, urine creatinine, CK-MB |
| 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 | none | none |
| Research-use-only assays/Tests in development | none/none | none/none |
| User-defined methods implemented for what analytes | none | none |
| Methods supported/Immunoassay methods | potentiometry/n/a | potentiometry, colorimetric, enzymatic/n/a |
| No. of direct ion selective electrode channels | 8 | 4 |
| • Must load separate reagent pack for each specimen/No. of diff. assays in pack | no/n/a | yes/1 |
| • Separate reagent pack for each test run | no | yes |
| No. of different measured assays onboard simultaneously | 8 | one per module (DT 60 II, DTE II, DTSC II) |
| No. of different assays programmed, calibrated at once | 8 | 1 |
| No. of user-definable (open) channels/No. active simultaneously | 0/n/a | none |
| No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set | 8/(@ 8,000 tests/mo): 2,700 tests | n/a/n/a |
| Shortest/Median onboard reagent stability/Refrigerated onboard | 21 days/21 days/no | n/a/n/a/no |
| Multiple reagent configurations supported | n/a | no |
| Reagent container placed directly on system for use | no, requires prehandling (remove clip from sealed bag & mix) | no |
| Instrument has same capabilities when 3rd-party reagent used | n/a | n/a |
| Reagent only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes | standard chemistries: @25 sam/d: \$0.40 (8-test panel); bundled instr., reagent, maint. cost per result: \$0.92 (8-test panel)/—/— | n/a/n/a/n/a |
| Walkaway capacity in minutes/No. of specimens/No. of tests-assays | 60 per tray/40 per tray/280 per tray | n/a/n/a/n/a |
| System is liquid, dry, or reconstituted onboard | n/a | dry |
| Uses disposable cuvettes/Max. No. stored | no/n/a | no/n/a |
| Uses washable cuvettes/Replacement frequency | n/a/n/a | no/n/a |
| Minimum sample volume aspirated precisely at one time | 50 µL | 10 µL |
| Supplied with UPS (backup power)/Requires floor drain | no/no | no/no |
| Requires dedicated water system/Water consumption in L per hour | no/n/a | no/none |
| Noise generated in decibels | minimal | — |
| Dedicated pediatric sample cup/Dead volume | n/a | n/a |
| Primary tube sampling/Pierces caps on primary tubes | yes/no | no/no |
| Sample bar-code reading capability/Autodiscrimination | yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes | no/— |
| Reagent bar-code reading capability | alternate method | yes |
| Bar-code placement per CLSI standard Auto2A | n/a | — |
| Onboard test auto inventory (determines volume in container) | yes | n/a |
| Measures No. of tests remaining/Short sample detection/Clot detection | no/yes/yes | n/a/n/a/n/a |
| Automatic detection of adequate reagent for aspir. & analysis | yes | n/a |
| Hemolysis/Turbidity detection-quantitation | no/no | no/no |
| Dilution of patient samples onboard/Automatic rerun capability | yes/yes | no/no |
| Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results | no/no | no/no |
| Autocalibration or autocalibration alert | yes | no |
| Calibrants stored onboard/Multipoint calibration supported | yes/n/a | no/yes |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | 2 hr/2 hr/n/a/n/a | reagent lot changes |
| Automatic shutdown/Startup programmable | n/a/n/a | no/no |
| Stat time to completion of all analytes, throughput per hr. for: | | |
| • Sodium, potassium, chloride, TCO ₂ | 52 sec, 69 specimens | 15 tests |
| • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine | 85 sec, 45 specimens | 75 tests |
| • Album., direct & total bili., AST, ALT, ALP | n/a | 20 tests |
| Typical time delay from ordering stat test to aspir. of sample | 9 sec | none |
| How often QC required/Onboard SW capability to review QC | CLIA minimum/yes | every 24 hr/no |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | no/yes | no/no |
| QC results transferred automatically to LIS | yes | yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard & optional add-on (\$9,225, SW mftr: Nova)/no | —/no |
| Interfaces up and running in active user sites with | most LIS vendors including Cerner, Misys, McKesson, Soft, others | — |
| Bidirectional interface capability | yes | no |
| Test results transmitted to LIS as soon as chem. time complete | yes | yes |
| LIS interface operates simultaneously with running assays | no | yes |
| Uses LOINC to transmit orders & results | no | — |
| How labs get LOINC codes for reagent kits | — | — |
| Lab can control analyzer remotely | yes | no |
| Interface avail. (or will be) to automated specimen handling system | no | no |
| Modem servicing available/Can diagnose own malfunctions/Determine malfunctioning component | no/yes/yes | no/yes/yes |
| On-site time of svc. engineer/Onboard error codes for troubleshooting | <8 business hr/yes | —/yes |
| Mean time between failures/To repair failures | n/a/n/a | — |
| Average time to complete maintenance by lab personnel | daily: <2 min; weekly: <5 min; monthly: <5 min | daily: 5 min; weekly: 5 min; monthly: none |
| Onboard maintenance records/Maint. training demo module | no/no | no/no |
| Training provided with purchase/Advanced oper. training avail. | 2 days on site/yes | yes/— |
| Annual service contract cost (24 h/7 d) | call for pricing | — |
| Distinguishing features (supplied by company) | whole blood analyzer for creatinine & TCO ₂ ; can analyze whole blood, serum, plasma, urine, CSF, and dialysate | disposable tips eliminate sample carryover; random access testing so chemistries can be run in any order, with no reagent prep.; indiv. packaged test slides elim. waste and facilitate rapid analysis; dry slide technology minimizes the effects of interferences to provide accurate results |

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

Chemistry analyzers (for low-volume laboratories)

| | | |
|---|---|--|
| <p>Part 8 of 9</p> <p>See accompanying article on page 20</p> | <p>Randox Laboratories marketing@randox.com 4065 Oceanside Blvd., Ste. Q Oceanside, CA 92056 760-639-1500 www.randox.com</p> | <p>Roche Diagnostics Corp. Todd Atkinson todd.atkinson@roche.com 9115 Hague Rd. Indianapolis, IN 46256 317-521-4564 www.roche.com</p> |
| <p>Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2005 No. units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Where reagents mftd. Operational type/Reagent type</p> | <p>Rx Daytona/2005 —/— >600 units worldwide Japan/Japan/U.K. random access, discrete/self-contained multi-use cartridges-packages-slides</p> | <p>Cobas Integra 400 Plus/1999 \$175,000/— >2,000/2,000 Switzerland/Switzerland/U.S. & Germany continuous random access/self-contained multi-use cassettes</p> |
| <p>Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint</p> | <p>removable ring/benchtop 30.2 x 24.8 x 20.2 sq ft/—</p> | <p>rack/benchtop 30 x 53 x 26/9.6 sq ft</p> |
| <p>Tests available on instrument in U.S.</p> | <p>*acid phos., alb., aldolase, ALT, ammonia, alk. phos., AST (GOT), amylase, panc. amylase, bilirubin (direct/total), calcium, total CO₂, cholesterol, HDL-C, LDL-C, CK-NAC, CK-MB, complement C3/C4, copper, CRP, HS CRP, FR CRP, creatinine, ferritin, fructosamine, homocysteine, glucose, GGT, HbA1c, IgA, IgE, IgG, IgM, LDH, lipase, lithium, ASO, lipoprotein(a), ApoA1, ApoB, microalb., magnes., myoglobin, sodium, prealbumin, phosphorus, potas., RF, iron, phenobarbital, phenytoin, digoxin, digitoxin, theophylline, gentamicin, valp. acid, carbamazepine, transferrin, TIBC, total protein, triglycerides, uric acid, BUN/urea, urinary protein, zinc, ISE Na, others</p> | <p>*α-1-acid glycoprot., α-1-antitryp., apo A1 & B, antistrepto.-O, comp. C3c & C4, cerul., CRP latex, CRP(hs), hapt., IgA/G/M, myo., prealb., RF, transferr., amph., barb., benz., coca., ethanol, LSD, meth., methaq., opia., PCP, PPX, S barb., S benz., THC, ACPP, ALP, ALT, α-amy. pancreatic, AP, AST, cholest., CK-MB, γ-glutamyltrans., LDH, lipase, alb., bil direct & total, Ca., chol., CO₂, creat. jaffe, creat. enzy., fructosam., gluc., HbA1c, HDL direct, iron, lact., LDL direct, Mg, ammon., phos., TP, TPU-C, trig., UA, UIBC, urea, Na, K, Cl, Li, acet., amik., carb., dig., gent., lido., NAPA, pheno., pheny., prim., proc., quin., sali., theo., tobra., valp. acid, vanc., T4, T-up, D-dimer, others</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</p> | <p>— — —</p> | <p>none none lipoprotein A none/MPA, tacrolimus, sirolimus</p> |
| <p>User-defined methods implemented for what analytes</p> | <p>*acetic acid, Apo E, Apo CIII, Apo CII, ApoAII, alpha-1-antitryp., α-1-acid glycoprotein, bile acids, butyryl choline., others/— acetaminophen, drugs of abuse, salicylate cyclosporine, alcohol, glycerol-3-phosphate, oxidase, phospholipids, maltose, T4, T-uptake</p> | <p>caffeine</p> |
| <p>Methods supported/Immunoassay methods</p> | <p>photometry, potentiometry (ISE), immunoturbidimetry, latex enhanced immunoturbidimetry/— 3 Na⁺, K⁺, Cl⁻ no/50-2,205 no 30 60 10/60 27/71-1,053</p> | <p>photometry, potentiometry, fluorescence polarization/turbidimetric, latex particle enhanced 4 no/1 no 36 tests plus applications for urine & CSF up to 999 0/0 36/50-800 tests, cassettes</p> |
| <p>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</p> | <p>8 hr/30 days/yes (8-15°C) yes yes yes —/—/— —/40/— liquid no/45 yes/5 years 2 μL no/no yes/7.5 L daily 60 yes/20 μL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 & 128)/yes</p> | <p>2 weeks/8-12 weeks/yes (12°C) yes yes no —/—/— 176/90/1,808 liquid yes/1,500 no/n/a 1 μL no/no no/2 L maximum — — yes/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes</p> |
| <p>Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/ Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable</p> | <p>yes — yes yes/yes/no yes yes/yes yes/yes yes/yes yes no/yes daily/28 days/7 days/— no/yes</p> | <p>yes — yes yes/yes/yes — no/no yes/yes yes/yes yes yes/yes 5 hr/once per lot/each lot & 12 weeks/each lot & 12 weeks yes/yes</p> |
| <p>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</p> | <p>—, 270 —, 315 —, 180 60 sec shortest: daily; longest: at customer discretion/yes yes/yes yes</p> | <p>369 tests 369 tests 250 tests none 24 hr/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 — yes (host query) yes yes no —</p> | <p>onboard/yes (add'l cost) all major LIS vendors yes (broadcast download & host query) yes yes — —</p> |
| <p>Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system</p> | <p>— no</p> | <p>yes —</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 within 24 hr/yes —/— daily: 5 min; weekly: 15 min no/no 3 days on site/yes —</p> | <p>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 —</p> |
| <p>Distinguishing features (supplied by company)</p> | <p>comprehensive clinical & research test menu, benchtop, low water consumption, automatic start, multi-speed mixing for improved reagent performance, comprehensive and easy to use Windows software</p> | <p>unique reagent cassette eliminates reagent preparation; menu consolidates testing, including direct LDL, whole blood, HbA1c, and lithium</p> |
| | <p>*Contact company for complete list</p> | <p>*Contact company for complete list</p> |

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Chemistry analyzers (for low-volume laboratories)

| Part 9 of 9 <i>See accompanying article on page 19</i> | Roche Diagnostics Corp. Todd Atkinson todd.atkinson@roche.com 9115 Hague Rd. Indianapolis, IN 46256 317-521-4564 www.roche.com | Thermo Electron Corp. Bola Nicholson bola.nicholson@thermo.com 171 Industry Drive Pittsburgh, PA 15275 800-558-9115 www.thermo.com/clinicalchem |
|---|--|--|
| Name of instrument/First year sold in U.S. List price/No. of analyzers sold in 2005 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 | Data Pro PLUS/2005 \$45,800/2 4/995 Argentina/Argentina/Australia batch, random access, discrete, continuous random access/self-contained multi-use cartridges-packages-slides, open reagent system ring/benchtop 33.5 x 18.5 x 22.8/51.63 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 | 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, acetaminophen, ACT P-5-P, AST P-5-P, CRP, (hs)latex, Apo A1, Apo B none none kappa/lambda light chains, %CDT, α-1-glycoprotein, α-1-microgl., cyclos., lipoprotein A none/homocysteine none | alb., alk. phos., amy., AST, BUN, Ca., chloride, chol., CK, CO ₂ , crea., direct bilirubin, GGT, glucose (HK), HDL, iron, LDH, Mg, phosphorus, total bilirubin, total protein, triglycerides, uric acid — — — —/ISE: Na, K, Cl; TDM: HbA1c none |
| Methods supported/Immunoassay methods No. of direct ion selective electrode channels • Must load separate reag. pack for each specimen/No. of diff. assays in pack • Separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set Shortest/Median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A Onboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable | photometry, potentiometry/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 hr/lot change (every 6 months)/3-5 days/56 days yes/— | photometry, turbidimetry/— 3 no/n/a no 48 48 12/12 48/225 —/—/yes yes yes yes —/—/— —/48/48 liquid yes/80 yes/once a week 3 µL no/no no/0.58 — yes/100 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/— yes — yes yes/yes/no yes no/no yes/yes yes/no no no/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 • 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 hr/yes yes/yes yes | — — — less than 60 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/yes (add'l cost) all major LIS vendors yes (host query) yes yes no — | onboard/no — yes (host query) no yes — — |
| Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system | no yes (GLAS) | 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 —/yes —/— daily: —; weekly: —; monthly: — yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes — | no/yes/yes —/yes —/— daily: 5 min; weekly: 15 min; monthly: 30 min yes/no 3 days on site, 5 days at vendor offices/no — |
| Distinguishing features (supplied by company) | sophisticated software with easy stat function provides instant stat selection; Roche Hitachi open system dependability and throughput | open system; compact benchtop; user friendly Windows software |

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