

Chemistry analyzers (for low-volume laboratories)

Don't leave patient safety to the roll of the dice

Raymond D. Aller, MD

Yesterday, I was consulting with my father's cardiologist about his indications for surgery. In reading a previous consultation note, the cardiologist became concerned—and I was worried emergency intervention was needed. Then, she realized she was reading a note that belonged to another patient.

Errors in patient identification don't occur solely in clinical medicine. Every day, thousands of patients in the U.S. are misidentified for a laboratory test. In some cases, a staff person forgets to check a hospital wristband and draws blood on a patient who has just arrived in a room, thinking it is the patient who was in that room until 30 minutes ago. In other settings, blood is drawn and placed unlabeled on a central desk, and confusing labeling instructions are given to a third party. When specimens reach the laboratory, they are over-labeled with an LIS accession number belonging to the wrong patient. When aliquots are made, the aide is distracted and places the wrong patient's serum in the aliquot tube.

Everyone is aware of the fatal consequences of misidentifying a blood bank specimen. Misidentifying a potassium specimen can have equally fatal results.

In this year's survey of chemistry analyzers for low-volume labs, we are delighted to see that the manufacturers are recognizing the importance of positive patient identification. At the moment, the most practical technique for positively identifying a chemistry specimen in a clinical analyzer is to automatically scan a bar-code label on the tube at the time the tube is aspirated. When I was consulted by i-Stat executives in 1997, one of my chief recommendations was that they add the capability to scan bar codes for patient, specimen, and reagent identifiers. They took this recommendation to heart, and the i-Stat 1 has this capability. But the need for positive sample identification on the patient and on all clinical analyzers is not a new idea; we have been writing about this in CAP TODAY since at least 1989.

The instruments in this year's lineup that have the greatest potential to maximize safety with regard to patient identification and the reliable, unambiguous transfer of results to the LIS are the Abbott i-Stat 1, the Alfa Wasserman Ace, and the Alfa Wasserman Nexct. An important capability of seven of the systems in this month's survey is the use of standard (LOINC) codes to transmit results unambiguously to the LIS. Some analyzers in the survey incorporate positive sample identification but lack operational interfaces to commercially installed LISs, so identification and results must be hand-transcribed into the reporting system. A number of vendors need to update their hardware and software to bring them to the minimal acceptable patient safety standard—positive ID of our lab specimens—for the 21st century laboratory.

The range of reagent costs per reportable result, as reported by the vendors in the tables on the following pages, is very wide. Systems with specialized single-use packs, such as the Abaxis Piccolo, Abbott i-Stats, Careside, Hema-gen Analyst, and Ortho Vitros DT60-II, tend to be more costly in reagents but are likely to require less technical expertise. In speaking with users of the lower-cost reagent alternatives, ask about the technical skills needed to operate and maintain the systems and determine if those match the skills of the staff you expect to be running these instruments in your lab.

On pages 60–84, we profile 23 analyzers from 15 vendors. We urge you not only to inquire about the capability to positively identify specimens, but also to speak with users of the systems to determine the instrument's reliability and true-life throughput and the vendor's responsiveness to requests for service and support.

Dr. Aller is based in Vista, Calif., and can be reached at raller@earthlink.net.

Part 1 of 12	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. List price No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd. Operational type/reagent type	Piccolo/1995 \$14,995 500/300 U.S./U.S./U.S. self-contained disc with multitest reag. panel
Sample handling system/model type Dimensions in inches (H x W x D)/instrument footprint	disc loaded directly into instrument/benchtop 9.5 x 6 x 11.5/1 sq ft
Tests available on instrument in U.S.	ALP, ALT, AST, GGT, amylase, albumin, total protein, bilirubin total, BUN, creatinine, calcium, cholesterol, glucose, uric acid, sodium, creatine kinase, potassium, TCO ₂ , chloride
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	none none none magnesium, phosphorus, lipid panel/cholesterol, triglycerides, HDL, LDL
User-defined methods implemented for what analytes	none
Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry 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 Reagent bar-code reading capability Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	photometry/n/a n/a yes/4–12 analytes (chemistries) for 8 diff. chem./elec. profiles; reagent self-contained with each disc no 19 12 0/n/a 4–12/self-contained disc with reagents 4–12 6 mos/6/no yes yes n/a \$1.33/n/a/n/a <15/1/12 reconstitutes onboard no/n/a no/n/a ~100 µL no/no no/n/a none no no/n/a no yes no n/a n/a/yes/yes yes yes/yes yes/no n/a/n/a yes yes/yes self-calibrated onboard/disc n/a/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Album., bili. direct & total, 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	15 min, 4 specimens 15 min, 4 specimens 15 min, 4 specimens (total bilirubin only, no phos.) n/a per disc/yes yes/yes yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/no
Interfaces up and running in active user sites with	n/a
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	no yes yes no
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	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/no/no 24 hr loaner/yes —/— daily: none; weekly: none; monthly: none —/— yes/yes 1 yr warranty, 1 yr \$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 min

Chemistry analyzers (for low-volume laboratories)

Part 2 of 12	Abbott Laboratories Eric Perreault eric.perreault@abbott.com 4A Crosby Dr. Bedford, MA 01730 781-276-6000 www.abbott.com	Abbott Laboratories Eric Perreault eric.perreault@abbott.com 4A Crosby Drive Bedford, MA 01730 781-276-6000 www.abbott.com
See accompanying comments on page 60		
Name of instrument/first year sold in U.S. List price No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd. Operational type/reagent type	i-Stat Portable Clinical Analyzer/1995 \$7,900 12,000/4,000 U.S./U.S./Canada n/a/self-contained single-use cartridges-packages-slides	i-Stat 1/2000 \$9,500 1,500/500 U.S./U.S./Canada —/self-contained single-use cartridges-packages-slides
Sample handling system/model type Dimensions in inches (H x W x D)/instrument footprint	n/a/handheld-portable 8.26 x 2.52 x 2.05/n/a	n/a/handheld 23.48 x 7.68 x 7.24 cm/—
Tests available on instrument in U.S.	sodium, potassium, chloride, ionized calcium, BUN, glucose, creatinine, lactate, Hct, pH, pCO ₂ , pO ₂ , ACT _c , Calculated: Hb, TCO ₂ , HCO ₃ , BE _{ecf} , anion gap, SO ₂	sodium, potassium, chloride, ionized calcium, BUN, glucose, creatinine, lactate, Hct, pH, pCO ₂ , pO ₂ , ACT _c , Calculated: Hb, TCO ₂ , HCO ₃ , BE _{ecf} , anion gap, SO ₂
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	PT ACT _k none none/aPTT, CK-MB, myoglobin, troponin none	PT ACT _k none none/aPTT, CK-MB, myoglobin, troponin none
Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates 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/specimens/tests-assays System is liquid or dry 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 Reagent bar-code reading capability Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	potentiometry/n/a 10 yes/1–7 yes 11 up to 16 n/a/n/a 1 cartridge at a time, each up to 7 tests 14 days at room temp./no no n/a n/a \$3–\$9/n/a/n/a approx. 2 min for any cartridge type depends on component no/n/a no/n/a 40 µL no/no no/n/a none no no/n/a no n/a n/a no no/yes/yes yes yes/yes no/no no/no yes yes/no each test/each test/n/a/n/a to start, insert cartridge/automatically powers down	potentiometry/— 10 yes/up to 16 yes 11 up to 16 n/a/n/a n/a/1 cartridge at a time, each up to 16 tests —/14 days/no no n/a n/a \$3–\$9/—/— 2 min/1/up to 16 — no no 40 µL no/no no/n/a none no no/no yes/patient, operator, identification (2 of 5 interleaved, UPC, Codabar codes 39 & 128) yes yes n/a n/a/yes/yes yes yes/yes no/no no/no yes yes/no each test/each test/—/— yes/yes
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	2 min, n/a 2 min, n/a n/a/n/a n/a 24 hrs, longest interval: each new lot/yes yes/yes yes	2 min, n/a 2 min, n/a n/a, — n/a shortest interval: 24 hrs; longest interval: each new lot/yes yes/yes yes
Data 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	optional add-on (\$23,000 including LIS interface, SW mfr: Abbott/Neon)/yes (addt'l cost) all systems yes (broadcast download & host query) yes yes yes	optional add-on (\$45,000 including LIS interface, SW mfr: Abbott/Neon)/yes all systems yes (broadcast download & host query) yes yes yes
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no n/a	yes n/a
Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of 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 replacement/yes not determined daily: none; weekly: none; monthly: none n/a/n/a yes (depends on need)/yes \$300	yes/yes/yes replacement/yes not determined/24 hrs daily: none; weekly: none; monthly: none n/a/n/a —/yes \$420
Distinguishing features	handheld portable analyzer	handheld portable analyzer

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

Chemistry analyzers (for low-volume laboratories)

Part 3 of 12	ACT Diagnostics LLC Robert Goewert rgoewert@actdiagnostics.com 4100 Avenida De La Plata Oceanside, CA 92056 760-631-8190 www.actdiagnostics.com	Alfa Wassermann Inc. Monty Hatcher info@alfawassermannus.com 4 Henderson Drive West Caldwell, NJ 07006 800-220-4488 alfawassermannus.com
See accompanying comments on page 60		
Name of instrument/first year sold in U.S. List price No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd. Operational type/reagent type Sample handling system/model type Dimensions in inches (H x W x D)/instrument footprint	Pronto Evolution/2001 \$26,000 20/400 Italy/Italy/U.S. random access, discrete, continuous random access/open reagent system ring/benchtop 15 x 24 x 20/3.3 sq ft	Ace Clinical Chemistry System/1993 \$64,900 1,000+/600+ U.S./U.S./U.S. batch, random access, discrete, cont. random access, stat/closed reag. system with open reag. system channels ring with segments (15–30 samples/seg.)/benchtop 15.75 x 27.25 x 22.50 (analyzer only)/8 sq ft (full system)
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes	albumin, alkaline phosphatase, ALT, amylase, AST, bilirubin direct, bilirubin total, calcium, chloride, cholesterol, creatine kinase, creatinine, γ -gt, glucose, LDH, magnesium, phosphorus, protein-total, triglycerides, urea nitrogen, uric acid, HDL cholesterol, LDL cholesterol, drugs of abuse, TDMS, open system none none n/a none/n/a n/a	albumin, bilirubin direct & total, calcium, creatinine, glucose, in. phosphorus, iron, magnesium, total protein, BUN, uric acid, ALP, ALT, amylase, AST, CK, gamma-GT, LDH, cholesterol, HDL chol., LDL chol., triglycerides, sodium, potassium, chloride, CO ₂ , digoxin, T ₄ , T-uptake, HbA1c none none special proteins none/serum proteins acetaminophen, alcohol, cortisol, CRP, CK-MB, folate, fructosamine, lipase, salicylate, transferrin, B ₁₂ , amphetamine, barbiturate, benzodiazepine, THC, cocaine, opiate, PCP
Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set Shortest/median onboard reag. stability/refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry 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 Reagent bar-code reading capability Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	photometry/immunoturbidometric 0 no no 15 30 50/15 15/minimum of 100 n/a/30 days/yes (8°C) yes yes yes \$0.05–0.10/\$2.50/\$2.50 450/50/750 liquid no no 3 μ L no/no no/0.5 40 no yes/no yes (by handheld scanner as tubes are loaded onto instrument, Codabar) no no yes yes/yes/no yes no/no yes/yes yes/no yes yes/yes n/a/daily/daily/daily yes/no	photometry, potentiometry/CEDIA, turbidimetric, homogeneous, EIA 3 no/n/a no 43 200 18/18 40/100–150 tests per bottle 120 hrs/30 days/yes (10–14°C) yes yes yes \$0.16/\$3.50/\$3.50 150/150/450 liquid yes/248 no/n/a 3 μ L yes/no no/n/a — yes/ \leq 50 μ L yes/yes yes, as sample is being aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes no yes yes/yes/no yes no/no yes/yes yes/no yes no/yes 3 hrs/30 days/45 days with 48 hr updates/TBD n/a/n/a
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	6 min, 50 specimens per hr (no Na or K) 6 min, 20 specimens per hr (no Na or K) 6 min, 16 specimens per hr 3–5 min user defined/yes yes/no user defined	3.5 min, 32 specimens <6 min, 25 specimens 9 min, 21 specimens immediate response, as soon as 10 sec daily/yes yes/yes yes
Data mgmt. capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	onboard/no — yes (broadcast download) — yes yes	onboard/no Schuyler House, Antek, LabDaq, others yes (broadcast download) yes yes yes
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	no no
Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/yes/yes <24 hrs/yes 280 days/4 hrs daily: 20 min; weekly: 20 min; monthly: 1 hr no/— 1 day on-site, 2 days at vendor offices/yes ask vendor	no/yes/yes <24 hrs/yes —/<1 hr daily: 3 min; weekly: 30 min; monthly: 30 min yes (includes audit trail of who replaced parts)/no 4 days at vendor offices/yes ask vendor
Distinguishing features	instrument software is extremely user-friendly; offers primary tube sampling and user-defined predilution or automatic sample dilution for repeat tests; system software permits variety of user-defined reports	easy-to-use, multitasking software; closed-tube sampling

Chemistry analyzers (for low-volume laboratories)

Part 4 of 12	Alfa Wassermann Inc. Monty Hatcher info@alfawassermannus.com 4 Henderson Drive West Caldwell, NJ 07006 800-220-4488 alfawassermannus.com	Analox Instrument U.S.A. Inc. Martin Widdowson P.O. Box 208 Lunenburg, MA 01462 978-582-9368 www.analox.com
See accompanying comments on page 60		
Name of instrument/first year sold in U.S. List price No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd. Operational type/reagent type Sample handling system/model type Dimensions in inches (H x W x D)/instrument footprint	Nexct Clinical Chemistry System/1998 \$37,400 200+ /200+ U.S./U.S./U.S. batch, random access, discrete, cont. random access, stat/closed reag. system with open reag. system channels ring with segments (15–30 samples/seg.)/benchtop 15.75 x 27.25 x 22.50 (analyzer only)/4.5 sq ft (full system)	GM7/1985 \$12,900 —/— U.K./U.K./U.K. discrete/open reagent system —/handheld 12 x 12 x 12/1 sq ft
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes	albumin, bilirubin direct & total, calcium, creatinine, glucose, in. phosphorus, iron, magnesium, total protein, BUN, uric acid, ALP, ALT, amylase, AST, CK, gamma-GT, LDH, cholesterol, HDL chol., LDL chol., triglycerides, CO ₂ , HbA1c none none none none/none acetaminophen, alcohol, CRP, CK-MB, folate, fructosamine, lipase, salicylate, transferrin, B ₁₂	glucose, lactate, ethanol, methanol, uric acid, cholesterol, urea creatinine, acetoacetate, β-hydroxybutyrate, lactose, sucrose, ammonia, glutamine, glycerol, triglyceride, pyruvate — — — ethanol, methanol, uric acid, cholesterol, creatinine, acetoacetate, β-hydroxybutyrate, lactose, sucrose, ammonia, glutamine, glycerol, triglyceride, pyruvate/none —
Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set Shortest/median onboard reag. stability/refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry 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 Reagent bar-code reading capability Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	photometry/CEDIA, turbidimetric, homogeneous, EIA 0 (optional ISE interface) no/n/a no 20 200 9/9 20/40–60 tests per bottle 120 hrs/30 days/no yes yes yes \$0.23/TBD/TBD 30/150/58 liquid yes/58 no/n/a 3 μL yes/no no/n/a — yes/≤50 μL yes/yes yes, as sample is being aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes no yes yes/yes/no yes no/no yes/yes yes/no yes no/yes n/a/30 days/TBD/TBD no/no	oxygen electrode/— — no yes 1 1 2/1 1/100–300 24 hrs/1 day/no no requires operator prehandling, preparation yes \$0.1–\$1/—/— n/a/—/— liquid no/— no/— 2.5 μL no/— no — no no/no no — — no no/yes/— yes not required/not required not required/no —/— yes no/not required —/1 hr/—/— no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	3.5 min (with offline ISE), 55 specimens (with offline ISE) <6 min (with offline ISE), 40 specimens (with offline ISE) 9 min, 21 specimens immediate response, as soon as 10 sec daily/yes yes/yes yes	—, — 20 sec, — —, — 1 min shortest interval: 4 hrs; longest: daily/yes yes/no yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/no	onboard/no
Interfaces up and running in active user sites with	LabDaq, Schuyler House, Antek, others	—
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes (broadcast download) yes yes yes	no yes no no
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	no no
Modem servicing available/can diagnose own malfunctions/ determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/yes/yes <24 hrs/yes —/<1 hr daily: 2 min; weekly: 1 min; monthly: 30 min yes (includes audit trail of who replaced parts)/no 4 days at vendor offices/yes ask vendor	no/—/— n/a/— —/— daily: 1 min; weekly: 1 min; monthly: 10 min no/— 1 day on-site/no \$500
Distinguishing features	easy-to-use, multitasking software; closed-tube sampling	large test menu; small sample size; cost per test; 20 sec analysis time

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Chemistry analyzers (for low-volume laboratories)

Part 5 of 12	Awareness Technology Inc. C. Schneider info@awaretech.com P.O. Box 1679 Palm City, FL 34991 772-283-6540 www.awaretech.com	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com
See accompanying comments on page 60		
Name of instrument/first year sold in U.S. List price No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd. Operational type/reagent type Sample handling system/model type Dimensions in inches (H x W x D)/instrument footprint	ChemWell/1999 \$25,000 2/190 U.S./U.S./open system batch, random access/open reagent system rack/benchtop 16 x 34 x 20/—	Synchron CX4 Pro/2001 \$162,400 —/— U.S./U.S./U.S. & Ireland continuous random access/open reagent system sectors, centrifugable/floor-standing 69 x 27 x 30/5.6 sq ft
Tests available on instrument in U.S.	unlimited, open system; Pointe Scientific reagents have been FDA cleared and given CLIA moderate complexity and include: ALT, albumin, amylase, AST, bilirubin direct & total, calcium, cholesterol enzymatic, CK, CK-MB, creatinine, GGT, glucose (hexokinase), glucose (oxidase), iron/TIBC, lactate dehydrogenase, LDL cholesterol, magnesium, inorganic phosphorus, total protein, triglyceride, urea (BUN), uric acid; Sigma Diagnostics assays include: albumin (bromcresol green & purple), alkaline phosphatase, ALT, AST, cholesterol, creatinine, GGT, glucose, total protein, triglycerides, BUN, uric acid	alb, ALP, ALT, amylase, AST, BUN, calc., CO ₂ , chloride, cholest., CK-MB, creatinine, dir. bilirubin, GGT, glucose, HDLD, iron/TIBC, lipase, LD, LDLD, magnesium, phosphorus, potassium, sodium, total protein, total bilirubin, triglyceride, triglyceride glycerol blanked, urea, uric acid; esoteric chemistries: ammonia, cholinesterase, hemoglobin A1c, lactate, micro-albumin, prealbumin, salicylate; drugs of abuse testing; therapeutic drug monitoring; proteins: anti-streptolysin O, IgA, IgM, IgG, rheumatoid factor, transferrin; thyroids: thyroxine, T-up
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes	none none unlimited, open system any colorimetric (340–700 nm), open system/n/a all colorimetric end points and kinetic assays; open systems	none none none none/none UIBC
Methods supported/immunoassay methods	photometry/EIA-microplate format	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay
No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set Shortest/median onboard reag. stability/refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry 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	n/a no no up to 27 unlimited unlimited/up to 27 27/assay dependent n/a/n/a/no yes reagent dependent yes assay dependent not limited/96/not limited liquid chemistry system yes/96 yes/weekly 2 µL no/no no/<1 L per hr 60 no no/no yes/by handheld scanner as tubes are loaded onto instrument	0 no no 24 50 96/24 24/2,400–9,600 (100–900 tests per container) 168 hr/30 days/yes (2–8°C) yes yes yes assay dependent 400/63/1,512 liquid no/n/a yes/permanent–2-yr warranty (80 stored on instrument) 3 µL yes/no yes/7 L per hr 70 yes/40 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	no no yes yes/yes/no yes no/no yes/yes yes/no yes yes/yes n/a/user defined/user defined/user defined yes/yes	yes yes yes yes/yes/yes yes yes/yes yes/no yes/no yes no/yes n/a/up to 90 days/60 days/14 days none required
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	sodium and potassium not available sodium and potassium not available 5.5 min/28 15 sec. user defined/yes yes/yes yes, if LIS is enabled	n/a, n/a n/a, n/a 10 min, 32 specimens 45 sec 24 hr/yes yes/yes yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard (Awareness Technology Inc.)/no	onboard & optional add-on (SW mfr: Beckman Coulter DataLink/yes (addt'l cost)
Interfaces up and running in active user sites with	n/a	Cerner, Sunquest, Meditech, Citation, MedLab, CHC, SMS, HBOC, Labquest, CCA, VA-Mumps, others
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes yes yes yes	yes (broadcast download & host query) yes yes no
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	no yes
Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes 48 hrs in U.S./— not specified/— daily: <10 min; weekly: <30 min; monthly: <1 hr no/— 2 days on-site, 3 d at vendor offices/yes \$4,000/yr	yes/yes/no metro: same day; rural: same or next day/yes —/— daily: 5 min; weekly: 15 min; monthly: 20 min no/no 1 day on-site, 5 days at vendor offices/no —
Distinguishing features	ChemWell can also be programmed to perform ELISA assays in the microwell format; optional reagent refrigeration unit is available	serum indices; centrifugable sectors; clot detection; bar-coded calibrators & controls; host query; reagent load while running; ready-to-use liquid reagents; Peltier thermal ring; pulsed xenon light source; polychromatic correction; semipermanent glass cuvettes; DataLink Sample Manager

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

Chemistry analyzers (for low-volume laboratories)

Part 6 of 12	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000 Brea, CA 92822-8000 800-526-3821 www.beckmancoulter.com	Careside Inc. 6100 Bristol Parkway Culver City, CA 90230 310-338-6767 www.careside.com
See accompanying comments on page 60		
Name of instrument/first year sold in U.S. List price No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd. Operational type/reagent type Sample handling system/model type Dimensions in inches (H x W x D)/instrument footprint	Synchron CX5 Pro/2001 \$193,500 —/— U.S./U.S./U.S. & Ireland continuous random access/open reagent system sectors, centrifugable/floor-standing 69 x 61 x 30/12.7 sq ft	Careside Analyzer/1999 \$18,000 —/— U.S./U.S./U.S. random access, discrete/self-contained single-use cartridges unit-of-use test cartridge/benchtop 16 x 14 x 12/~1 sq ft
Tests available on instrument in U.S.	alb, ALP, ALT, amylase, AST, BUN, calc., CO ₂ , chloride, cholest., CK-MB, creatinine, dir. bilirubin, GGT, glucose, HDLD, iron/TIBC, lipase, LD, LDLD, magnesium, phosphorus, potassium, sodium, total protein, total bilirubin, triglyceride, triglyceride glycerol blanked, urea, uric acid; esoteric chemistries: ammonia, cholinesterase, hemoglobin A1c, lactate, micro-albumin, prealbumin, salicylate; drugs of abuse testing; therapeutic drug monitoring; proteins: anti-streptolysin O, IgA, IgM, IgG, rheumatoid factor, transferrin; thyroids: thyroxine, T-up	electrochemistry: anion gap, chloride, potassium, sodium; chem-istry: A/G ratio, albumin, ALP, ALT, ALT/AST ratio, ammonia, amylase, AST, bilirubin direct & total, bilirubin indirect (calc.), BUN, BUN/creatinine ratio, calcium total, carbon dioxide, HDL chol., LDL chol. (calc.), chol. total, chol./HDL chol. ratio, CK, CK-MB, % CK-MB, creatinine, GGT, globulin (calc.), glucose, LDH, magnesium, osmolal-ity (calc.), phosphorus, total protein, triglycerides, uric acid, cholinesterase; hematology: hemoglobin, hematocrit (calc.); coagulation: prothrombin time
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes	none none none none/none UIBC	aPTT none none none/ionized calcium none
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/bidentate turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay	potentiometry, optical transmission, reflectance/n/a
No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set Shortest/median onboard reag. stability/refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry 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	5 (indirect) no no 29 50 100/29 29/2,900–69,600 (100–2,400 tests per container)	3 no/n/a 1 pack for 3 tests (Na, K, Cl) n/a total menu 0/n/a n/a/n/a
168 hr/30 days/yes (2–8°C) yes yes yes assay dependent		n/a/n/a/no yes yes no varies/n/a/n/a
400/63/1,827 liquid no/n/a yes/permanent–2-yr warranty (80 stored on instrument) 3 µL yes/no yes/7 L per hr 70 yes/40 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination		12/1/8 dry no/n/a no/n/a n/a no/no no/none <60 no no/n/a no
yes yes yes yes/yes/yes yes yes/yes yes/no yes/no		yes n/a n/a n/a/yes/no n/a no/no no/no no/no
yes yes yes yes/yes/yes yes yes/yes yes/no yes/no		yes n/a n/a n/a/yes/no n/a no/no no/no no/no
yes no/yes 24 hr/up to 90 days/60 days/14 days none required		yes no/yes calibration verification every 6 mos/6 mos/n/a/n/a no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	52 sec, 75 specimens 8 min, 75 specimens 10 min, 32 specimens 45 sec 24 hr/yes yes/yes yes	~10 min, 1 specimen (Na, K, Cl: 6 min) ~12 min, 1 specimen ~12 min, 1 specimen immediate daily for electronic QC/yes yes/yes yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard & optional add-on (SW mfr: Beckman Coulter DataLink)/yes (addt'l cost)	onboard/yes Careside Connect DMS (addt'l cost)
Interfaces up and running in active user sites with	Cerner, Sunquest, Meditech, Citation, MedLab, CHC, SMS, HBOC, Labquest, CCA, VA-Mumps, others	—
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes (broadcast download & host query) yes yes no	yes yes yes yes
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no yes	yes no
Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/no metro: same day; rural: same or next day/yes —/— daily: 5 min; weekly: 15 min; monthly: 20 min no/no 1 day on-site, 5 days at vendor offices/no —	no/yes/yes replacement/yes TBD/TBD daily: none; weekly: none; monthly: 5 min n/a/n/a yes/yes TBD
Distinguishing features	serum indices; centrifugable sectors; clot detection; bar-coded calibrators & 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; DataLink Sample Manager	POC test device with easy-to-use user interface and a comprehensive test menu

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Chemistry analyzers (for low-volume laboratories)

Part 7 of 12	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101 800-242-3233 www.dadebehring.com	Elan Diagnostics 2 Thurber Blvd. Smithfield, RI 02917 401-233-3526 elandiagnostics.com
See accompanying comments on page 60		
Name of instrument/first year sold in U.S. List price No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd. Operational type/reagent type Sample handling system/model type Dimensions in inches (H x W x D)/instrument footprint	Dimension Xpand Integrated Chemistry System/2001 \$165,000 —/— U.S./U.S./U.S. continuous random access/self-contained multi-use cartridges-pakages-slides & open reagent system sample segments/floor-standing 45 x 31 x 51/—	Atac 6000 Chemistry System/1990 — —/— —/—/— discrete/open reagent system sample wheel/benchtop 21 x 23 x 18.5/~3 sq ft
Tests available on instrument in U.S.	album., calcium, cholest., creatinine, dir. & total bili., glucose, HDLC, auto. HDL, iron, magnes., phosphorus, total iron-binding capacity (& no pretreat), total protein, triglyc., urea nitrogen, uric acid, carbon dioxide, chloride, potassium, sodium	albumin, ALP, Apo A, Apo B, amylase, bilirubin direct & total, BUN, CO ₂ , calcium, cholesterol, CPK, creatinine, fructosamine, GGT, glucose, AST, ALT, HDL, iron-total, phos., LDH, magnesium, total protein, triglycerides, uric acid, sodium, potassium, chloride-ISE
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes	n/a CSA CSA none/fPSA, tPSA n/a	none none none none/none none
Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set Shortest/median onboard 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/specimens/tests-assays System is liquid or dry 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 Reagent bar-code reading capability Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calibration frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	photometry, potentiometry, turbidimetric assays/Petinia, Emit, Acmia, mag. part. sep. 3 no no 47 75+ 10/10 47/480 24 hrs/5 days/yes (2–8°C) no yes yes n/a 420/60/1,800 liquid & reconstitutes onboard yes/12,000 —/— 2 µL yes/no yes/2 L per hr <70 no/30 µL with standard cup yes/no yes/on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/autodiscrimination yes yes yes yes/yes/no no no/no yes/yes yes/no yes no/yes 2 hrs (auto)/90 days/60 days/60 days —/—	photometry, potentiometry/n/a 3 no/n/a no 16 16 48/16 16/30 6 hrs/2 days/no no no, requires operator prehandling/prep. no —/—/— —/—/96 liquid yes/96 no/n/a 2 µL no/no no/yes — no no/no no no/no no/no no/no no no/no 4 hrs/daily/n/a/n/a no/—
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Albumin, bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	2 min, 62 4 min, 62 8 min, 42 60 sec steady state, 2 min from standby daily/yes yes/— yes	—, — —, — —, — — 2 levels daily/yes yes/yes yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/no	onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	interfaces available for all major LIS vendors	Fletcher-Flora
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes (broadcast download & host query) yes yes no	yes (host query) yes yes no
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	no no
Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes situation dependent/yes n/a/n/a daily: 5 min; weekly: n/a; monthly: 20 min no/no 4 days at vendor offices/yes n/a	no/no/no within 24 hrs/yes —/— daily: 5 min; weekly: 15 min; monthly: 15 min no/— 5 days on-site/no —
Distinguishing features	specifically designed for low-volume testing laboratories; the analyzer performs the most requested chemistry and heterogeneous immunoassay tests on a single, easy-to-use instrument	batch mode with broad test menu; high level of flexibility & performance; includes LIS

Chemistry analyzers (for low-volume laboratories)

Part 8 of 12	Elan Diagnostics 2 Thurber Blvd. Smithfield, RI 02917 401-233-3526 elandiagnostics.com	Hemagen Diagnostics Inc. sales@hemagen.com 9033 Red Branch Rd. Columbia, MD 21045 800-436-2436 www.hemagen.com
See accompanying comments on page 60		
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	Atac 8000 Random Access Chemistry System/1995 — —/— —/—/— continuous random access/open reagent system sample wheel/benchtop 19.5 x 39 x 20.5/5.5 sq ft	Analyst Benchtop Chemistry System/1986 \$5,500–\$9,900 —/— France-U.S./U.S./U.S. batch/self-contained single-use cartridges-packages-slides, rotors —/benchtop 8.5 x 25 x 13/2.25 sq ft
Tests available on instrument in U.S. Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes	albumin, ALP, amylase, Apo A1, Apo B, bilirubin direct & total, BUN, calcium, cholesterol, CPK, CK-MB, creatinine, fructosamine, glycohemoglobin, GGT, glucose, AST, ALT, direct HDL, direct LDL, total iron, TIBC, LDH, magnesium, microalbumin, phosphorus, total protein, triglycerides, uric acid [CO ₂ , chloride, potassium, sodium—ISE] none none none none/none none	ALP, GGT, GPT, Got, BUN, glucose, calcium, cholesterol, triglycerides, amylase, uric acid, total bilirubin, total protein, HDL-chol., albumin, direct bilirubin, CO ₂ , phosphorus none none none none/— none
Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set Shortest/median onboard reag. stability/refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry 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 Reagent bar-code reading capability Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reag. for aspir. & analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	photometry, potentiometry/n/a 4 no/n/a no 40 40 320/40 40/150 5 days/12 days/yes yes yes yes —/—/— 240+/50/1,200 liquid no/n/a yes/5 yrs 2 µL yes/no no/yes — no yes/no no no — yes yes/yes/no yes —/— yes/yes yes/yes yes no/yes 4 hrs/14 days/n/a/n/a yes/yes	photometry/n/a n/a yes/14 per rotor per patient no — 14 —/— 14/14 —/—/no — yes no —/—/— 10/1/14 dry no (uses rotors) no/n/a 10 µL & 80 µL no/no no/n/a — no no/no no yes — no no/no/no no no/no no/no no/no no no/— n/a/60 days/n/a/n/a no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	60 sec, 60 specimens 6 min, 45 specimens 7 min, 36 patients with specified panel 20 sec 2 levels daily/yes yes/yes yes	—, — 10 min, 6 specimens (glu, urea, crea) 10 min, 6 specimens — —/— no/no —
Data mgmt. capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	onboard/yes (add'l cost) Fletcher-Flora yes (broadcast download & host query) yes yes no	—/yes (included in price) in development — — — —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	— —
Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/yes/yes within 24 hrs/yes —/— daily: none; weekly: 15 min; monthly: 30 min yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices, 5 days on-site/yes —	no/yes/yes most troubleshooting via phone/yes 14–16 mos/— daily: 2 min; weekly: 15 min; monthly: 30 min no/— 1 day on-site/yes \$650
Distinguishing features	475 tests/hr of general chemistry & ISE; reusable glass cuvettes, ensuring low reag. cost; onboard refrigeration; includes LIS	uses only 90 µL of sample & requires <60 sec of prep work; minimal maintenance required; offered with sodium, potassium, and chloride ISE units

Chemistry analyzers (for low-volume laboratories)

Part 9 of 12	Landmark Scientific Inc. Valerie Brady vbrady@landmarkscientific.com 101-B Creek Ridge Rd. Greensboro, NC 27406 336-373-0274 www.landmarkscientific.com	Nova Biomedical Corp. Nova Sales Department 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 info@novabiomedical.com
See accompanying comments on page 60		
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	AGII Chemistry System (w/ISE)/1998 \$31,527 39/225 U.S./U.K./U.S. batch, random access/open reagent system wheel/benchtop 24 x 24 x 14/4 sq ft	Stat Profile M/1998 \$55,750 —/— U.S./U.S./U.S. random access/self-contained multiuse packages stat sampling directly from sample container/benchtop 20.5 x 19.2 x 20.7/2.75 sq ft
Tests available on instrument in U.S.	albumin, alk. phos., ALT, AST, amylase, total/direct bilirubin, BUN, calcium, cholesterol, creatinine, CO ₂ , CK/CPK, CRP, GGTP, HDL cholesterol, total iron, LDH, LDL direct, magnesium, phosphorus, total protein, triglycerides, uric acid; w/ISE: sodium, potassium, chloride	sodium, potassium, chloride, glucose, BUN, ionized magnesium, ionized calcium, lactate, Hct, hemoglobin, pH, pCO ₂ , pO ₂ , SO ₂ %
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes	n/a n/a open system n/a/thyroid (T ₃ , T ₄ , T-uptake, TSH), auto HDL n/a	none none none none/none none
Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set Shortest/median onboard 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/specimens/tests-assays System is liquid or dry 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 Reagent bar-code reading capability Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear- range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	photometry/n/a none no yes 16 16 unlimited/16 16/average 600–1,000 per kit 2 hrs/7days/no yes requires operator prehandling, preparation yes \$0.02 to \$0.52/n/a/— 10 min/38/38 either liquid or powder no yes/after 10 uses 2 µL yes/no no/0.25 L per hr ~35 no no/no no no no no no/no/no no no/no no/no no/no no/no no no/no ISE separate unit/n/a/n/a/n/a no/no	potentiometry, optical, reflectance/n/a 12 no/n/a no 14 14 0/n/a 14/(@ 14,700 tests/mo): 6,300 tests 21 days/21 days/no n/a yes n/a standard chemistries: @35 sam/d: \$0.40 (14-test panel); bundled instr., reagent, maint. cost: \$1.39 (14-test panel) n/a n/a no/n/a n/a 150 µL no/no no/n/a minimal n/a yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interl., UPC, Codabar, codes 39 & 128)/autodiscrimination alternate method n/a yes yes/yes/yes yes no/no no/no no/no yes yes/n/a 2 hrs/2 hrs/n/a/n/a n/a/n/a
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	30 sec, 180 13 min, 50 15 min, 35 <30 sec shortest interval: each rotor; longest: 1 8-hr shift/yes n/a/yes yes	75 sec, 35 specimens 75 sec, 35 specimens n/a 9 sec CLIA minimum/yes no/yes yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/no (additional)	onboard & optional add-on (\$9,225; SW mfr.: Nova)/no
Interfaces up and running in active user sites with	LabDaq, LabPak	most LIS vendors including Cerner, Sunquest, HBO, Soft, others
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes yes yes —	yes yes no no
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no 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)	no/no/no 24–48 hrs/no once every 27 months/2 hrs daily: 5 min; weekly: 5 min; monthly: 30 min no/no 3 days at vendor offices/yes Cap service agreement—no service fee if not needed, no more than \$4,200 per year with reagent agreement	yes/yes/yes <8 business hrs/yes —/— daily: <2 min; weekly: <5 min; monthly: <5 min no/no 3 days on-site/yes call for pricing
Distinguishing features	cost per test; Cap service agreement, long-term mean time between failures; reusable rotors; user friendly; true Windows-based software; software very flexible; onboard QC; load and analyze at the same time; economical; small footprint; open system	combines up to 14 onboard critical care tests; only combined blood gas analyzer with BUN & iMg

Chemistry analyzers (for low-volume laboratories)

Part 10 of 12	Nova Biomedical Corp. Nova Sales Department 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 info@novabiomedical.com	Nova Biomedical Corp. Nova Sales Department 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 info@novabiomedical.com
See accompanying comments on page 60		
Name of instrument/first year sold in U.S. List price No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd. Operational type/reagent type Sample handling system/model type	Stat Profile M7/1999 \$55,750 —/— U.S./U.S./U.S. random access/self-contained multiuse packages stat sampling directly from sample container/benchtop	Nova 16/1995 \$22,500–\$25,500 —/— U.S./U.S./U.S. batch, random access/self-contained multiuse packages 40-position tray, stat sampling directly from sample container/benchtop 20.5 x 19.2 x 20.7/2.75 sq ft
Dimensions in inches (H x W x D)/instrument footprint	20.5 x 19.2 x 20.7/2.75 sq ft	20.5 x 19.2 x 20.7/2.75 sq ft
Tests available on instrument in U.S.	sodium, potassium, chloride, glucose, BUN, creatinine, ionized calcium, lactate, Hct, hemoglobin, pH, pCO ₂ , pO ₂ , SO ₂ %	sodium, potassium, chloride, total CO ₂ , glucose, BUN, creatinine, Hct
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes	none none none none/none none	none none none none/none none
Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry 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 Reagent bar-code reading capability Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reagent for aspirate & analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calibration frequency for ISE/metabolites/therapeutic drugs/drugs of abuse Automatic shutdown/startup programmable	potentiometry, optical, reflectance/n/a 12 no/n/a no 14 14 0/n/a 14/(@14,700 tests/mo): 6,300 tests 21 days/21 days/no n/a no, requires operator prehandling/prep. (remove clip from sealed bag & mix) n/a standard chemistries: @35 sam/d: \$0.40 (14-test panel); bundled instr.; reagent, maintenance cost: \$1.39 (14-test panel) n/a n/a no/n/a n/a 150 µL no/no no/n/a minimal n/a yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interl., UPC, Codabar, codes 39 & 128)/autodiscrimination alternate method n/a yes yes/yes/yes yes no/no no/no no/no yes yes/n/a 2 hrs/2 hrs/n/a/n/a n/a/n/a	potentiometry/n/a 8 no/n/a no 8 8 0/n/a 8/(@ 8,000 tests/mo): 2,700 tests 21 days/21 days/no n/a no, requires prehandling (remove clip from sealed bag & mix) n/a standard chemistries: @25 sam/d: \$0.40 (8-test panel); bundled instr., reagent, maintenance cost per result: \$0.92 (8-test panel) 60 per tray/40 per tray/280 per tray n/a no/n/a n/a/n/a 385 µL no/no no/n/a minimal n/a yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interl., UPC, Codabar, codes 39 & 128)/autodiscrimination alternate method n/a yes no/yes/yes yes no/no yes/yes no/no yes yes/n/a 2 hrs/2 hrs/n/a/n/a n/a/n/a
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Albumin, bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspirate of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	75 sec, 35 specimens 75 sec, 35 specimens n/a/n/a 9 sec CLIA minimum/yes no/yes yes	90 sec, 39 specimens 90 sec, 39 specimens n/a 9 sec CLIA minimum/yes no/yes yes
Data management capability/instrument vendor supplies LIS interface	onboard & optional add-on (\$9,225, SW mfr.: Nova)/no	onboard & optional add-on (\$9,225, SW mfr.: Nova)/no
Interfaces up and running in active user sites with	most LIS vendors including Cerner, Sunquest, HBO, Soft, others	most LIS vendors including Cerner, Sunquest, HBO, Soft, others
Bidirectional interface capability Test results transmitted to LIS as soon as chemistry time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes yes no no	yes yes no no
Lab can control analyzer remotely Interface available (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 service engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maintenance training demo module Training provided with purchase/advanced operator training available Annual service contract cost (24 h/7 d)	yes/yes/yes <8 business hrs/yes —/— daily: <2 min; weekly: <5 min; monthly: <5 min no/no 3 days on-site/yes call for pricing	no/yes/yes <8 business hrs/yes —/— daily: <2 min; weekly: <5 min; monthly: <5 min no/no 2 days on-site/yes call for pricing
Distinguishing features	first & only analyzer to offer Chem 7 & blood gases; can interface with Sysmex Kx 4500 hematology analyzer through Nova data manager	the only whole blood analyzer for creatinine & TCO ₂ available; can analyze whole blood, serum, plasma, urine, CSF, & dialysate

Chemistry analyzers (for low-volume laboratories)

Part 12 of 12	Roche Diagnostics Corp. 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.us.labsystems.roche.com	Roche Diagnostics Corp. 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.us.labsystems.roche.com
See accompanying comments on page 60		
Name of instrument/first year sold in U.S. List price No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd. Operational type/reagent type Sample handling system/model type Dimensions in inches (H x W x D)/instrument footprint	Roche Hitachi 912/1997 \$159,000 >1,100 Japan-U.S./Japan-U.S./U.S.-Germany continuous random access/open reagent system disk/floor-standing 46 x 40 x 30/8.3 sq ft	Cobas Mira Plus CC/1992 \$50,000 2,500/12,500 Switzerland/Switzerland/Germany-U.S. random access/open reagent system rack/benchtop 26 x 29 x 23/4.63 sq ft
Tests available on instrument in U.S.	alb., ALP, ALT, ammonia, amy. total & panc., AST, bili. total & direct, BUN, Ca, cholest., cholinest., CK, CK-MB, CO ₂ , crea., 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, soluble transferrin receptor	ACP, alb., alk. phos., ALT, amy., amm., Apo A1 & B, AST, bili. direct & total, BUN, Ca., chol., CK, CO ₂ , crea., alcohol, iron TIBC, GGT, HDL direct, HDL, glu., LDH, LDL direct, Mg, phosphorus, TP, triglycerides, UA, fruct., HbA1c, amph., barb., benz., THC, coca., methad., methaq., opia., PCP, propoxy., dig., acetamin., salic, Na, K, Cl by ISE
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	none none kappa/lambda light chains, %CDT, α -1-glycoprotein, Apo A1, Apo B, α -1-microgl., cyclos., lipoprotein A	none none none
Research-use-only assays/tests in development User-defined methods implemented for what analytes	none/homocysteine none	none/information to be released at test launch none
Methods supported/immunoassay methods	photometry, potentiometry/turbidimetric, latex particle enhanced, CEDIA	photometry, potentiometry/n/a
No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set Shortest/median onboard reag. stability/refrigerated onboard Multiple reag. configurations supported Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry 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	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 μ L no/yes yes/30 L \leq 65 yes/— yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination yes yes yes yes/yes/no (not necessary due to sampling method) yes yes/yes yes/yes yes/yes yes yes/yes 24 hrs/lot change (every 6 mos)/3–5 days/56 days yes/—	max. 30 104 + profiles & ratios 104 + profiles & ratios/max. 30 max. 30/40–50 6–8 hrs/30 days/yes (10–14° below ambient) yes yes, but requires some operator prehandling/prep. no —/—/— max. 120 min/90/depends on test vol. liquid yes/— no/n/a 1 μ L no/no no/4 L daily \leq 62 no yes/no yes, as soon as tubes loaded & start key activated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination no — no no/yes/no yes no/no yes/yes yes/yes yes yes/yes every hr/30–60 days/—/n/a no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO ₂ • Sodium, potassium, chloride, TCO ₂ , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	3.5 min, 180 specimens 5.5 min, 90 specimens 10.5 min, 60 specimens 30 sec 24 hrs/yes yes/yes yes	4 min, 15 specimens 7 min, 9 specimens 7.5 min, 8 specimens none 8 hrs, longest interval: daily/yes yes/no yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/yes (add'l cost)	onboard & optional add-on (\$5,000, SW mfr: Antek, Fletcher Flora)/no
Interfaces up and running in active user sites with	all major LIS vendors	—
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes (host query) yes yes no	yes yes yes —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no yes (CLAS)	yes (limited) no
Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/yes/yes —/yes —/— daily: —; weekly: —; monthly: — yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes —	no/—/— 24 hrs/yes 4 mos/2 hrs daily: 10 min; weekly: 10 min; monthly: 5 min no/no 4 days at vendor offices/no approx. \$9,000
Distinguishing features	sophisticated software with easy stat function provides instant stat selection; Roche Hitachi open system dependability and throughput	level detection of the sample & reag.; user friendliness of entire system