Smaller, but sophisticated

Anne Ford

Dan Siegenthaler, Beckman 0 Coulter chemistry marketing manager, just because a laboratory does a low volume of testing doesn't mean it has low-capability needs. "Advanced technology is important to lower-volume labs just like it is to the large core labs and reference laboratories," he says. "They still need analyzers with a large test menu. Just like larger labs, smaller-volume labs want to consolidate workstations, too." Taking heed of these requirements are the vendors of chemistry analyzers for low-volume labs whose instruments are profiled in this issue. From new instrumentation and new tests to enhanced technological capabilities, these manufacturers have much to offer the lower-volume market.

Practicing what Siegenthaler preaches, Beckman Coulter recently launched the UniCel DxC 600 clinical system for low- to mid-volume laboratories (profiled in the July issue of CAP TO-DAY, page 68). With an onboard capacity of 65 reagents, the DxC 600 can perform more than 100 chemistry tests, "which is comparable to that of our larg e r-volume chemistry systems," Siegenthaler adds. And like the company's higher-volume instruments, the DxC 600 features closed-tube sampling. "While cappiercing technology is widely available on many different hematology platforms, we're the only company in the world to offer such a device on our chemistry systems for low- to highvolume hospitals," he says. Beckman Coulter also plans to make closed-tube sampling available on the UniCel DxC 600i, an integrated chemistry-immunoassay system in development now.

Several other companies are offering or will

soon offer new assays for their existing low-volume analyzers—such as Abaxis, which has added the Lipid Plus with an AST/ALT/glucose assay and a chemotherapy evaluation panel to its Piccolo point-of-care analyzer. The Piccolo, says company representative Ron Blasig, "provides complete chem panel results in 13 minutes." Meanwhile, Thermo Electron plans to make an ISE module for sodium, potassium, and chloride testing available on its Data Pro line of analyzers by September. "The Data Pro is a benchtop analyzer with a throughput of 240 tests per hour," says company representative Bola Nicholson. "It comes in four different models that make it cost-effective for different laboratory needs." Potential customers can also look forward to Abbott's i-Stat cartridge, the Chem8+, which the company plans to introduce by the end of the year. Designed for low- to midvolume testing, it will offer testing for sodium, potassium, chloride, BUN/creatinine, glucose, calcium, and total carbon dioxide. "The test cartridge will also provide hematocrit and hemoglobin results," says Joe Baugh, senior product manager.

When it comes to technology improvements, the consensus is clear: The shortage of medical technologists increases smaller-volume laboratories' reliance on instrument automation and ease-of-use just as much as it does for their higher-volume counterparts. "Labs just don't have access to the labor resources they need to operate at an optimal level, so chemistry and other systems are going to have to do many of those functions for them," Siegenthaler says. Nicholson concurs: "Laboratories are forced to train staff that normally would not have responsibilities for instrumentation. This leaves it up to instrument manufacturers to provide instruments that are not complicated and require minimum maintenance."

That explains technological enhancements such as those on Roche's Integra 400 Plus, which, says product manager Todd Atkinson, "incorporates key new features including clot detection, an external data station with flatscreen monitor, and LED FP lamp, and autostart software update." The Integra 400 Plus, he adds, features the same multiple measuring technologies and reagent cassette format as its predecessor, the Integra 400. At Abbott, recent improvements in technology include what Baugh calls "a new downloader/recharge docking station system that allows our customers to use a very robust rechargeable battery pack instead of lithium batteries. This product really helps in those busy emergency departments."

Besides the improved automation, quality control, ease of use, and cost efficiency, what else are customers likely to clamor for in the future? Baugh sums it up: "Wireless! I think in the next few years you will see many vendors' products with wireless capabilities." If Baugh is right, the wireless technology that's made it possible to surf the Internet on a laptop at Starbucks may soon sweep laboratories as well.

CAP TODAY's survey of chemistry analyzers for low-volume laboratories includes products from the manufacturers listed above and from Alfa Wassermann, Analox Instruments, Clinical Data, Dade Behring, Hemagen Diagnostics, Nova Biomedical, Ortho-Clinical Diagnostics, and Randox Laboratories. 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.

| Part 1 of 10 | Abaxis Inc. |
|---|--|
| | Kon Blasgronblasig@abaxis.com 3240 Whipple Rd. |
| | Union City, CA 94587 800-822-2947 |
| | www.abaxis.com |
| Name of instrument/First year sold in U.S. List price | Piccolo/1995 \$18,000 |
| No. units in clinical use in U.S./Outside U.S. | 500/500 |
| Operational type/Reagent type | u.s./u.s./u.s. self-contained disc with multi-test reag. panel |
| Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | disc loaded directly into instrument/benchtop 9.5 x 6 x 11.5/1 sq ft |
| Tests available on instrument in U.S. | ALP, ALT, AST, GGT, amylase, albumin, total protein, bilirubin total, |
| | BUN, creatinine, calcium, cholesterol, glucose, uric acid, sodium, creatine kinase, potassium, TCO ₂ , chloride, cholesterol, HDL ratio, HDL, LDL, triglycerides-VLDL, phosphorus, direct bilirubin, magnesium |
| Tests cleared but not clinically released | |
| 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 • Must load separate reag, pack for each specimen/No, of diff, assays in pack | n/a ves/4–14 analytes (chemistries) for 11 diff. chem./ elec. profiles: |
| • Senarate rear nack for each tect run | reag. self-contained with each disk |
| No. of different measured assays onboard simultaneously | 26 |
| No. of different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously | 14 0/n/a |
| No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set | 4–14/self-contained disk with reagents 4–12 |
| Shortest/Median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported | 6 months/12 months/n/a ves |
| Read, container placed directly on system for use | yes r/c |
| Reag. only cost per reportable result for standard chemistries/ | \$0.64/n/a/n/a |
| Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays | <15/1/14 |
| System is liquid, dry, or reconstituted onboard Uses disposable cuvettes/Max, No, stored | reconstitutes onboard |
| Uses washable cuvettes/Replacement frequency | no/n/a |
| Supplied with UPS (backup power)/Requires floor drain | no/no |
| Requires dedicated water system/Water consumption in L per hour Noise generated in decibels | no/n/a none |
| Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes | no no/n/a |
| Sample bar-code reading capability/Autodiscrimination | yes/— |
| Reagent bar-code reading capability | no |
| Onboard test auto inventory (determines volume in container) | n/a |
| Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag. for aspir. & analysis | n/a/yes/yes yes |
| Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability | yes/yes ves/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 |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | yes/yes 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, TCO₂, glucose, urea, creatinine Album., direct & total bili. AST. ALP. | 15 min, 4 specimens 15 min, 4 specimens |
| Typical time delay from ordering stat test to aspir. of sample | n/a automatic OC onhoard/ves |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | yes/yes |
| ev resurts transferred autOfficturent vender cumplice LIC interface | yes onhoard/no |
| Data mynt, capability/instrument venuor supplies Lis Interface | 15 |
| | |
| Test results transmitted to LIS as soon as chem. time complete | yes |
| LIS Interface operates simultaneously with running assays Uses LOINC to transmit orders & results | yes no |
| How labs get LOINC codes for reagent kits | _ |
| Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system | no 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 Mean time between failures/To repair failures | 24-hr loaner/yes 3 years/— |
| Average time to complete maintenance by lab personnel | daily: none; weekly: none; monthly: none |
| 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 | 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

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Chemistry analyzers (for low-volume laboratories)

| Part 2 of 10 | Abbott Laboratories | Alfa Wassermann Diagnostic Technologies LLC |
|---|--|--|
| | Joey Baugh joey.baugh@abbott.com 104 Windsor Center Dr. | info@alfawassermannus.com 4 Henderson Dr. |
| | East Windsor, NJ 08520 800-827-7828 | West Caldwell, NJ 07006 800-220-4488 |
| See accompanying article on page 20 | www.istat.com | www.alfawassermannus.com |
| Name of instrument/First year sold in U.S. | i-STAT 1/2000 | ACE/1993; ACE Alera Clinical Chemistry System/2004 |
| List price No. units in clinical use in U.S./Outside U.S. | \$6,900 1.700/500 | \$69,995 1.000+/600+ |
| Country where designed/Manufactured/Where reagents mftd. | U.S./U.S./Canada | U.S./U.S./ |
| Operational type/Reagent type | —/self-contained single-use cartridges-packages-slides | batch, random access, discrete, cont. random access, stat/closed reag. system with open reag. system channel |
| Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | n/a/handheld 23.48 x 7.68 x 7.24 cm/— | 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 sg ft |
| Tests available on instrument in U.S. | sodium notassium chlorida ionizad calcium BIN ducosa | alhumin namma GT hiliruhin direct & total calcium creatinine |
| | creatinine, lactate, Hct, pH, pCO ₂ , pO ₂ , ACT _c , Calculated: Hb, TCO ₂ , | glucose, in. phosphorus, total iron, magnesium, total protein, BUN, |
| | HCU_3 , BEECT, anion gap, SU_2 , P1/INK, ACI_k , C1ni | LDH, cholesterol, HDL-C, LDL-C, triglycerides, sodium, potassium, |
| | | chloride, CO ₂ , digoxin, T ₄ , T-uptake, HbA1c, hsCRP |
| Tests cleared but not clinically released | none | none |
| Tests not available in U.S. but submitted for 510(k) clearance | none | none |
| Research-use-only assays/Tests in development | none/APTT, CK-MB none | none/none alpha-1-antitrynsin, acetaminophen, alcobol (Ethanol), ammonia |
| | | CRP, CK-MB isoenzymes, folate, fructosamine, lipase, salicylate, |
| | | cocaine, opiate, Apo A1, Apo B, bile acids, C3, C4, cannabinoid, |
| | | carbamazepine, ferritin, fibrinogen, haptoglobin, homocysteine, IgA/G/M, microalbumin, phencyclidine, phenobarbital, phenytoin, |
| | | prealbumin, transferrin, theophylline, UIBC, Lp(a) |
| Methods supported/Immunoassay methods | potentiometry/ | photometry, potentiometry, turbidimetric/homogeneous EIA |
| No. of direct ion selective electrode channels Must load separate reag, pack for each specimen/No. of diff. assays in pack | iu yes/up to 16 | 3 no/n/a |
| Separate reag. pack for each test run No. of different measured assays onhoard simultaneously | yes 11 | no 40 |
| No. of different assays programmed, calibrated at once | up to 16 | 200 |
| No. of user-definable (open) channels/No. active simultaneously No. of different analytes for which system accommodates | n/a/n/a n/a/1 cartridge at a time, each up to 16 tests | 15/15 40/100–150 tests per bottle |
| reag. containers onboard at once/Tests per container set | /14 doug/no | 120 kr/20 days (voc (10, 14°P) |
| Multiple reag. configurations supported | no | yes |
| Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used | n/a n/a | yes yes |
| Reag. only cost per reportable result for standard chemistries/ Theraneutic drugs/Special analytes | \$3-\$9/—/— | \$0.16/\$3.50/\$3.50 |
| Walkaway capacity in minutes/No. of specimens/No. of tests-assays | 2 min/1/up to 16 | 75/75/248 |
| Uses disposable cuvettes/Max. No. stored | no | yes/248 |
| Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time | no 40 uL | no/n/a 3 uL |
| Supplied with UPS (backup power)/Requires floor drain | no/no | yes/no |
| Noise generated in decibels | none | 55 |
| Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes | no no/no | no/n/a yes/yes |
| Sample bar-code reading capability/Autodiscrimination | yes, patient, operator, identification (2 of 5 interleaved, UPC, Codebar, codes 39 & 128)/ | yes, as sample is being aspirated (2 of 5 interleaved, Codabar, code |
| Reagent bar-code reading capability | yes | yes, proprietary dot coding |
| Onboard test auto inventory (determines volume in container) | yes n/a | no yes |
| Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate reag, for aspir, & analysis | n/a/yes/yes ves | yes/yes/no ves |
| Hemolysis/Turbidity detection-quantitation | yes/yes | bichromatic correction for both |
| Sample volume can be reduced to rerun out-of-linear-range high results/ | no/no | yes/yes yes/no |
| Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert | yes | yes |
| Calibrants stored onboard/Multipoint calibration supported | yes/no each test/each test// | no/yes 3 hr/30 days/45 days with 48 hr undates/n/a |
| Automatic shutdown/Startup programmable | yes/yes | n/a/n/a |
| Stat time to completion of all analytes, throughput per hr. for: | | |
| Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, glucose, urea. creatinine | 2 min, n/a 2 min, n/a | 4 min, 35 specimens 8 min, 20 specimens |
| Album., direct & total bili., AST, ALT, ALP Tunied time delay from extering stat total conin, of comple | n/a, — | 12 min, 12 specimens |
| How often QC required/Onboard SW capability to review QC | shortest interval: 24 hr; longest interval: each new lot/yes | daily/yes |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS | yes/yes yes | yes/yes yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | optional add-on (\$45.000 including LIS interface. SW mftr: | onboard/no |
| | Abbott/Sybase)/yes | Sobuular House Antole Lab Dale attain |
| Bidirectional interface capability | an systems yes (broadcast download & host query) | yes (broadcast download) |
| Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays | yes ves | yes, when requisition is done yes |
| Uses LOINC to transmit orders & results | yes | no n/a |
| | | |
| Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system | yes n/a | no no |
| Modem servicing available/Can diagnose own malfunctions/ | yes/yes | no/yes/yes |
| On-site time of svc. engineer/Onboard error codes for troubleshooting | replacement/yes | <24 hr/yes |
| Average time to complete maintenance by lab personnel | not determined/24 nr daily: none; weekly: none; monthly: none | 2 per yr/<1 nr daily: 3 min; weekly: 30 min; monthly: 30 min |
| Onboard maintenance records/Maint. training demo module Training provided with purchase/Advanced oper. training avail. | n/a/n/a —/ves | yes/no 4.5 days at manufacturer's facility/ves |
| Annual service contract cost (24 h/7 d) | \$420 | varies, several programs available |
| Distinguishing features | handheld portable analyzer | easy-to-use, multitasking software; closed-tube sampling; stat |
| | | merrupt capability; extensive test menu; onboard sample and reagent refrigeration; onboard reagent inventory management |

| Devit 0 of 40 | | |
|--|--|---|
| Part 3 of 10 | Analox Instruments U.S.A. Inc. | Beckman Coulter Inc. 200 South Kraemer Blvd |
| | P O Rox 208 | $P \cap Rox 8000$ |
| | Lunenburg, MA 01462 | Brea, CA 92822-8000 |
| | 978-582-9368 | 800-526-3821 |
| See accompanying article on page 20 | www.analox.com | www.beckmancoulter.com |
| Nome of instrument/First year cold in U.S. | CM7/100E | Synahran CV2 Dalta /1005 |
| list nrice | \$13,500 | \$72 300 |
| No. units in clinical use in U.S./Outside U.S. | —/— | —/— |
| Country where designed/Manufactured/Where reagents mftd. | U.K./U.K./U.K. | U.S./U.S. & Ireland |
| Operational type/Reagent type | discrete/open reagent system | continuous random access/open reagent system |
| Sample handling system/Model type | —/benchtop | sectors, centrifugable/floor-standing |
| Dimensions in inches (H x W x D)/Instrument footprint | 12 x 12 x 12/1 sq ft | 69 x 27 x 30/5.6 sq ft |
| Tests available on instrument in U.S. | glucose, lactate, cholesterol, urea | sodium, potassium, chloride, CO., calcium, creatinine, BUN, glucose, |
| | 5 · · · · · , · · · · , · · · · , · · · · , · · · · , · · · · , · · · · , · · · · , · · · · , · · · · , · · · · · , · · · · · , · · · · · , · · · · · , · · · · · , · · · · · , · · · · · , · · · · · , · · · · · , · · · · · , · · · · · , · · · · · , · · · · · , · · · · · , · · · · · · , · · · · · , · · · · · , · · · · · · , · · · · · , · · · · · , · · · · · · , · · · · · , · · · · · , · · · · · · , · · · · · · , · · · · · · · · · , · · · · · · , · · · · · , · · · · · , · · · · · , · · · · · · , · · · · · · · , · · · · · · , · · · · · · , · · · · · · · · , · · · · · · · , · | total protein |
| _ | | |
| Tests cleared but not clinically released | _ | none |
| Tests not available in U.S. but available in other countries | _ | |
| Research-use-only assays/Tests in development | | none/none |
| ······ | ammonia, glutamine, glycerol, triglyceride, pyruvate/none | |
| User-defined methods implemented for what analytes | - | none |
| Mathada aupported//mmunaceasay mathada | ovuran alastrada/ | nhatamatau natantiamatau/turbidimatria diraat turbidimatria nartiala |
| methous supporteu/minunoassay methous | oxygen electrode/— | enhanced turbidimetric. enzyme immunoassay |
| No. of direct ion selective electrode channels | _ | 4 |
| Must load separate reag. pack for each specimen/No. of diff. assays in pack | (no | no |
| Separate reag. pack for each test run | yes | no |
| No. of different measured assays onboard simultaneously | | 9 |
| No. of different assays programmed, calibrated at once | 2/1 | 9 |
| No. of different analytes for which system accommodates | 1/100-300 | 9/400–2.400 tests per container |
| reag. containers onboard at once/Tests per container set | | |
| Shortest/Median onboard reag. stability/Refrigerated onboard | 24 hr/1 day/no | 168 hr/30 days/yes (2–8°C) |
| Multiple reag. configurations supported | no | yes |
| Reag. container placed directly on system for use | requires operator prehandling, preparation | yes |
| Instrument has same capabilities when 3rd-party reag. used | yes | yes accountered and |
| neay. Unity cost per reportable result for standard chemistries/ | φυ. ι-φ1/—/— | assay uepenueni |
| Walkaway capacity in minutes/No. of specimens/No. of tests-assays | n/a/—/— | 400/63/1,827 |
| System is liquid, dry, or reconstituted onboard | liquid | liquid |
| Uses disposable cuvettes/Max. No. stored | no/— | no/n/a |
| Uses washable cuvettes/Replacement frequency | no/— | yes/permanent-2-yr warranty |
| Minimum sample volume aspirated precisely at one time | 2.5 μL | 3 µL |
| Supplied with UPS (backup power)/Requires floor drain | no/— | yes/no yes/7 l |
| Noise generated in decibels | | yes// L 70 |
| Dedicated pediatric sample cup/Dead volume | no | ves/40 uL |
| Primary tube sampling/Pierces caps on primary tubes | no/no | yes/no |
| Sample bar-code reading capability/Autodiscrimination | no/— | yes, on sample transport, shortly before sample is aspirated |
| _ | | (2 of 5 interleaved, Codabar, codes 39 & 128)/yes |
| Reagent bar-code reading capability Bar-code placement per CLSI standard Auto2A | _ | yes |
| Onboard test auto inventory (determines volume in container) | no | ves |
| Measures No. of tests remaining/Short sample detection/Clot detection | no/ves/— | ves/ves |
| Automatic detection of adequate reag. for aspir. & analysis | yes | yes |
| Hemolysis/Turbidity detection-quantitation | not required/not required | yes/yes |
| Dilution of patient samples onboard/Automatic rerun capability | not required/no | yes/no |
| Sample volume can be reduced to rerun out-of-linear-range high results/ | —/— | <i>—</i> /— |
| Autocalibration or autocalibration alert | 294 | 29V |
| Calibrants stored onboard/Multipoint calibration supported | no/not required | no/yes |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | —/1 hr/—/— | 24 hr/n/a/n/a/n/a |
| Automatic shutdown/Startup programmable | no/no | none required |
| Stat time to completion of all analytes, throughout per br. for | | |
| Sodium, potassium. chloride. TC02 | _ | 52 sec, 75 |
| Sodium, potassium, chloride, TCO2, glucose, urea, creatinine | 20 sec, — | 8 min, 75 |
| Album., direct & total bili., AST, ALT, ALP | - | n/a, n/a |
| Typical time delay from ordering stat test to aspir. of sample | 1 min | 45 sec |
| now often up required/Unboard SW capability to review QC | snortest interval: 4 nr; longest: daily/yes | 24 nr/yes |
| QC results transferred automatically to LIS | Ves | yes Ves |
| | | |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard/no | onboard & optional add-on (SW mftr: Beckman Coulter DL2000)/yes |
| Interfaces up and rupning in active user sites with | | (2001/1 COST) Cerner Micks Meditoph Citation Modern CHC Ciamons |
| חונכוזמניס עף מונע ועווווווא וו מכוויל עשלו שונט שווו | | McKesson, Labquest. CCA. VA-Mumps. others |
| Bidirectional interface capability | no | yes (broadcast download & host query) |
| Test results transmitted to LIS as soon as chem. time complete | yes | yes |
| LIS interface operates simultaneously with running assays | no | yes |
| Uses LUINC to transmit orders & results | 00 | no |
| How labe get LOINC codes for reagant kits | n/a | |
| How labs get LOINC codes for reagent kits | n/a | - |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely | n/a no | no |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system | n/a no no | no no |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ | n/a no no no// | no no ves/yes/no |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component | n/a no no// | no no yes/yes/no |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component On-site time of svc. engineer/Onboard error codes for troubleshooting | n/a no no no/—/— n/a/— | no no yes/yes/no metro: same day; rural: same or next day/yes |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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 | n/a no no// n/a/ / | no no yes/yes/no metro: same day; rural: same or next day/yes n/a/n/a |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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 of the table is a service. | n/a no no// n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ | no no 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 |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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 oner, training avail | n/a no no// n/a/ n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ 1 day on site/no | no no 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 |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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// n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ 1 day on site/no \$500 | no no 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 |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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) | n/a no no// n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ 1 day on site/no \$500 | no no 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 |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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) Distinguishing features | no no no no// n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ 1 day on site/no \$500 large test menu; small sample size; cost per test; 20-second analysis time | no no 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 fast stat chemistry analyzer; centrifugable sectors; bar-coded cellibrations and controls; best guard respect load while suminary |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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) Distinguishing features | no no no no// n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ 1 day on site/no \$500 large test menu; small sample size; cost per test; 20-second analysis time | no no 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 fast stat chemistry analyzer; centrifugable sectors; bar-coded calibrations and controls; host query; reagent load while running; ready-to-use liquid reagents: ISE system: nulsed vanon light source: |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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) Distinguishing features | no no no// n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ 1 day on site/no \$500 large test menu; small sample size; cost per test; 20-second analysis time | no no 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 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 Samole Manager |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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) Distinguishing features | no no no// n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ 1 day on site/no \$500 large test menu; small sample size; cost per test; 20-second analysis time | no no 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 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 |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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) Distinguishing features | no no no// n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ 1 day on site/no \$500 large test menu; small sample size; cost per test; 20-second analysis time | no no 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 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 |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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) Distinguishing features | no no no// n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ 1 day on site/no \$500 large test menu; small sample size; cost per test; 20-second analysis time | no no 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 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 |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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) Distinguishing features | no no no// n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ 1 day on site/no \$500 large test menu; small sample size; cost per test; 20-second analysis time | no no 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 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 |
| How labs get LOINC codes for reagent kits Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system 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) Distinguishing features | no no no// n/a/ daily: 1 min; weekly: 1 min; monthly: 10 min no/ 1 day on site/no \$500 large test menu; small sample size; cost per test; 20-second analysis time | no no 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 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 |

| Part 4 of 10 | Beckman Coulter Inc. | Beckman Coulter Inc. |
|--|--|---|
| | 200 South Kraemer Blvd. | 200 South Kraemer Blvd. |
| | P.O. Box 8000 | P.O. Box 8000 |
| | Brea, CA 92822-8000 | Brea, CA 92822-8000 |
| See accompanying article on page 20 | 800-526-3821 www.beckmancoulter.com | 800-526-3821 www.beckmancoulter.com |
| | Ormahusur OVA Due /0004 | Ormakuran OVE Dua (0004 |
| Name of instrument/First year sold in U.S. | Synchron GX4 Pro/2001 \$162.400 | Synchron GX5 Pro/2001 |
| No. units in clinical use in U.S. (Autoide U.S. | φισ2,400 / | φτουμούου |
| NO. UNITS IN CIINICALUSE IN U.S./OUTSIDE U.S. Country where designed/Menufactured/Where response mftd | | —/— IIS/IIS/IIS & Iroland |
| Country where designed/manufactured/where reagents initd. | U.S./U.S./U.S. & Ifelallu | U.S./U.S./U.S. & Ireland |
| Operational type/Reagent type | continuous random access/open reagent system | continuous random access/open reagent system |
| Sample nanoling system/woolel type | sectors, centringable/noor-standing | sectors, centrifugable/floor-standing |
| Dimensions in inches (n x w x D)/instrument lootprint | 09 X 47 X 30/9.0 SQ IL | 09 X 01 X 30/12.7 SQ IL |
| Tests available on instrument in U.S. | alb ALP ALT amylase AST RUN calc. CO. chloride cholest. CK-MR | alb ALP ALT amylase AST RUN calc. CO., chloride cholest. CK-MR |
| | creatinine, dir, bilirubin, GGT, glucose, HDLD, iron/TIBC, lipase, LD, LDLD, | creatinine, dir. bilirubin, GGT, ducose, HDLD, iron/TIBC, linase, LD, LDLD, |
| | Mg. phosphorus, potassium, sodium, total protein, total bilirubin. | Mg, phosphorus, potassium, sodium, total protein, total bilirubin. |
| | triglyceride, triglyceride glycerol blanked, urea, uric acid; esoteric | triglyceride, triglyceride glycerol blanked, urea, uric acid; esoteric |
| | chemistries: ammonia. cholinesterase. hemodobin A1c. lactate. micro- | chemistries: ammonia. cholinesterase. hemoglobin A1c. lactate. micro- |
| | albumin, prealbumin, salicylate: drugs of abuse testing: therapeutic drug | albumin, prealbumin, salicylate: drugs of abuse testing: therapeutic drug |
| | monitoring: proteins: anti-streptolysin 0. IgA. IgM. IgG. rheumatoid | monitoring: proteins: anti-streptolysin (). IgA. IgA. IgG. rheumatoid |
| | factor, transferrin; thyroids: thyroxine, T-up, P-amylase, c-reactive | factor, transferrin; thyroids: thyroxine, T-up, P-amylase, C-reactive |
| | protein, creatine kinase | protein, creatine kinase |
| 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 | UIBC, cyclosporine, homocysteine, lithium | UIBC, cyclosporine, homocysteine, lithium |
| | | |
| Methods supported/Immunoassay methods | photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct | photometry, potentiometry, turbidimetric/bidentate turbidimetric, |
| | turbidimetric, particle enhanced turbidimetric, enzyme immunoassay | direct turbidimetric, particle enhanced turbidimetric, enzyme |
| | | Immunoassay |
| No. of direct ion selective electrode channels | n/a | 5 (indirect) |
| wust load separate reag. pack for each specimen/No. of diff. assays in pack | no | no |
| Separate reag. pack for each test run | NO | 10 |
| No. of different measured assays onboard simultaneously | 24 | 29 |
| No. of different assays programmed, calibrated at once | DU 06/04 | 00/00 |
| No. of user-definable (open) channels/No. active simultaneously | 30/24 | 100/29 20/2 000 60 600 (100 - 2 400 tests new container) |
| No. of uniferent analytes for which system accommodates | 24/2,400-3,000 (100-300 tests per container) | 29/2,900-09,000 (100-2,400 tests per container) |
| reag. containers onboard at once/ lests per container set | 169 br/20 dava/vaa /2 0°0 | 169 hr/20 days/yes /2 |
| Shortest/Median onboard reag. stability/Retrigerated onboard | 168 nr/30 days/yes (2–8 C) | 168 nr/30 days/yes (2–8 C) |
| Multiple reag. configurations supported | yes | yes |
| Reag. container placed directly on system for use | yes | yes |
| Deer, only oper ner reportable result for standard chemistrics/ | yes accountered ant | yes aaaay dahah daht |
| Therapoutie drugs/Special analytics | assay uepenuent | assay uepenueni |
| Walkaway canacity in minutes/No. of enerimene/No. of tests-assays | 400/63/1 512 | /00/63/1 827 |
| System is liquid dry or reconstituted onhoard | 400/03/1,312 | 400/03/1,027 liquid |
| lices disnesable cuvettes/May. No. stored | ngunu | no/n/a |
| lises washahle cuvettes/Renlacement frequency | ves/nermanent_2-vr warranty (80 stored on instrument) | ves/nermanent_2.vr warranty /80 stored on instrument) |
| Minimum sample volume aspirated precisely at one time | 3 ul | 3 ul |
| Sunnlied with IIPS (backun nower)/Bequires floor drain | ves/no | ves/no |
| Requires dedicated water system/Water consumption in L per hour | ves/7 L | ves/7 L |
| Noise generated in decibels | 70 | 70 |
| Dedicated pediatric sample cup/Dead volume | ves/40 µL | ves/40 µL |
| Primary tube sampling/Pierces caps on primary tubes | ves/no | ves/no |
| Sample bar-code reading capability/Autodiscrimination | yes, on sample transport, shortly before sample is aspirated (2 of 5 | yes, on sample transport, shortly before sample is aspirated (2 of 5 |
| | interleaved, Codabar, codes 39 & 128)/yes | interleaved, Codabar, codes 39 & 128)/yes |
| Reagent bar-code reading capability | yes | yes |
| Bar-code placement per CLSI standard Auto2A | yes | yes |
| Onboard test auto inventory (determines volume in container) | yes | yes |
| Measures No. of tests remaining/Short sample detection/Clot detection | yes/yes | yes/yes |
| Automatic detection of adequate reag. for aspir. & analysis | yes | yes |
| Hemolysis/Turbidity detection-quantitation | yes/yes | yes/yes |
| Dilution of patient samples onboard/Automatic rerun capability | yes/no | yes/no |
| Sample volume can be reduced to rerun out-of-linear-range high results/ | yes/no | yes/no |
| Increased to rerun out-of-linear-range low results | | |
| Autocalibration or autocalibration alert | yes | yes |
| Calibrants stored onboard/Multipoint calibration supported | no/yes | no/yes Ad hafen ha 90 dawa (60 dawa (14 dawa |
| Typical callb. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | n/a/up to 90 days/60 days/14 days | 24 hr/up to 90 days/60 days/14 days |
| Automatic shutdown/Startup programmable | none required | none required |
| Stat time to completion of all analytes, throughout new by few | | |
| Stat unie to completion of all analytes, throughput per nr. tor: | n/a n/a | 52 cao 75 choolmana |
| Sodium notassium chlorida TCO2 ducesa uraa arcetinina | n/a, n/a n/a | az adu, 70 aprolinicha 8 min 75 enorimene |
| • Album, direct & total hili AST ALT ALP | 10 min. 32 specimens | 10 min, 32 specimens |
| Typical time delay from ordering stat test to asnir, of sample | 45 sec | 45 sec |
| How often QC required/Onboard SW canability to review OC | 24 hr/ves | 24 hr/ves |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | yes/yes | yes/yes |
| QC results transferred automatically to LIS | yes | yes |
| | | |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard & optional add-on (SW mftr: Beckman Coulter DL2000)/yes | onboard & optional add-on (SW mftr: Beckman Coulter DL2000)/yes |
| | (addt'l cost) | (additional cost) |
| Interfaces up and running in active user sites with | Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, | Cerner, Misys, Meditech, Citation, MedLab, CHC, Siemens, |
| | McKesson, Labquest, CCA, VA-Mumps, others | McKesson, Labquest, CCA, VA-Mumps, others |
| Bidirectional interface capability | yes (broadcast download & host query) | yes (broadcast download & host query) |
| Test results transmitted to LIS as soon as chem. time complete | yes | yes |
| LIS interface operates simultaneously with running assays | yes | yes |
| Uses LOINC to transmit orders & results | no | no |
| How labs get LOINC codes for reagent kits | — | n/a |
| Lab and another second states | | |
| Lau Gall Collicol allalyzer remotely Interface avail (or will be) to automated specimen bandling system | liu Ves | |
| יותכוזמטים מעמוו. (טי שווו שבי נט מענטווומנעט באפטווופוו וומוועווווע system | Jua | jus |
| Modem servicing available/Can diagnose own malfunctions/ | ves/ves/no | ves/ves/no |
| Determine malfunctioning component | | |
| On-site time of svc. engineer/Onboard error codes for troubleshooting | metro: same day: rural: same or next day/yes | metro: same day: rural: same or next dav/ves |
| Mean time between failures/To repair failures | _/ | _/ |
| Average time to complete maintenance by lab personnel | daily: 5 min; weekly: 15 min; monthly: 20 min | daily: 5 min; weekly: 15 min; monthly: 20 min |
| Onboard maintenance records/Maint. training demo module | no/no | no/no |
| Training provided with purchase/Advanced oper. training avail. | 1 day on site, 5 days at vendor offices/no | 1 day on site, 5 days at vendor offices/no |
| Annual service contract cost (24 h/7 d) | - | - |
| | | |
| Distinguishing features | serum indices; centrifugable sectors; clot detection; bar-coded | serum indices; centrifugable sectors; clot detection; bar-coded |
| | calibrators and controls; host query; reagent load while running; | calibrators and controls; host query; reagent load while running; |
| | ready-to-use liquid reagents; Peltier thermal ring; pulsed xenon light | ready-to-use liquid reagents; Peltier thermal ring; ISE system; |
| | source; polychromatic correction; semipermanent glass cuvettes; | pulsed xenon light source; polychromatic correction; semiperma- |
| | | HEIL HIASS CUVELLES, AVAILADIE DLZUUU SAMDIE MANAUEL |

| Part 5 of 10 | Clinical Data Inc. | Dade Behring Inc. |
|--|--|--|
| | 2 INURDER BIVO. Smithfield BI 02917 | P 0 Box 6101 |
| | 800-345-2822 | Newark, DE 19714-6101 |
| See accompanying article on page 20 | www.clda.com | 800-242-3233 www.dadebehring.com |
| Name of instrument/First year sold in U.S. | Vitalab Selectra E/— | Dimension Xpand Plus Integrated Chemistry System/2004 |
| List price | | 1 200/200 |
| No. units in clinical use in U.S./Uutside U.S. Country where designed/Manufactured/Where reagents mftd | //5,000 Netherlands/Netherlands/ILS | 1,200/800 |
| Operational type/Reagent type | random access/self-contained multi-use cartridges-packages-slides | continuous random access/self-contained single-use & multi-use |
| | | cartridges-packages-slides & open reagent system |
| Sample handling system/Model type | rotor/benchtop | racks/floor-standing |
| Dimensions in inches (H x W x D)/Instrument footprint | 19 x 45 x 22/8 sq. ft. | 45 x 51 x 31 (without monitor)/10.6 sq ft |
| Tests available on instrument in U.S. | ALT, alkaline phosphatase, albumin, amylase, aspartate transami- | alb., calc., cholest., creatin., dir. & tot. bilir., enz. carbon., gluc., |
| | nase, bilirubin direct & total, calcium, CO_2 , chloride, choles terol, | gluc./GLUC (liq.), HDL-C, auto. HDL-C, iron, auto. LDL, Mg, phosphor., |
| | CPK, creatinine, digoxin, direct HDL & LDL, GGT, glucose, total iron, | TIBC, IBCT, tot. protein, triblyc., urea nitro., uric acid, CO2, chlor., |
| | LDL, magnesium, pnenobarbital, pnenytoin, pnospnorus, potassium, total protein, sodium, theophylline, triglycerides, BUN, uric acid | potas., sod., MBA1C, I-uptake, trilodotn., acid phosph., alan. aminotransf, alkal, phosphat, amyl, aspart, aminotransf, CK, CK- |
| | HbA1c | MB isoenz., gluta, transfer., lac. dehvdrog., lipase. |
| | | pseudocholinesterase, card. trop I, ferrit., fPSA, free thyr., others |
| Tests cleared but not clinically released | - | - |
| Tests not available in U.S. but submitted for 510(K) clearance | _ | _ |
| Research-use-only assays/Tests in development | none/hsCRP | —/quinidine, sirolimus, tacrolimus |
| User-defined methods implemented for what analytes | - | |
| | nkatawatau astautiawatau (ICE) (inawunatu kidiwatais | nkatawatwa watawiiawatwa tuukidiwatwia agagua (Datinia Ewit |
| wemous supporteu/mmunoassay methods | photometry, potentiometry (ISE)/immunoturblaimetric | Acmia, mag, part, sep. |
| No. of direct ion selective electrode channels | 4 | 3 |
| Must load separate reag. pack for each specimen/No. of diff. assays in pack | no | no |
| Separate reag. pack for each test run An of different measured assaus annound simultaneously | no 26 | N0 47 |
| No. of different assays programmed, calibrated at once | | 190 |
| No. of user-definable (open) channels/No. active simultaneously | 6/26 | 10/10 |
| No. of different analytes for which system accommodates | 31/— | 47/15–360 |
| reag. containers onboard at once/Tests per container set | 72 br/7 dovo/voo (1900 balaw ambiant) | 72 hr/20 doug/ugg (2, 0%) |
| Subrest/Median onboard reag. stability/Ketrigerated onboard | /2 III// days/yes (12°C delow amplent) ves | 12 III/3U DAYS/YES (2-8°C) |
| Reag. container placed directly on system for use | yes | yes |
| Instrument has same capabilities when 3rd-party reag. used | yes | yes |
| Reag. only cost per reportable result for standard chemistries/ | <i>—/—/—</i> | - |
| Therapeutic drugs/Special analytes Walkaway canacity in minutes/No. of specimens/No. of tests-assays | 120/50/1 500 | can he hrs/60/>1 000 |
| System is liquid, dry, or reconstituted onboard | liauid | liquid, no reagent prep required |
| Uses disposable cuvettes/Max. No. stored | no | yes/12,000 |
| Uses washable cuvettes/Replacement frequency | yes/~10,000 tests | no/— |
| Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Poquires floor drain | | 2 µL |
| Requires dedicated water system/Water consumption in L per hour | no/~0.5 L | yes/up to 2 µL |
| Noise generated in decibels | - | <70 |
| Dedicated pediatric sample cup/Dead volume | yes/20 μL | yes/10–20 μL |
| Primary tube sampling/Pierces caps on primary tubes | yes/no | yes/yes |
| Sample bar-code reading capability/Autodiscrimination | yes, by handheid scanner as tubes are loaded onto instrument (2 of 5 interleaved LIPC Codabar codes 30 & 128)/ | yes (2 of 5 interleaved, Godabar, codes 39 & 128)/yes |
| Reagent bar-code reading capability | no | ves |
| Bar-code placement per CLSI standard Auto2A | yes | yes |
| Onboard test auto inventory (determines volume in container) | yes | yes was kusa kusa |
| Automatic detection of adequate read, for asnir & analysis | yes/yes/yes | yes/yes ves |
| Hemolysis/Turbidity detection-quantitation | no/no | yes/yes |
| 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/ | yes/no | yes/yes |
| Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert | 29V | 201 |
| Calibrants stored onboard/Multipoint calibration supported | yes/— | yes(Na, K, Cl)/yes |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | 4 hr/7 days/—/— | —/up to 90 days/—/— |
| Automatic shutdown/Startup programmable | yes/yes | not required |
| Stat time to completion of all analytes, throughout per hr. for: | | |
| Sodium, potassium, chloride, TCO2 | 8 min, — | 2 min, 62 |
| Sodium, potassium, chloride, TC02, glucose, urea, creatinine | 10 min, — | 4 min, 62 |
| Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat text to spring of seconds | 10 min, — 6 min | 8 min, 62 60 sec staady state 2 min from standby |
| How often QC required/Onboard SW canability to review OC | 4 hr/daily | daily/ves |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | yes/yes | yes/yes |
| QC results transferred automatically to LIS | - | yes |
| Data mamt, canability/Instrument vender symplics LIC interface | antional add_on/une (additional cost) | antional add_on/uge (additional aget) |
| vata mymt. capavinty/instrument vendor supplies LIS Interface | opuonai auu-on/yes (auullonai cost) | optional auu-on/yes (auultional cost) |
| Interfaces up and running in active user sites with | - | interfaces available for all major LIS vendors |
| | | |
| Bidirectional interface capability | yes voc | yes (broadcast download & host query) |
| LIS interface operates simultaneously with running assays | yes Ves | yes Ves |
| Uses LOINC to transmit orders & results | _ | no |
| How labs get LOINC codes for reagent kits | - | - |
| Lah can control angluzor remotely | no | no |
| Law can control analyzer remotely Interface avail, (or will be) to automated specimen handling system | no | Ves |
| | | |
| Modem servicing available/Can diagnose own malfunctions/ | no/yes/yes | yes/yes/yes |
| Determine malfunctioning component | within 24 hr/vee | 2-8 hr/ves |
| Mean time between failures/To renair failures | 6 months/4 hr | |
| Average time to complete maintenance by lab personnel | daily: 10 min; weekly: 20 min; monthly: 60 min | daily: 5 min; weekly: 10 min; monthly: 15 min |
| Onboard maintenance records/Maint. training demo module | no/yes | yes/no |
| Training provided with purchase/Advanced oper. training avail. | 5 days on site/yes | 5 days on site, 4 days at vendor offices/no |
| Annual service contract cost (24 n/7 d) | 11/a | inuiupie types |
| | | |
| Distinguishing features | reusable cuvette; dry ISE with CO $_2;$ 2–30 μL sample size; onboard | consolidated low-volume workstation that integrates immunoassays |
| | wash system; ready-to-use liquid reagents | onboard with other chemistries; allows single platform to meet over |
| | | so percent of testing needs; eliminates sample splitting, aliquotting |
| | | |
| | | |
| | | |

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Chemistry analyzers (for low-volume laboratories)

| Part 6 of 10 | Hemagen Diagnostics Inc. | Nova Biomedical Corp. |
|---|--|---|
| | 9033 Red Branch Rd. | 200 Prospect St. |
| Saa aaamnanving articla on naga 20 | 443-367-5500 | 800-458-5813 |
| See accompanying a licle on page 20 | Analyst Banchton Chamistry System/1986 | Stat Profile Critical Care Ynrees/2002 |
| List price No units in clinical use in ILS /Outside ILS | \$6,900 | \$25,000-\$59,000 |
| Country where designed/Manufactured/Where reagents mftd. | , France/U.S./U.S. hateb/self_contained_single_use_cartridges_nackades_slides | U.S./U.S./U.S. discrete/celf-contained multi-use cartridges |
| Comple heading system /Madel tune | vatore/konstaton | |
| Dimensions in inches (H x W x D)/Instrument footprint | 8.5 x 25 x 13/2.25 sq ft | tube/benchtop 17.2 x 17.3 x 22.3/2.7 s q ft |
| Tests available on instrument in U.S. | ALP, GGT, GPT, GOT, BUN, glucose, calcium, cholesterol, creatinine, | pH, PCO ₂ , PO ₂ , SO ₂ %, hematocrit, hemoglobin, sodium, potassium, |
| | trigiycerides, amylase, uric acid, total bilirubin, total protein, HDL cholesterol | chioride, ionized calcium, ionized Mg, 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 | none none | none none |
| Tests not available in U.S. but available in other countries Research-use-only assays/Tests in development | none none/— | none none |
| User-defined methods implemented for what analytes | none | none |
| Methods supported/Immunoassay methods No. of direct ion selective electrode channels | photometry/— — | potentiometry (ISE), optical, reflectance/n/a 12 |
| Must load separate reag, pack for each specimen/No. of diff. assays in pack | c yes/14 | no/n/a |
| Separate reag. pack for each test run No. of different measured assays onboard simultaneously | | no 19 |
| No. or different assays programmed, calibrated at once No. of user-definable (open) channels/No. active simultaneously | 14 | 19 0/n/a |
| No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set | 14/14 | 19/200–500 samples (2,600–6,500 tests), depending on lab |
| Shortest/Median onboard reag. stability/Refrigerated onboard Multiple reag. configurations supported | _/_/_ _ | 45 days/45 days/no n/a |
| Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used | yes no | requires operator prehandling, preparation n/a |
| Reag. only cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes | <i>—!—!—</i> | \$.06-\$.28 per test (cost varies with volume); bundled instr. reag. maint. cost per result \$.07-\$.31 per test (5-yr reagent rental)/n/a/n/a |
| Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry. or reconstituted onboard | 10/1/14 drv | n/a/n/a ISE |
| Uses disposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency | no (uses rotors) no/n/a | no/n/a no/n/a |
| Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain | 10 μL & 80 μL no/no | 60 μL no (ontional)/no |
| Requires dedicated water system/Water consumption in L per hour Noise generated in decibels | no/none | no/n/a minimal |
| Dedicated pediatric sample cup/Dead volume | no no/no | no/n/a |
| Sample bar-code reading capability/Autodiscrimination | no/— | yes/no yes (optional), by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved UPC, Codebox, and a 20,8120)/use |
| Reagent bar-code reading capability | yes | yes |
| Onboard test auto inventory (determines volume in container) | no | yes |
| Automatic detection of adequate reag. for aspir. & analysis | | yes/yes yes |
| Dilution of patient samples onboard/Automatic rerun capability | no/no no/no | yes (on co-oximeter module)/yes (on co-oximeter module) yes (on co-oximeter module)/no |
| Sample volume can be reduced to rerun out-of-linear-range high results/ Increased to rerun out-of-linear-range low results | n0/n0 | n0/n0 |
| Autocalibration or autocalibration alert Calibrants stored onboard/Multipoint calibration supported | no no/— | yes yes/yes |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable | —/60 days/—/— no/no | 30–120 min/30–120 min/n/a/n/a yes/yes |
| Stat time to completion of all analytes, throughput per hr. for: | | 62 sec. 23-38 depending on use mode |
| Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album, diract & total bill, AST, ALT, ALT, ALT, ALT, ALT, ALT, ALT, AL | 10 min, 6 specimens | 134 sec, 23–38, depending on use mode |
| Typical time delay from ordering stat test to aspir. of sample | - , | 1//d, 1//d <2 Sec 9. by/www |
| On board real-time QC/Support multiple QC lot Nos. per analyte | —, — no/no | o m/yes yes/yes |
| uu results transferred automatically to LIS | | yes onhoard/no |
| Interfaces up and running in active user sites with | in development | n/a |
| Bidirectional interface capability | no | ves |
| Test results transmitted to LIS as soon as chem, time complete | - | yes ves |
| Uses LOINC to transmit orders & results How labs get LOINC codes for reagent kits | _ | no n/a |
| Lab can control analyzer remotely | _ | yes |
| Interrace avail. (or will be) to automated specimen handling system | | |
| Determine malfunctioning component | | yearyea |
| Mean time between failures/To repair failures | | n/a/n/a daily ango wookhy 25 min, monthly 21 min |
| Average time to complete maintenance by lab personnel Onboard maintenance records/Maint. training demo module | no/no | uany: none; weekiy: <> min; monthly: <15 min yes (includes audit trail of who replaced parts)/yes |
| raining provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d) | i day on site/yes \$650 per year | 1 day on site/yes \$3,750-\$7,685 |
| Distinguishing features | uses only 90 µL of sample & requires less than 60 seconds of | comprehensive 19-test critical care profile, including ionized Mg, |
| | prep work; minima maintenance required; offered with sodium, potassium, and chloride ISE units | co-oximeter; open software architecture; onboard data management; automated onboard quality control poled works output |
| | | monitoring of QC and reagent packs; tankless gas calibration; automated maintenance |
| | | |

| Part 7 of 10 | Nova Biomedical Corp. | Nova Biomedical Corp. |
|--|--|--|
| | info@novabiomedical.com | Info@novabiomedical.com |
| | Waltham, MA 02454-9141 | 200 Prospect St. Waltham, MA 02454-9141 |
| | 800-458-5813 | 800-458-5813 |
| See accompanying article on page 20 | www.novabiomedical.com | www.novabiomedical.com |
| Name of instrument/First year sold in U.S. | Stat Profile nHAv Series/1998 | Nova 16/1995 |
| List price | \$12,000-\$32,000 | \$22,500-\$25,500 |
| No. units in clinical use in U.S./Outside U.S. | <u> </u> | <u> </u> |
| Country where designed/Manufactured/Where reagents mftd. | U.S./U.S./U.S. | U.S./U.S./U.S. |
| Operational type/Reagent type Sample handling system/Medel type | discrete/self-contained multi-use cartridges-packages-slides | batch, random access/self-contained multiuse cartridges |
| Sample nanuning system/model type | tube/benchtop | top |
| Dimensions in inches (H x W x D)/Instrument footprint | 15 x 15 x 18/1.9 sq f t | 20.5 x 19.2 x 20.7/2.75 sq ft |
| Teste susilable en instrument in U.C. | nu ROO RO 60 % homotoorit komorishin oodium potoosium | andium nataonium ablavida tatal 00 - slucens DIN exectining llat |
| Tests available on instrument in 0.5. | pH, PCO ₂ , PO ₂ , SO ₂ %, nematocrit, nemoglobin, sodium, potassium, chloride, ionized calcium, dlucose, lactate | sodium, potassium, chioride, total 60 ₂ , giucose, Bow, creatinine, HCt |
| | | |
| | | |
| | | |
| 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 |
| Kesearch-use-only assays/lests in development | none | none/none |
| osei-uenneu methous implementeu for what analytes | | |
| Methods supported/Immunoassay methods | potentiometry (ISE), optical, reflectance/n/a | potentiometry/n/a |
| No. of direct ion selective electrode channels | 5 | 8 |
| wust toat separate reag, pack for each specimen/No. of diff. assays in nack | 110/11/a | 10/11/8 |
| Separate reag. pack for each test run | no | no |
| No. of different measured assays onboard simultaneously | 11 | 8 |
| No. of different assays programmed, calibrated at once | 11 0/n/a | 8 |
| No. of different analytes for which system accommodates | v/II/a 11/varies by analyzer and laboratory use nattern | 0/11/a 8/(@ 8.000 tests/mo): 2.700 tests |
| reag. containers onboard at once/Tests per container set | anos of analyzor and laboratory use pattern | |
| Shortest/Median onboard reag. stability/Refrigerated onboard | 45 days/45 days/no | 21 days/21 days/no |
| Multiple reag. configurations supported | n/a | n/a |
| neag. container placed directly on system for use | requires operator prenanciing, preparation n/a | no, requires prenandling (remove clip from sealed bag & mix) n/a |
| Reag. only cost per reportable result for standard chemistries/ | varies by model/n/a/n/a | standard chemistries: @25 sam/d: \$0.40 (8-test panel); bundled instr., |
| Therapeutic drugs/Special analytes | | reag., maint. cost per result: \$0.92 (8-test panel)// |
| Walkaway capacity in minutes/No. of specimens/No. of tests-assays | n/a/n/a | 60 per tray/40 per tray/280 per tray |
| System is liquid, dry, or reconstituted ondoard lises disposable cuvettes/Max. No. stored | ISE no/n/a | n/a no/n/a |
| Uses washable cuvettes/Replacement frequency | no/n/a | n/a/n/a |
| Minimum sample volume aspirated precisely at one time | 45 μL | 385 µL |
| Supplied with UPS (backup power)/Requires floor drain | no (optional)/no | no/no |
| Requires dedicated water system/water consumption in L per nour Noise generated in decibels | no/n/a minimal | no/n/a minimal |
| Dedicated pediatric sample cup/Dead volume | no/n/a | n/a |
| Primary tube sampling/Pierces caps on primary tubes | yes/no | yes/no |
| Sample bar-code reading capability/Autodiscrimination | yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 | yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 |
| Reagent bar-code reading capability | interieaved, UPC, Codabar, codes 39 & 128)/yes ves | alternate method |
| Bar-code placement per CLSI standard Auto2A | no | n/a |
| Onboard test auto inventory (determines volume in container) | yes | yes |
| Measures No. of tests remaining/Short sample detection/Clot detection Automatic detection of adequate read, for aspir, & analysis | yes/yes ves | no/yes/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 | / no/no | no/no |
| Increased to rerun out-or-linear-range low results Autocalibration or autocalibration alert | 294 | 201 |
| Calibrants stored onboard/Multipoint calibration supported | yes/yes | yes/n/a |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | 30–120 min/30–120 min/n/a/n/a | 2 hr/2 hr/n/a/n/a |
| Automatic shutdown/Startup programmable | yes/yes | n/a/n/a |
| Stat time to completion of all analytes, throughput per hr. for: | | |
| Sodium, potassium, chloride, TCO2 | 52 sec, 40 | 85 sec, 45 specimens |
| Sodium, potassium, chloride, TCO2, glucose, urea, creatinine | n/a, n/a | 85 sec, 45 specimens |
| Album., direct & total bill., AST, ALT, ALP Typical time delay from ordering stat test to aspir, of sample | n/a, n/a <2 sec | N/a 9 sec |
| How often QC required/Onboard SW capability to review QC | 8 hr (CLIA)/yes | CLIA minimum/yes |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | yes/yes | no/yes |
| QC results transferred automatically to LIS | yes | yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | no/no | onboard & optional add-on (\$9.225. SW mftr: Nova)/no |
| | | , |
| Interfaces up and running in active user sites with | virtually all | most LIS vendors including Cerner, Sunquest, HBO, Soft, others |
| Ridirectional interface canability | ves (broadcast download & bost query) | Ves |
| Test results transmitted to LIS as soon as chem. time complete | yes Yes | yes |
| LIS interface operates simultaneously with running assays | yes | no |
| Uses LOINC to transmit orders & results | no | no |
| | II/ d | — |
| Lab can control analyzer remotely | yes | yes |
| Interface avail. (or will be) to automated specimen handling system | no | no |
| Modem servicing available/Can diagnose own malfunctions/ | voelvoel | |
| Determine malfunctioning component | y 661 y 661 y 66 | 10/ 303/ 303 |
| On-site time of svc. engineer/Onboard error codes for troubleshooting | <8 business hr/yes | <8 business hr/yes |
| Mean time between failures/To repair failures | n/a/n/a dailu papa waakhu 25 min maathuu 45 min | n/a/n/a doily a2 min workly. E min monthly E min |
| Average time to complete maintenance by lab personnel Onboard maintenance records/Maint, training demo module | uany: none; weekiy: <> min; monunly: <15 min ves/ves | uany: <2 mm; weekty: <5 mm; montnly: <5 mm no/no |
| Training provided with purchase/Advanced oper. training avail. | 1 day on site/yes | 2 days on site/yes |
| Annual service contract cost (24 h/7 d) | varies by analyzer configuration & geographic location; discounts for | call for pricing |
| | multiple-year contract or 5-year reagent rental or lease | |
| Distinguishing features | onboard quality control; liquid calibration eliminates gas tanks: remote | whole blood analyzer for creatinine & TCO2; can analyze whole blood. |
| | control; remote review; space saving design | serum, plasma, urine, CSF, and dialysate |
| | | |
| | | |
| | * on co-oximeter module | |
| | | |

 $\label{eq:constraint} \ensuremath{\mathsf{Tabulation}}\xspace \ensuremath{\mathsf{obs}}\xspace \ensuremath{\mathsf{obs$

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Chemistry analyzers (for low-volume laboratories)

| Part 8 of 10 | Ortho-Clinical Diagnostics | Randox Laboratories |
|---|---|---|
| | Sales Support | marketing@randox.com |
| See accompanying article on page 20 | 1001 U.S. Highway 202, Karitan, NJ 08869 800-457-7848 orthoclinical.com | 4065 Oceanside Blvd., Ste. Q, Oceanside, CA 92056 760-639-1500 www.randox.com |
| | | |
| Name of instrument/First year sold in U.S. List price | Vitros DT60-II System (DT 60 II, DTE, DTSC)/1993 — | Rx Daytona/2005 \$69.900 |
| No. units in clinical use in U.S./Outside U.S. | 15,000 units worldwide | >400 units worldwide |
| Country where designed/Manufactured/Where reagents mftd. | U.S./U.S./U.S. hatch_random_access_discrete/self-contained_single-use_car- | Japan/Japan/U.K. random access_discrete/self-contained multi-use cartridges- |
| | tridges-packages-slides | packages-slides |
| Sample handling system/Model type | —/benchtop 6 75 x 19 75 x 12 75/1 9 cg ff (DT 60 II) | removable ring/benchtop |
| | 0.73 x 10.73 x 13.73/1.8 sq ft (D1 00 ll) | 30.2 X 24.0 X 20.2 SQ 10- |
| Tests available on instrument in U.S. | ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, | amm., alb., acid phos, ALT, AST, alk phos, amyl., P. amylase, dir & |
| | glucose, Mg, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, | C4, CRP, hs-CRP, FRCRP, creatin., copper, ferrit., fructos., gluc., GGT, |
| | ALP, calcium, iron, lithium, ALT, cholinesterase, LDH, theophylline, | HbA1c, ISE sodium K and chor., IgA/E/G/M, LDH, lipase, lith., ASO, |
| | CO ₂ , sodium, potassium, chloride, urine creatinine, CK-MB | Lp(a), apo A1, apo B, microalb., Mg, myoglo., enzym. Na & K, RF, iron, |
| | | phyll., gentam., val. acid, carbemaz., transfer., TIBC, tot. protein, |
| Tasta slaavad kut vat sliviasllu valaasad | | triglycer., uric acid, BUN/urea, homocyst., haptoglob., urin. protein |
| 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 | α-1-antitryp., α-1-glycoprot., tot. bile acids, cholinest., gluc./fruc- tose, glutathione reductase, glutathione peroxidase, glycerol, apo |
| | | All, apo CII, apo CIII, apo E, β -hydroxybut., amik., lidoc., quinid., zinc, |
| | | TAS, LAP, total antioxidant status, super oxid dismutase, GLDH, enz. |
| User-defined methods implemented for what analytes | none | DAT, acetominophen, salicylate, cyclosp., alcoh., clycerol-3- |
| | | phosphate oxidase, phospholipids, maltose |
| Methods supported/Immunoassay methods | potentiometry, colorimetric, enzymatic/n/a | photometry, potentiometry (ISE), immunoturbidimetry. latex en- |
| | | hanced immunoturbidimetry/- |
| No. of direct ion selective electrode channels Must load separate read, nack for each specimen/No. of diff. assays in pact | 4 x ves/1 | 3 Na ', K ', CL no/50–2.205 |
| Separate reag. pack for each test run | yes | no |
| No. of different measured assays onboard simultaneously | n/a 1 | 30 |
| No. of user-definable (open) channels/No. active simultaneously | none | —/60 |
| No. of different analytes for which system accommodates | n/a/n/a | 27/40-900 |
| reag. containers onboard at once/Tests per container set Shortest/Median onboard reag. stability/Refrigerated onboard | n/a/n/a/no | 8 hr/30 davs/ves (8–15°C) |
| Multiple reag. configurations supported | no | yes |
| Reag. container placed directly on system for use | no n/a | yes ves |
| Reag. only cost per reportable result for standard chemistries/ | n/a/n/a | -// |
| Therapeutic drugs/Special analytes | | (40) |
| System is liquid, drv, or reconstituted onboard | n/a/n/a drv | —/40/— liquid |
| Uses disposable cuvettes/Max. No. stored | no/n/a | no/45 |
| Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time | no/n/a 10 ul | yes/5 years 2 ul |
| Supplied with UPS (backup power)/Requires floor drain | no/no | no/no |
| Requires dedicated water system/Water consumption in L per hour | no/none | yes/7.5 L daily |
| Dedicated pediatric sample cup/Dead volume | — n/a | ου ves/20 μL |
| Primary tube sampling/Pierces caps on primary tubes | no/no | yes/no |
| Sample bar-code reading capability/Autodiscrimination | no/— | yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, LIPC, Codabar, codes 39 & 128)/yes |
| Reagent bar-code reading capability | yes | yes |
| Bar-code placement per CLSI standard Auto2A | — n/a | |
| Measures No. of tests remaining/Short sample detection/Clot detection | n/a/n/a/n/a | yes/yes/no |
| Automatic detection of adequate reag. for aspir. & analysis | n/a | yes |
| Dilution of patient samples onboard/Automatic rerun capability | / no/no | yes/yes ves/ves |
| Sample volume can be reduced to rerun out-of-linear-range high results/ | no/no | yes/yes |
| Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert | 10 | Ves |
| Calibrants stored onboard/Multipoint calibration supported | no/yes | no/yes |
| Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse | reagent lot changes | daily/28 days/—/— no/ves |
| ראנטוומוט פווענעטשוו/פנמונעף µיטערמווווומטוע | | 110/302 |
| Stat time to completion of all analytes, throughput per hr. for: | 15 tasts | - 270 |
| Sodium, potassium, chloride, TCO2 Sodium, potassium, chloride, TCO2, qlucose, urea. creatinine | 75 tests | —, 210 —, 315 |
| Album., direct & total bili., AST, ALT, ALP | 20 tests | —, 180 |
| I ypical time delay from ordering stat test to aspir. of sample How often OC required/Onboard SW canability to review OC | none everv 24 hr/no | ou sec shortest: daily: longest: at customer discretion/ves |
| Onboard real-time QC/Support multiple QC lot Nos. per analyte | no/no | yes/yes |
| QC results transferred automatically to LIS | | yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | —/no | onboard/no |
| Interfaces up and running in active user sites with | 10 | |
| Test results transmitted to LIS as soon as chem. time complete | yes | yes (nost query) |
| LIS interface operates simultaneously with running assays | yes | yes |
| How labs get LOINC codes for reagent kits | Ξ | |
| | | |
| Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system | no no | no |
| | naluaaluaa | |
| Determine malfunctioning component | nu/yes/yes | nu/yes/yes |
| On-site time of svc. engineer/Onboard error codes for troubleshooting | —/yes | within 24 hr/yes |
| Mean time between failures/To repair failures Average time to complete maintenance by lab percented | | —/— daily: 5 min: weekly: 15 min |
| Onboard maintenance records/Maint. training demo module | no/no | no/no |
| Training provided with purchase/Advanced oper. training avail. | yes/— | 3 days on site/yes |
| Annual service contract cost (24 n// 0) | - | — |
| Distinguishing features | disposable tips eliminate sample carryover; random access testing so | most comprehensive clinical & research test menu, benchtop, low water |
| | test slides elim. waste and facilitate rapid analysis; dry slide technoloov | performance, comprehensive and easy to use Windows software |
| | minimizes the effects of interferences to provide accurate results | |

| Part 9 of 10 | Roche Diagnostics Corp. Todd Atkinsontodd.atkinson@roche.com 9115 Hague Rd. Indianapolis, IN 46256 317-521-4564 www.roche.com | Roche Diagnostics Corp. Todd Atkinsontodd.atkinson@roche.com 9115 Hague Rd. Indianapolis, IN 46256 317-521.4564 www.roche.com |
|---|---|---|
| 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 | Cobas Integra 400 Plus/1999 \$175,000 >2,000/2,000 Switzerla nd/Switzerla nd/U.S. & Germa ny continuous random access/self-contained multi-use cassettes rack/benchtop 30 x 53 x 26/9.6 sq ft | Roche Hitachi 912/1997 \$159,000 >1,100 Japan-U.S./Japan-U.S./U.SGermany continuous random access/open reagent system disk/floor-standing 46 x 40 x 30/8.3 sq ft |
| Tests available on instrument in U.S. Tests cleared but not clinically released | α -1-acid glycoprot, α -1-antitryp., apo A1 & B, antistreptoO, AT III, complement C3c & C4, cerul., CRP latex, ferr., hapt., IgA/G/M, myo., prealb., RF, transferr., amph., barb., benz., coca., ethanol, LSD, meth., methaq., opia., PCP, PPX, S barb., S benz., THC, ACPP, ALP, ALT, α -amy. pancreatic, AP, AST, cholinest. & Che-D, CK-MB, γ -glutamyltrans., LDH, lipase, alb., bil direct & total, Ca., chol., CO ₂ , creat. jaffe, creat. enzymatic, fructosam., gluc., HbA1c, HDL direct, iron, lact., LDL direct, Mg, ammon., phos., TP, TPU-C, trig., UA, UIBC, urea, Na, K, Cl, Li, acet., amik., carb., dig., gent., lido., NAPA, pheno., pheny., prim., proc., quin., sali., theo., tobra., valp. acid, vanc., T_4, T-up, D-dimer, soluble transferrin receptor, cyclosp., total amylase, total CK, free phenytoin, free VPA, microalbumin none | alb., ALP, ALT, ammonia, amy. total & panc., AST, bili. total & direct, BUN, Ca, cholest., cholinest., CK, CO ₂ , fruct., GGT, glu., HDL direct, iron, lact., LD, LD-1, LDL direct, lipase, Mg, phos., TIBC (calc.), NAPA, procainamide, TP, trig., T_4 , T-up, UIBC, UA, Na, K, Cl, α -1-antitryp., ASLO, B-2-microgl., C3c, C4, ceru., CRP, ferr., fol., hapt., HbA1c, IgA/E/G/M, microalb., myo., prealb., RF, transferrin, B ₁₂ , carb., dig., gent., pheno., pheny., salicy., theo., tobra., valp. acid, alcohol, amph., barb., benz., coca ., methad., opia., PCP, propoxy., THC; also CSF and urine chemistries, D-dimer, sol. transfer. recept., microalb., creat. jaffe, creat. enzym., (hs)CRP, LDH, TPU-c, aceta-minophen, ACT P-5-P, AST P-5-P, CRP, (hs)latex, Apo A1, Apo B none |
| 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 | none lipoprotein A none/homocysteine, lipoprotein A | none kappa/lambda light chains, %CDT, α -1-glycoprotein, α -1-microgl., cyclos., lipoprotein A none/homocysteine |
| Nethods supported/immunoscessy methods | canone | none |
| Meanous supporteu/minunuassay methods | latex particle enhanced | photomeury, potentiometry/turbiumetric, iatex particle ennanced, CEDIA |
| No. of direct ion selective electrode channels Must load separate reag, pack for each specimen/No. of diff. assays in pacl Separate reag, pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of different (specificable (spec)) channels (No. active simultaneously | 4 k no/1 no 36 tests plus applications for urine & CSF up to 999 0/0 | 3 no/n/a no 35 tests plus applications for urine & CSF 68 65 /CF |
| No. of different analytes for which system accommodates | 36/50–800 tests, cassettes | 35/100-500 |
| 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 | 2 weeks/8–12 weeks/yes (12°C) yes yes | —/30 days/yes (2–12°C) yes yes |
| Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/ | no —/—/— | no —/—/— |
| Therapeutic drugs/Special analytes Walkaway capacity in minutes/No. of specimens/No. of tests-assays System is liquid, dry, or reconstituted onboard Uses disposable cupettes/May. No. stored | 176/90/1,808 liquid ves/1 500 | 408/70/2,450 liquid no/n/a |
| Uses washable cuvettes/Replacement frequency | no/n/a | yes/monthly (120 stored on instrument) |
| Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/Requires floor drain | 1 μL no/no | 2 µL no/yes |
| Requires dedicated water system/Water consumption in L per hour Noise generated in decibels | no/2 L maximum — | yes/30 L 65 |
| Delicated pediatric sample cup/Dead volume | | yes/— |
| Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination Reagent bar-code reading capability | yes/no yes (2 of 5 interleaved, Codabar, codes 39 & 128)/yes ves | yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/yes ves |
| Bar-code placement per CLSI standard Auto2A | | yes |
| Measures No. of tests remaining/Short sample detection/Clot detection | yes yes/yes/yes | yes yes/yes/no (not necessary due to sampling method) |
| Automatic detection of adequate reag. for aspir. & analysis Hemolysis/Turbidity detection-quantitation | no/no | yes yes/yes |
| Dilution of patient samples onboard/Automatic rerun capability | yes/yes ves/yes | yes/yes |
| Increased to rerun out-of-linear-range low results | | J03/J03 |
| Autocalibration of autocalibration alert Calibrants stored onboard/Multipoint calibration supported Typical calib. frequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable | yes yes/yes 5 hr/once per lot/each lot & 12 weeks/each lot & 12 weeks yes/yes | yes yes/yes 24 hr/lot change (every 6 months)/3–5 days/56 days yes/— |
| Stat time to completion of all analytes, throughput per hr. for: | | |
| Sodium, potassium, chloride, TCO₂ Sodium, potassium, chloride, TCO₂, glucose, urea, creatinine | Joy Tests 369 tests | 3.5 min, 180 specimens 5.5 min, 90 specimens |
| Album., direct & total bili., AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample | 250 tests none | 10.5 min, 60 specimens 30 sec |
| How often QC required/Onboard SW capability to review QC | 24 hr/yes | 24 hr/yes |
| QC results transferred automatically to LIS | yes yes | yes yes |
| Data mgmt. capability/Instrument vendor supplies LIS interface | onboard/yes (addt'l cost) | onboard/yes (addt'l cost) |
| Interfaces up and running in active user sites with Bidirectional interface capability | all major LIS vendors yes (broadcast download & host querv) | all major LIS vendors yes (host query) |
| Test results transmitted to LIS as soon as chem. time complete | yes | yes |
| Uses LOINC to transmit orders & results | <u> </u> | no |
| | 100 | 70 |
| Interface avail. (or will be) to automated specimen handling system | yes — | no yes (CLAS) |
| Modem servicing available/Can diagnose own malfunctions/ Determine malfunctioning component | yes/yes | no/yes/yes |
| On-site time of svc. engineer/Onboard error codes for troubleshooting Mean time between failures/To renair failures | —/yes —/— | —/yes —/— |
| Average time to complete maintenance by lab personnel | daily: none; weekly: 5 min; monthly: none | daily: —; weekly: —; monthly: — |
| Training provided with purchase/Advanced oper. training avail. Annual service contract cost (24 h/7 d) | yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes — | yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes — |
| Distinguishing features | unique reagent cassette eliminates reagent preparation; menu consolidates testing, including direct LDL, whole blood, HbA1c, and lithium | sophisticated software with easy stat function provides instant stat selection; Roche Hitachi open system dependability and throughput |

 $\label{eq:constraint} \ensuremath{\mathsf{Tabulation}}\xspace \ensuremath{\mathsf{obs}}\xspace \ensuremath{\mathsf{obs$

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Chemistry analyzers (for low-volume labs)

| Part 10 of 10 | Thermo Electron Corp John McClellan john.mcclellan@thermo.com 331 South 104th St. Louisville, C0 80027 800-558-9115 |
|---|--|
| See accompanying article on page 20 | www.thermo.com/clinicalchem |
| 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 | Data Pro PLUS/2005 \$45,800 4/995 Argentina/Argentina/Australia batch, random access, discrete, continuous random access/self-contained multi upo partridges packages plides open respont system |
| Sample handling system/Model type Dimensions in inches (H x W x D)/Instrument footprint | ring/benchtop 33.5 x 18.5 x 22.8/51.63 sq ft |
| Tests available on instrument in U.S. | 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 |
| Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance | _ |
| Research-use-only assays/Tests in development User-defined methods implemented for what analytes | — —/ISE: Na, K, Cl; TDM: wrCRP, HbA1c none |
| Methods supported/Immunoassay methods/ | photometry, turbidimetry/— |
| Must load separate reag, pack for each specimen/No. of diff. assays in pack | no/n/a |
| Separate reag. pack for each test run | 10 |
| NO. OF OFFICER MEASURED ASSAYS ONDOARD SIMUltaneously | 4ŏ 48 |
| No. of user-definable (open) channels/No. active simultaneously | 12/12 |
| No. of different analytes for which system accommodates | 48/225 |
| reag. containers onboard at once/Tests per container set | _/_/ves |
| Multiple reag. configurations supported | yes |
| Reag. container placed directly on system for use | yes |
| Instrument has same capabilities when 3rd-party reag. used | yes |
| neag. unity cost per reportable result for standard chemistries/ Therapeutic drugs/Special analytes | — <i>i</i> — <i>i</i> — |
| Walkaway capacity in minutes/No. of specimens/No. of tests-assays | —/48/48 |
| System is liquid, dry, or reconstituted onboard | liquid |
| uses aisposable cuvettes/Max. No. stored Uses washable cuvettes/Replacement frequency | yes/ouce a week |
| Minimum sample volume aspirated precisely at one time | 3 µL |
| Supplied with UPS (backup power)/Requires floor drain | no/no |
| Requires dedicated water system/Water consumption in L per hour | no/0.58 |
| Dedicated pediatric sample cup/Dead volume | yes/100 µL |
| Primary tube sampling/Pierces caps on primary tubes | yes/no |
| Sample bar-code reading capability/Autodiscrimination | yes, on sample transport, shortly before sample is aspirated (2 of 5 |
| Reagent bar-code reading capability | yes |
| Bar-code placement per CLSI standard Auto2A | - |
| Unboard test auto inventory (determines volume in container) Measures No. of tests remaining/Short sample detection/Clot detection | yes ves/ves/no |
| Automatic detection of adequate reag, for aspir. & analysis | yes |
| Hemolysis/Turbidity detection-quantitation | no/no |
| Dilution of patient samples onboard/Automatic rerun capability | yes/yes |
| Increased to rerun out-of-linear-range low results | ycaniu |
| Autocalibration or autocalibration alert | no |
| Calibrants stored onboard/Multipoint calibration supported | no/yes |
| i ypical callb. Trequency for ISE/Metabolites/Ther. drugs/Drugs of abuse Automatic shutdown/Startup programmable | -/-/-/ no/no |
| | |
| Stat time to completion of all analytes, throughput per hr. for: | |
| Sodium, potassium, chloride, TCO₂ Sodium, potassium, chloride, TCO₃, glucose. urea. creatinine | _ |
| Album., direct & total bili., AST, ALT, ALP | - |
| Typical time delay from ordering stat test to aspir. of sample | less than 60 sec |
| now orien do required/onboard Sw capability to review QC Onboard real-time OC/Support multiple OC lot Nos, per analyte | uany/yes ves/ves |
| QC results transferred automatically to LIS | yes |
| Data mont, canability//petrument vender cumplice LIS interface | onboard/no |
| Interfaces up and running in active user sites with | |
| Bidirectional interface capabilities | yes (host query) |
| LIS interface operates simultaneously with running accourt | |
| Uses LOINC to transmit orders & results | |
| How labs get LOINC codes for reagent kits | - |
| Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system | no no |
| Modem servicing available/Cap diagnose own malfunctions/ | no/ves/ves |
| Determine malfunctioning component | |
| On-site time of svc. engineer/Onboard error codes for troubleshooting | —/yes |
| Mean time between failures/To repair failures | -/ daily: 5 min: weekly: 15 min: monthly: 20 min |
| Onboard maintenance records/Maint. training demo module | yes/no |
| Training provided with purchase/Advanced oper. training avail. | 3 days on site, 5 days at vendor offices/no |
| Annual service contract cost (24 h/7 d) | _ |
| Distinguishing features | open system; compact benchtop; user friendly Windows software |
| | |
| | |
| | |



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Versatile bins and shelves maximize limited lab storage.

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