# 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, Hemagen 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.

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 <sub>2</sub> , 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/cholestero 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 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	photometry/n/a n/a yes/4–12 analytes (chemistries) for 8 diff. chem elec. profiles; reag. self-contained with each dir 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
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	no/n/a ~100 µL no/no no/n/a none no no no n/a n/a/yes/yes yes yes yes/yes yes/yes yes/no n/a/n/a
<ul> <li>Stat time to completion of all analytes, throughput per hr. for:</li> <li>Sodium, potassium, chloride, TCO2</li> <li>Sodium, potassium, chloride, TCO2, glucose, urea, creatinine</li> <li>Album., bili. direct &amp; total, AST, ALT, ALP</li> <li>Typical time delay from ordering stat test to aspir. of sample</li> <li>How often QC required/onboard SW capability to review QC</li> <li>Onboard real-time QC/support multiple QC lot nos. per analyte</li> <li>QC results transferred automatically to LIS</li> </ul>	15 min, 4 specimens 15 min, 4 specimens 15 min, 4 specimens (total bilirubin only, no pho 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 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	n/a 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 o whole blood, serum, or plasma provides turn-

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Part 2 of 12	Abbott Laboratories Eric Perreault eric.perreault@abbott.com 4A Crosby Dr. Bedford, MA 01730	Abbott Laboratories Eric Perreault eric.perreault@abbott.com 4A Crosby Drive Bedford, MA 01730
See accompanying comments on page 60	781-276-6000 www.abbott.com	781-276-6000 www.abbott.com
Name of instrument/first year sold in U.S.	i-Stat Portable Clinical Analyzer/1995	i-Stat 1/2000
List price	\$7,900	\$9,500
No. units in clinical use in U.S./outside U.S.	12,000/4,000	1,500/500
Country where designed/manufactured/where reagents mftd.	U.S./U.S./Canada	U.S./U.S./Canada
Operational type/reagent type	n/a/self-contained single-use cartridges-packages-slides	—/self-contained single-use cartridges-packages-slides
Sample handling system/model type	n/a/handheld-portable	n/a/handheld
Dimensions in inches (H x W x D)/instrument footprint Tests available on instrument in U.S.	8.26 x 2.52 x 2.05/n/a sodium, potassium, chloride, ionized calcium, BUN, glucose,	23.48 x 7.68 x 7.24 cm/— sodium, potassium, chloride, ionized calcium, BUN, glucose,
	creatinine, lactate, Hct, pH, $pCO_2$ , $pO_2$ , $ACT_c$ , Calculated: Hb, $TCO_2$ , HCO <sub>3</sub> , BEecf, anion gap, SO <sub>2</sub>	creatinine, lactate, Hct, pH, pCO <sub>2</sub> , pO <sub>2</sub> , ACT <sub>c</sub> , Calculated: Hb, TCO <sub>2</sub> , HCO <sub>3</sub> , BEecf, anion gap, SO <sub>2</sub>
Tests cleared but not clinically released	PT	РТ
Tests not available in U.S. but submitted for 510(k) clearance	ACT <sub>k</sub>	ACT <sub>k</sub>
Tests not available in U.S. but available in other countries	none none/aDTT_CK_MP_myoglabin_transmin	none none/aPTT, CK-MB, myoqlobin, troponin
Research-use-only assays/tests in development User-defined methods implemented for what analytes	none/aPTT, CK-MB, myoglobin, troponin none	none
Methods supported/immunoassay methods	potentiometry/n/a	potentiometry/—
No. of direct ion selective electrode channels • must load separate reag, pack for ea. spec./no. diff. assays in pack	10 yes/1–7	10 yes/up to 16
		J-0.4P 10 10
separate reag. pack for each test run	yes	yes
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	11 up to 16	11 up to 16
No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously	up to 16 n/a/n/a	up to 16 n/a/n/a
No. of different analytes for which system accommodates	1 cartridge at a time, each up to 7 tests	n/a/1 cartridge at a time, each up to 16 tests
reag. containers onboard at once/tests per container set		
Shortest/median onboard reag. stability/refrigerated onboard	14 days at room temp./no	—/14 days/no
Multiple reag. configurations supported Reag. container placed directly on system for use	no n/a	no n/a
Instrument has same capabilities when 3rd-party reag. used	n/a	n/a
Reag. only cost per reportable result for standard chemistries/	\$3-\$9/n/a/n/a	\$3-\$9/—/—
therapeutic drugs/special analytes	anneau 2 min far ann a-shidea tar	2 min/1/up to 1/
Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry	approx. 2 min for any cartridge type depends on component	2 min/1/up to 16
Uses disposable cuvettes/max. no. stored	no/n/a	no
Uses washable cuvettes/replacement frequency	no/n/a	no
Minimum sample volume aspirated precisely at one time	40 µL	40 µL
Supplied with UPS (backup power)/requires floor drain	no/no	no/no
Requires dedicated water system/water consumption in L per hour Noise generated in decibels	no/n/a none	no/n/a none
Dedicated pediatric sample cup/dead volume	no	no
Primary tube sampling/pierces caps on primary tubes	no/n/a	no/no
Sample bar-code reading capability	no	yes/patient, operator, identification (2 of 5 interleaved, UPC, Codaba
Reagent bar-code reading capability	n/a	codes 39 & 128) yes
Bar-code placement per NCCLS standard Auto2A	n/a	yes
Onboard test auto inventory (determines volume in container)	no	n/a
Measures no. tests remaining/short sample detection/clot detection	no/yes/yes	n/a/yes/yes
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/turbidity detection-quantitation	yes yes/yes	yes yes/yes
Dilution of patient samples onboard/automatic rerun capability	no/no	no/no
Sample volume can be reduced/increased to rerun out-of-linear-	no/no	no/no
range high/low results		
Autocalibration or autocalibration alert	yes yes (no	yes
Calibrants stored onboard/multipoint calibration supported Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	yes/no each test/each test/n/a/n/a	yes/no each test/each test/—/—
Automatic shutdown/startup programmable	to start, insert cartridge/automatically powers down	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
<ul> <li>Sodium, potassium, chloride, TCO2</li> </ul>	2 min, n/a	2 min, n/a
Sodium, potassium, chloride, TCO2, glucose, urea, creatinine	2 min, n/a	2 min, n/a
Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	n/a/n/a n/a	n/a, — n/a
How often QC required/onboard SW capability to review QC	24 hrs, longest interval: each new lot/yes	shortest interval: 24 hrs; longest interval: each new lot/yes
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	optional add-on (\$23,000 including LIS interface, SW mftr:	optional add-on (\$45,000 including LIS interface, SW mftr:
	Abbott/Neon)/yes (addt'l cost)	Abbott/Neon)/yes
Interfaces up and running in active user sites with	all systems	all systems
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	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/	yes/yes	yes/yes
determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting	replacement/yes	replacement/yes
Mean time between failures/to repair failures	not determined	not determined/24 hrs
	daily: none; weekly: none; monthly: none	daily: none; weekly: none; monthly: none
Average time to complete maintenance by lab personnel	n/a/n/a	n/a/n/a
Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module	voo (dopondo an nood) (voo	—/yes
Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail.	yes (depends on need)/yes \$300	\$420
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)	\$300	\$420
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)		\$420 handheld portable analyzer
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)	\$300	
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)	\$300	
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)	\$300	
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)	\$300	
Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail.	\$300	
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)	\$300 handheld portable analyzer	

## Chemistry analyzers (for low-volume laboratories)

Part 3 of 12 See accompanying comments on page 60	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	www.actdiagnostics.com	
Name of instrument/first year sold in U.S.	Pronto Evolution/2001	Ace Clinical Chemistry System/1993
List price No. units in clinical use in U.S./outside U.S.	\$26,000 20/400	\$64,900 1,000+/600+
Country where designed/manufactured/where reagents mftd.	Italy/Italy/U.S.	U.S./U.S./U.S.
Operational type/reagent type	random access, discrete, continuous random access/open reagent	batch, random access, discrete, cont. random access, stat/closed
Sample handling system/model type	system ring/benchtop	reag. system with open reag. system channels ring with segments (15–30 samples/seg.)/benchtop
Dimensions in inches (H x W x D)/instrument footprint	15 x 24 x 20/3.3 sq ft	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, fructosamin lipase, salicylate, transferrin, B <sub>12</sub> , amphetamine, barbiturate, benzodiazepine, THC, cocaine, opiate, PCP
Methods supported/immunoassay methods	photometry/immunoturbidometric	photometry, potentiometry/CEDIA, turbidimetric, homogeneous, El
No. of direct ion selective electrode channels <ul> <li>must load separate reag. pack for ea. spec./no. diff. assays in pack</li> </ul>	0 no	3 no/n/a
		20
<ul> <li>separate reag. pack for each test run</li> <li>No. of different measured assays onboard simultaneously</li> </ul>	no 15	no 43
No. of different assays programmed, calibrated at once	30	200
No. of user-definable (open) channels/no. active simultaneously	50/15	18/18
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	15/minimum of 100	40/100–150 tests per bottle
Shortest/median onboard reag. stability/refrigerated onboard	n/a/30 days/yes (8°C)	120 hrs/30 days/yes (10–14°C)
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use Instrument has same capabilities when 3rd-party reag. used	yes yes	yes yes
Reag. only cost per reportable result for standard chemistries/	\$0.05-0.10/\$2.50/\$2.50	\$0.16/\$3.50/\$3.50
therapeutic drugs/special analytes Nalkaway capacity in minutes/specimens/tests-assays	450/50/750	150/150/450
System is liquid or dry	liquid	liquid
Jses disposable cuvettes/max. no. stored	no	yes/248
Jses washable cuvettes/replacement frequency Ainimum sample volume aspirated precisely at one time	no 3 μL	no/n/a 3 μL
Supplied with UPS (backup power)/requires floor drain	no/no	yes/no
Requires dedicated water system/water consumption in L per hour	no/0.5	no/n/a
Noise generated in decibels Dedicated pediatric sample cup/dead volume	40 no	 γes/≤50 μL
Primary tube sampling/pierces caps on primary tubes	yes/no	yes/yes
Sample bar-code reading capability	yes (by handheld scanner as tubes are loaded onto instrument,	yes, as sample is being aspirated (2 of 5 interl., Codabar, codes 39 128)/autodiscrimination
Reagent bar-code reading capability	Codabar) no	yes
Bar-code placement per NCCLS standard Auto2A	no	no
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection	yes yes/yes/no	yes yes/yes/no
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-	yes/yes yes/no	yes/yes yes/no
range high/low results	Josho	Jeano
Autocalibration or autocalibration alert	yes	yes na kua
Calibrants stored onboard/multipoint calibration supported Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	yes/yes n/a/daily/daily/	no/yes 3 hrs/30 days/45 days with 48 hr updates/TBD
Automatic shutdown/startup programmable	yes/no	n/a/n/a
Stat time to completion of all analytes, throughput per hr. for:		
<ul> <li>Sodium, potassium, chloride, TCO2</li> <li>Sodium, potassium, chloride, TCO2, glucose, urea, creatinine</li> </ul>	6 min, 50 specimens per hr (no Na or K) 6 min, 20 specimens per hr (no Na or K)	3.5 min, 32 specimens <6 min, 25 specimens
Album., bili. direct & total, AST, ALT, ALP	6 min, 16 specimens per hr	9 min, 25 specimens
Typical time delay from ordering stat test to aspir. of sample	3–5 min	immediate response, as soon as 10 sec
How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte	user defined/yes yes/no	daily/yes yes/yes
2C results transferred automatically to LIS	user defined	yes
ata mgmt. capability/instrument vendor supplies LIS interface	onboard/no	onboard/no
nterfaces up and running in active user sites with	_	Schuyler House, Antek, LabDaq, others
	vas (hvasdasst territes t)	
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete	yes (broadcast download) —	yes (broadcast download) yes
LIS interface operates simultaneously with running assays	yes	yes
Jses LOINC to transmit orders & results	yes	yes
ab can control analyzer remotely nterface avail. (or will be) to automated specimen handling system	no no	no no
Nodem servicing available/can diagnose own malfunctions/	no/yes/yes	no/yes/yes
determine malfunctioning component		
On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures	<24 hrs/yes 280 days/4 hrs	<24 hrs/yes —/<1 hr
Average time to complete maintenance by lab personnel	daily: 20 min; weekly: 20 min; monthly: 1 hr	daily: 3 min; weekly: 30 min; monthly: 30 min
Onboard maintenance records/maint. training demo module	no/—	yes (includes audit trail of who replaced parts)/no
Fraining provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	1 day on-site, 2 days at vendor offices/yes ask vendor	4 days at vendor offices/yes ask vendor
Distinguishing features	instrument software is extremely user-friendly; offers primary tube	easy-to-use, multitasking software; closed-tube sampling
סיסנוווקעוסוווווץ וכמנעוכס	sampling and user-defined predilution or automatic sample dilution for repeat tests; system software permits variety of user-defined reports	כמסירנט-מסק, ווועונונמסגוווע סטונשמוע, טוטסעע-נעשע למוווµוווע

## Chemistry analyzers (for low-volume laboratories)

	Monty Hatcher info@alfawassermannus.com 4 Henderson Drive	Martin Widdowson P.O. Box 208
	West Caldwell, NJ 07006	Lunenburg, MA 01462
ee accompanying comments on page 60	800-220-4488 alfawassermannus.com	978-582-9368 www.analox.com
ame of instrument/first year sold in U.S. st price	Nexct Clinical Chemistry System/1998 \$37,400	GM7/1985 \$12,900
o. units in clinical use in U.S./outside U.S.	200+/200+	_/_
ountry where designed/manufactured/where reagents mftd. perational type/reagent type	U.S./U.S./U.S. batch, random access, discrete, cont. random access, stat/closed	U.K./U.K./U.K. discrete/open reagent system
	reag. system with open reag. system channels	uisciele/openreagent system
ample handling system/model type	ring with segments (15-30 samples/seg.)/benchtop	
imensions in inches (H x W x D)/instrument footprint	15.75 x 27.25 x 22.50 (analyzer only)/4.5 sq ft (full system)	12 x 12 x 12/1 sq ft
ests available on instrument in U.S.	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 <sub>2</sub> , HbA1c	glucose, lactate, ethanol, methanol, uric acid, cholesterol, urea creatinine, acetoacetate, $\beta$ -hydroxybutyrate, lactose, sucrose, ammonia, glutamine, glycerol, triglyceride, pyruvate
ests cleared but not clinically released	none	_
ests not available in U.S. but submitted for 510(k) clearance ests not available in U.S. but available in other countries	none	—
esearch-use-only assays/tests in development	none none/none	ethanol, methanol, uric acid, cholesterol, creatinine, acetoacetate,
		β-hydroxybutyrate, lactose, sucrose, ammonia, glutamine, glycero
ser-defined methods implemented for what analytes	acetaminophen, alcohol, CRP, CK-MB, folate, fructosamine, lipase,	triglyceride, pyruvate/none —
	salicylate, transferrin, B <sub>12</sub>	
lethods supported/immunoassay methods	photometry/CEDIA, turbidimetric, homogeneous, EIA	oxygen electrode/—
o. of direct ion selective electrode channels	0 (optional ISE interface)	_
must load separate reag. pack for ea. spec./no. diff. assays in pack	no/n/a	no
separate reag. pack for each test run	no	yes
<ul> <li>of different measured assays onboard simultaneously</li> <li>of different assays programmed, calibrated at once</li> </ul>	20 200	1
o. of user-definable (open) channels/no. active simultaneously	9/9	2/1
o. of different analytes for which system accommodates	20/40-60 tests per bottle	1/100–300
reag. containers onboard at once/tests per container set hortest/median onboard reag. stability/refrigerated onboard	120 hrs/30 days/no	24 hrs/1 day/no
lultiple reag. configurations supported	yes	no
eag. container placed directly on system for use strument has same capabilities when 3rd-party reag. used	yes ves	requires operator prehandling, preparation yes
eag. only cost per reportable result for standard chemistries/	\$0.23/TBD/TBD	\$0.1-\$1/—/—
therapeutic drugs/special analytes /alkaway capacity in minutes/specimens/tests-assays	30/150/58	n/a/—/—
ystem is liquid or dry	liquid	liquid
ses disposable cuvettes/max. no. stored	yes/58	no/—
ses washable cuvettes/replacement frequency	no/n/a	no/—
inimum sample volume aspirated precisely at one time upplied with UPS (backup power)/requires floor drain	3 µL yes/no	2.5 µL no/—
equires dedicated water system/water consumption in L per hour	no/n/a	no
oise generated in decibels edicated pediatric sample cup/dead volume	 γes/≤50 μL	 P0
rimary tube sampling/pierces caps on primary tubes	yes/yes	no no/no
ample bar-code reading capability	yes, as sample is being aspirated (2 of 5 interl., Codabar, codes	no
eagent bar-code reading capability	39 & 128)/autodiscrimination yes	_
ar-code placement per NCCLS standard Auto2A	no	_
nboard test auto inventory (determines volume in container) leasures no. tests remaining/short sample detection/clot detection	yes voc/voc/no	no no/wos/
utomatic detection of adequate reag. for aspir. & analysis	yes/yes/no yes	no/yes/— yes
emolysis/turbidity detection-quantitation	no/no	not required/not required
ilution of patient samples onboard/automatic rerun capability ample volume can be reduced/increased to rerun out-of-linear-	yes/yes yes/no	not required/no —/—
range high/low results	yeshio	_,_
utocalibration or autocalibration alert	yes	yes
alibrants stored onboard/multipoint calibration supported ypical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	no/yes n/a/30 days/TBD/TBD	no/not required —/1 hr/—/—
utomatic shutdown/startup programmable	no/no	no/no
tat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TC02	3.5 min (with offline ISE), 55 specimens (with offline ISE)	
<ul> <li>Sodium, potassium, chloride, TCO2, glucose, urea, creatinine</li> <li>Album., bili. direct &amp; total, AST, ALT, ALP</li> </ul>	<6 min (with offline ISE), 40 specimens (with offline ISE) 9 min, 21 specimens	20 sec, —
ypical time delay from ordering stat test to aspir. of sample	immediate response, as soon as 10 sec	—, — 1 min
ow often QC required/onboard SW capability to review QC	daily/yes	shortest interval: 4 hrs; longest: daily/yes
nboard real-time QC/support multiple QC lot nos. per analyte C results transferred automatically to LIS	yes/yes yes	yes/no yes
	•	•
ata mgmt. capability/instrument vendor supplies LIS interface	onboard/no	onboard/no
terfaces up and running in active user sites with	LabDaq, Schuyler House, Antek, others	-
idirectional interface capability	yes (broadcast download)	no
est results transmitted to LIS as soon as chem. time complete	yes	yes
S interface operates simultaneously with running assays ses LOINC to transmit orders & results	yes yes	no no
	-	
ab can control analyzer remotely terface avail. (or will be) to automated specimen handling system	no no	no no
odem servicing available/can diagnose own malfunctions/ determine malfunctioning component	no/yes/yes	no/—/—
n-site time of svc. engineer/onboard error codes for troubleshooting	<24 hrs/yes	n/a/—
lean time between failures/to repair failures	—/<1 hr	_/
verage time to complete maintenance by lab personnel nboard maintenance records/maint. training demo module	daily: 2 min; weekly: 1 min; monthly: 30 min yes (includes audit trail of who replaced parts)/no	daily: 1 min; weekly: 1 min; monthly: 10 min no/—
raining provided with purchase/advanced oper. training avail.	4 days at vendor offices/yes	1 day on-site/no
	ask vendor	\$500
nnual service contract cost (24 h/7 d)		
nnual service contract cost (24 h/7 d) istinguishing features	easy-to-use, multitasking software; closed-tube sampling	large test menu; small sample size; cost per test; 20 sec analysis
	easy-to-use, multitasking software; closed-tube sampling	large test menu; small sample size; cost per test; 20 sec analysis time

Part 5 of 12	Awareness Technology Inc. C. Schneider info@awaretech.com P.O. Box 1679	Beckman Coulter Inc. 200 South Kraemer Blvd. P.O. Box 8000
	P.U. Box 1679 Palm City, FL 34991 772-283-6540	P.0. Box 8000 Brea, CA 92822-8000 800-526-3821
See accompanying comments on page 60	www.awaretech.com	www.beckmancoulter.com
Name of instrument/first year sold in U.S. List price	ChemWell/1999 \$25,000	Synchron CX4 Pro/2001 \$162,400
No. units in clinical use in U.S./outside U.S.	2/190	_/ <u>_</u>
Country where designed/manufactured/where reagents mftd. Operational type/reagent type	U.S./U.S./open system batch, random access/open reagent system	U.S./U.S./U.S. & Ireland continuous random access/open reagent system
Sample handling system/model type Dimensions in inches (H x W x D)/instrument footprint	rack/benchtop 16 x 34 x 20/—	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, magne- sium, 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 <sub>2</sub> , 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	none	none
Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	none unlimited, open system	none
Research-use-only assays/tests in development	any colorimetric (340–700 nm), open system/n/a	none/none
User-defined methods implemented for what analytes	all colorimetric end points and kinetic assays; open systems	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	n/a no	0 no
<ul> <li>separate reag. pack for each test run</li> </ul>	no	no
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	up to 27 unlimited	24 50
No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates	unlimited/up to 27 27/assay dependent	96/24 24/2,400–9,600 (100–900 tests per container)
reag. containers onboard at once/tests per container set Shortest/median onboard reag. stability/refrigerated onboard	n/a/n/a/no	168 hr/30 days/yes (2-8°C)
Multiple reag. configurations supported Reag. container placed directly on system for use	yes reagent dependent	yes yes
Reag. only cost per reportable result for standard chemistries/	yes assay dependent	yes assay dependent
therapeutic drugs/special analytes		
Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry	not limited/96/not limited liquid chemistry system	400/63/1,512 liquid
Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency	yes/96 yes/weekly	no/n/a yes/permanent-2-yr warranty (80 stored on instrument)
Minimum sample volume aspirated precisely at one time	2μL	3μL
Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption in L per hour	no/no no/<1 L per hr	yes/no yes/7 L per hr
Noise generated in decibels Dedicated pediatric sample cup/dead volume	60 no	70 yes/40 μL
Primary tube sampling/pierces caps on primary tubes Sample bar-code reading capability	no/no yes/by handheld scanner as tubes are loaded onto instrument	yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5
Reagent bar-code reading capability	no	interl., Codabar, codes 39 & 128)/autodiscrimination yes
Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container)	no yes	yes yes
Measures no. tests remaining/short sample detection/clot detection	yes/yes/no	yes/yes
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/turbidity detection-quantitation	yes no/no	yes yes/yes
Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-	yes/yes yes/no	yes/no yes/no
range high/low results Autocalibration or autocalibration alert		
Calibrants stored onboard/multipoint calibration supported	yes yes/yes	yes no/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	n/a/user defined/user defined/user defined yes/yes	n/a/up to 90 days/60 days/14 days none required
Stat time to completion of all analytes, throughput per hr. for:	codium and notactium not cupiloble	
<ul> <li>Sodium, potassium, chloride, TCO2</li> <li>Sodium, potassium, chloride, TCO2, glucose, urea, creatinine</li> </ul>	sodium and potassium not available sodium and potassium not available	n/a, n/a n/a, n/a
Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	5.5 min/28 15 sec.	10 min, 32 specimens 45 sec
How often QC required/onboard SW capability to review QC	user defined/yes	24 hr/yes
Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	yes/yes yes, if LIS is enabled	yes/yes yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard (Awareness Technology Inc.)/no	onboard & optional add-on (SW mftr: 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	yes	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays	yes yes	yes yes
Uses LOINC to transmit orders & results	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	yes/yes	yes/yes/no
On-site time of svc. engineer/onboard error codes for troubleshooting	48 hrs in U.S./—	metro: same day; rural: same or next day/yes
Mean time between failures/to repair failures Average time to complete maintenance by lab personnel	not specified/— daily: <10 min; weekly: <30 min; monthly: <1 hr	—/— daily: 5 min; weekly: 15 min; monthly: 20 min
Onboard maintenance records/mainte by hap bersonner Training provided with purchase/advanced oper. training avail.	no/	no/no
Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	2 days on-site, 3 d at vendor offices/yes \$4,000/yr	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 ligh source; polychromatic correction; semipermanent glass cuvettes; DataLink Sample Manager

#### Chemistry analyzers (for low-volume laboratories)

Part 6 of 12	Beckman Coulter Inc.	Careside Inc.
	200 South Kraemer Blvd.	6100 Bristol Parkway
	P.O. Box 8000	Culver City, CA 90230
	Brea, CA 92822-8000	310-338-6767
San accompanying comments on page 40	800-526-3821 www.beckmancoulter.com	www.careside.com
See accompanying comments on page 60	www.beckmancoulter.com	
Name of instrument/first year sold in U.S.	Synchron CX5 Pro/2001	Careside Analyzer/1999
List price No. units in clinical use in U.S./outside U.S.	\$193,500 —/—	\$18,000 —/—
Country where designed/manufactured/where reagents mftd.	U.S./U.S./U.S. & Ireland	—/— U.S./U.S./U.S.
Operational type/reagent type	continuous random access/open reagent system	random access, discrete/self-contained single-use cartridges
Sample handling system/model type	sectors, centrifugable/floor-standing	unit-of-use test cartridge/benchtop
Dimensions in inches (H x W x D)/instrument footprint	69 x 61 x 30/12.7 sq ft	16 x 14 x 12/~1 sq ft
Tests available on instrument in U.S.	alb, ALP, ALT, amylase, AST, BUN, calc., CO <sub>2</sub> , chloride, cholest., CK-MB,	electrochemistry: anion gap, chloride, potassium, sodium; chem-
	creatinine, dir. bilirubin, GGT, glucose, HDLD, iron/TIBC, lipase, LD, LDLD,	istry: A/G ratio, albumin, ALP, ALT, ALT/AST ratio, ammonia,
	magnesium, phosphorus, potassium, sodium, total protein, total bilirubin,	amylase, AST, bilirubin direct & total, bilirubin indirect (calc.), BUN
	triglyceride, triglyceride glycerol blanked, urea, uric acid; esoteric	BUN/creatinine ratio, calcium total, carbon dioxide, HDL chol., LDL
	chemistries: ammonia, cholinesterase, hemoglobin A1c, lactate, micro-	chol. (calc.), chol. total, chol./HDL chol. ratio, CK, CK-MB, % CK-MB
	albumin, prealbumin, salicylate; drugs of abuse testing; therapeutic drug monitoring; proteins: anti-streptolysin 0, IgA, IgM, IgG, rheumatoid	creatinine, GGT, globulin (calc.), glucose, LDH, magnesium, osmola ity (calc.), phosphorus, total protein, triglycerides, uric acid,
	factor, transferrin; thyroids: thyroxine, T-up	cholinesterase; hematology: hemoglobin, hematocrit (calc.);
		coagulation: prothrombin time
Tests cleared but not clinically released	none	aPTT
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 User-defined methods implemented for what analytes	none/none UIBC	none/ionized calcium none
osci-acilica metrious imprementea for what dildigies		
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric/bidentate turbidimetric,	potentiometry, optical transmission, reflectance/n/a
	direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay	
No. of direct ion selective electrode channels	5 (indirect)	3
must load separate reag. pack for ea. spec./no. diff. assays in pack	no	no/n/a
<ul> <li>separate reag. pack for each test run</li> </ul>	no	1 pack for 3 tests (Na, K, CI)
No. of different measured assays onboard simultaneously	29	n/a
No. of different assays programmed, calibrated at once	50	total menu
No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates	100/29 29/2,900–69,600 (100–2,400 tests per container)	0/n/a n/a/n/a
reag. containers onboard at once/tests per container set	27/2,700-07,000 (100-2,400 tests per container)	11/ d/ 11/ d
Shortest/median onboard reag. stability/refrigerated onboard	168 hr/30 days/yes (2-8°C)	n/a/n/a/no
Multiple reag. configurations supported	yes	yes
Reag. container placed directly on system for use	yes	yes
Instrument has same capabilities when 3rd-party reag. used	yes	no veries /n /s /n /s
Reag. only cost per reportable result for standard chemistries/ therapeutic drugs/special analytes	assay dependent	varies/n/a/n/a
Walkaway capacity in minutes/specimens/tests-assays	400/63/1,827	12/1/8
System is liquid or dry	liquid	dry
Uses disposable cuvettes/max. no. stored	no/n/a	no/n/a
Uses washable cuvettes/replacement frequency	yes/permanent-2-yr warranty (80 stored on instrument)	no/n/a
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain	3 µL yes/no	n/a no/no
Requires dedicated water system/water consumption in L per hour	yes/10 yes/10 per hr	no/none
Noise generated in decibels	70	<60
Dedicated pediatric sample cup/dead volume	yes/40 µL	no
Primary tube sampling/pierces caps on primary tubes	yes/no	no/n/a
Sample bar-code reading capability	yes, on sample transport, shortly before sample is aspirated (2 of 5	no
Reagent bar-code reading capability	interl., Codabar, codes 39 & 128)/autodiscrimination yes	Ves
Bar-code placement per NCCLS standard Auto2A	yes	yes n/a
Onboard test auto inventory (determines volume in container)	yes	n/a
Measures no. tests remaining/short sample detection/clot detection	yes/yes/yes	n/a/yes/no
Automatic detection of adequate reag. for aspir. & analysis	yes .	n/a
Hemolysis/turbidity detection-quantitation	yes/yes	no/no no/no
Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-	yes/no yes/no	no/no
range high/low results	,	
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/multipoint calibration supported	no/yes	no/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	24 hr/up to 90 days/60 days/14 days none required	calibration verification every 6 mos/6 mos/n/a/n/a no/no
Automatic shutuown/startup programmable	none required	
Stat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TCO2     Sodium, potassium, chloride, TCO2	52 sec, 75 specimens	~10 min, 1 specimen (Na, K, Cl: 6 min)
<ul> <li>Sodium, potassium, chloride, TCO2, glucose, urea, creatinine</li> <li>Album., bili. direct &amp; total, AST, ALT, ALP</li> </ul>	8 min, 75 specimens	~12 min, 1 specimen
• Album, bill direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	10 min, 32 specimens 45 sec	~12 min, 1 specimen immediate
How often QC required/onboard SW capability to review QC	24 hr/yes	daily for electronic QC/yes
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	onboard/yes Careside Connect DMS (addt'l cost)
ingini capazing monanon tondor suppres Lo micraec	DataLink)/yes (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	yes (broadcast download & host query)	yes
Test results transmitted to LIS as soon as chem. time complete	yes	yes

Eldirectional interface capability	yes (broadcast download & host query)	yes
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no	yes
Lab can control analyzer remotely	no	yes
Interface avail. (or will be) to automated specimen handling system	yes	no
Modem servicing available/can diagnose own malfunctions/ determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	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; semiperma- nent glass cuvettes; DataLink Sample Manager	POC test device with easy-to-use user interface and a comprehen- sive test menu

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

## Chemistry analyzers (for low-volume laboratories)

Part 7 of 12		
	Dade Behring Inc.	Elan Diagnostics
	P.O. Box 6101	2 Thurber Blvd.
	Newark, DE 19714-6101 800-242-3233	Smithfield, RI 02917 401-233-3526
	www.dadebehring.com	elandiagnostics.com
See accompanying comments on page 60		
Name of instrument/first year sold in U.S.	Dimension Xpand Integrated Chemistry System/2001	Atac 6000 Chemistry System/1990
List price	\$165,000	
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.	
Operational type/reagent type	continuous random access/self-contained multi-use cartridges- pakages-slides & open reagent system	discrete/open reagent system
Sample handling system/model type	sample segments/floor-standing	sample wheel/benchtop
Dimensions in inches (H x W x D)/instrument footprint	45 x 31 x 51/—	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,	albumin, ALP, Apo A, Apo B, amylase, bilirubin direct & total, BUN,
	auto. HDL, iron, magnes., phosphorus, total iron-binding capacity (&	CO <sub>2</sub> , calcium, cholesterol, CPK, creatinine, fructosamine, GGT,
	no pretreat), total protein, triglyc., urea nitrogen, uric acid, carbon	glucose, AST, ALT, HDL, iron-total, phos., LDH, magnesium, total
	dioxide, chloride, potassium, sodium	protein, triglycerides, uric acid, sodium, potassium, chloride-ISE
Tests cleared but not clinically released	n/a	none
Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries	CSA	none
Research-use-only assays/tests in development	CSA none/fPSA, tPSA	none none/none
User-defined methods implemented for what analytes	n/a	none
Malla de como de d'Anno de como de como	which we are a standing to the table of the state of the	ala da se ala se da se da da la
Methods supported/immunoassay methods	photometry, potentiometry, turbidimetric assays/Petinia, Emit, Acmia, mag. part. sep.	photometry, potentiometry/n/a
No. of direct ion selective electrode channels	3	3
• must load separate reag. pack for ea. spec./no. diff. assays in pack	no	no/n/a
separate reag. pack for each test run No. of different measured assays onboard simultaneously	no 47	no 16
No. of different assays programmed, calibrated at once	75+	16
No. of user-definable (open) channels/no. active simultaneously	10/10	48/16
No. of different analytes for which system accommodates	47/480	16/30
reag. containers onboard at once/tests per container set Shortest/median onboard reag. stability/refrigerated onboard	24 hrs/5 days/yes (2–8°C)	6 hrs/2 days/no
Multiple reag. configurations supported	no	no
Reag. container placed directly on system for use	yes	no, requires operator prehandling/prep.
Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/	yes n/a	no //
therapeutic drugs/special analytes	n/a	,, <b></b>
Walkaway capacity in minutes/specimens/tests-assays	420/60/1,800	<i>—/—/</i> 96
System is liquid or dry	liquid & reconstitutes onboard	liquid
Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency	yes/12,000 —/—	yes/96 no/n/a
Minimum sample volume aspirated precisely at one time	2 µL	2 µL
Supplied with UPS (backup power)/requires floor drain	yes/no	no/no
Requires dedicated water system/water consumption in L per hour Noise generated in decibels	yes/2 L per hr <70	no/yes
Dedicated pediatric sample cup/dead volume	no/30 µL with standard cup	no
Primary tube sampling/pierces caps on primary tubes	yes/no	no/no
Sample bar-code reading capability	yes/on sample transport, shortly before sample is aspirated (2 of 5	no
Reagent bar-code reading capability	interleaved, Codabar, codes 39 & 128)/autodiscrimination yes	_
Bar-code placement per NCCLS standard Auto2A	yes	_
Onboard test auto inventory (determines volume in container)	yes	no
Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reag. for aspir. & analysis	yes/yes/no no	no/no/no no
Hemolysis/turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/automatic rerun capability	yes/yes	no/no
Sample volume can be reduced/increased to rerun out-of-linear-	yes/no	no/no
range high/low results Autocalibration or autocalibration alert	yes	no
Calibrants stored onboard/multipoint calibration supported	no/yes	no/no
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	2 hrs (auto)/90 days/60 days/60 days	4 hrs/daily/n/a/n/a
Automatic shutdown/startup programmable	—/—	no/—
Stat time to completion of all analytes, throughput per hr. for:		
<ul> <li>Sodium, potassium, chloride, TCO2</li> </ul>	2 min, 62	—, —
<ul> <li>Sodium, potassium, chloride, TCO2, glucose, urea, creatinine</li> <li>Album., bili. direct &amp; total, AST, ALT, ALP</li> </ul>	4 min, 62 8 min, 42	—, — —, —
Typical time delay from ordering stat test to aspir. of sample	60 sec steady state, 2 min from standby	_
How often QC required/onboard SW capability to review QC	daily/yes	2 levels daily/yes
Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	yes/— yes	yes/yes yes
es rooms nanorered automaticany to LIS	<u> </u>	-
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/no	onboard/yes (addt'l cost)
		Fletcher-Flora
Interfaces up and running in active user sites with	interfaces available for all major LIS vendors	
Interfaces up and running in active user sites with	interfaces available for all major LIS vendors	
Bidirectional interface capability	yes (broadcast download & host query)	yes (host query)
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete	yes (broadcast download & host query) yes	yes (host query) yes
Bidirectional interface capability	yes (broadcast download & host query)	yes (host query)
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
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 Lab can control analyzer remotely	yes (broadcast download & host query) yes yes no no	yes (host query) yes yes no no
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 Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	yes (broadcast download & host query) yes yes no no	yes (host query) yes yes no
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 Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system Modem servicing available/can diagnose own malfunctions/	yes (broadcast download & host query) yes yes no no	yes (host query) yes yes no no
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 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	yes (broadcast download & host query) yes yes no no no yes/yes/yes	yes (host query) yes yes no no no no no/no/no
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 Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system Modem servicing available/can diagnose own malfunctions/	yes (broadcast download & host query) yes yes no no	yes (host query) yes yes no no no
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 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	yes (broadcast download & host query) yes yes no no no no yes/yes/yes situation dependent/yes n/a/n/a daily: 5 min; weekly: n/a; monthly: 20 min	yes (host query) yes yes no no no no/no/no within 24 hrs/yes / daily: 5 min; weekly: 15 min; monthly: 15 min
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 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	yes (broadcast download & host query) yes yes no no no yes/yes/yes situation dependent/yes n/a/n/a daily: 5 min; weekly: n/a; monthly: 20 min no/no	yes (host query) yes yes no no no no no/no/no within 24 hrs/yes / daily: 5 min; weekly: 15 min; monthly: 15 min no/
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 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.	yes (broadcast download & host query) yes yes no no no no yes/yes/yes situation dependent/yes n/a/n/a daily: 5 min; weekly: n/a; monthly: 20 min	yes (host query) yes yes no no no no/no/no within 24 hrs/yes / daily: 5 min; weekly: 15 min; monthly: 15 min
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 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)	yes (broadcast download & host query) yes yes no no no 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	yes (host query) yes no no no no/no/no within 24 hrs/yes / daily: 5 min; weekly: 15 min; monthly: 15 min no/ 5 days on-site/no 
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 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.	yes (broadcast download & host query) yes yes no no no 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 specifically designed for low-volume testing laboratories; the	yes (host query) yes yes no no no no no/no/no within 24 hrs/yes / daily: 5 min; weekly: 15 min; monthly: 15 min no/ 5 days on-site/no  batch mode with broad test menu; high level of flexibility & perform-
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 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)	yes (broadcast download & host query) yes yes no no no 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 specifically designed for low-volume testing laboratories; the analyzer performs the most requested chemistry and heterogeneous	yes (host query) yes no no no no no/no/no within 24 hrs/yes / daily: 5 min; weekly: 15 min; monthly: 15 min no/ 5 days on-site/no 
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 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)	yes (broadcast download & host query) yes yes no no no 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 specifically designed for low-volume testing laboratories; the	yes (host query) yes yes no no no no no/no/no within 24 hrs/yes / daily: 5 min; weekly: 15 min; monthly: 15 min no/ 5 days on-site/no  batch mode with broad test menu; high level of flexibility & perform
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 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)	yes (broadcast download & host query) yes yes no no no 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 specifically designed for low-volume testing laboratories; the analyzer performs the most requested chemistry and heterogeneous	yes (host query) yes yes no no no no no/no/no within 24 hrs/yes / daily: 5 min; weekly: 15 min; monthly: 15 min no/ 5 days on-site/no  batch mode with broad test menu; high level of flexibility & perform
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 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)	yes (broadcast download & host query) yes yes no no no 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 specifically designed for low-volume testing laboratories; the analyzer performs the most requested chemistry and heterogeneous	yes (host query) yes yes no no no no no/no/no within 24 hrs/yes / daily: 5 min; weekly: 15 min; monthly: 15 min no/ 5 days on-site/no  batch mode with broad test menu; high level of flexibility & perform

	Smithfield, RI 02917 401-233-3526	9033 Red Branch Rd. Columbia, MD 21045
See accompanying comments on page 60	elandiagnostics.com	800-436-2436 www.hemagen.com
ame of instrument/first year sold in U.S.	Atac 8000 Random Access Chemistry System/1995	Analyst Benchtop Chemistry System/1986
ist price o. units in clinical use in U.S./outside U.S.		\$5,500-\$9,900 —/—
Sountry where designed/manufactured/where reagents mftd. Iperational type/reagent type	// // continuous random access/open reagent system	—, — France-U.S./U.S./U.S. batch/self-contained single-use cartridges-packages-slides, rotors —/benchtop
ample handling system/model type bimensions in inches (H x W x D)/instrument footprint	sample wheel/benchtop 19.5 x 39 x 20.5/5.5 sq ft	8.5 x 25 x 13/2.25 sq ft
Tests available on instrument in U.S.	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 <sub>2</sub> , chloride, potassium, sodium—ISE]	ALP, GGT, GPT, Got, BUN, glucose, calcium, cholesterol, triglyc- erides, amylase, uric acid, total bilirubin, total protein, HDL-chol., albumin, direct bilirubin, CO <sub>2</sub> , phosphorus
Fests cleared but not clinically released Fests not available in U.S. but submitted for 510(k) clearance	none none	none
Tests not available in U.S. but available in other countries	none	none none
Research-use-only assays/tests in development User-defined methods implemented for what analytes	none/none none	none/— none
Methods supported/immunoassay methods	photometry, potentiometry/n/a	photometry/n/a
<ul> <li>Vo. of direct ion selective electrode channels</li> <li>must load separate reag. pack for ea. spec./no. diff. assays in pack</li> </ul>	4 no/n/a	n/a yes/14 per rotor per patient
separate reag. pack for each test run	no	no
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	40 40	 14
No. of user-definable (open) channels/no. active simultaneously	320/40 40/150	
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	40/150	14/14
Shortest/median onboard reag. stability/refrigerated onboard	5 days/12 days/yes	//no
Multiple reag. configurations supported Reag. container placed directly on system for use	yes yes	yes
Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/	yes —/—/—	no //
therapeutic drugs/special analytes		
Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry	240+/50/1,200 liquid	10/1/14 dry
Uses disposable cuvettes/max. no. stored	no/n/a	no (uses rotors)
Uses washable cuvettes/replacement frequency Vinimum sample volume aspirated precisely at one time	yes/5 yrs 2 µL	no/n/a 10 µL & 80 µL
Supplied with UPS (backup power)/requires floor drain	yes/no	no/no
Requires dedicated water system/water consumption in L per hour Noise generated in decibels	no/yes —	no/n/a
Dedicated pediatric sample cup/dead volume	no	no
Primary tube sampling/pierces caps on primary tubes Sample bar-code reading capability	yes/no no	no/no no
Reagent bar-code reading capability	no	yes
Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container)	 yes	— no
Measures no. tests remaining/short sample detection/clot detection	yes/yes/no	no/no/no
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/turbidity detection-quantitation	yes —/—	no no/no
Dilution of patient samples onboard/automatic rerun capability	yes/yes	no/no
Sample volume can be reduced/increased to rerun out-of-linear- range high/low results	yes/yes	no/no
Autocalibration or autocalibration alert	yes na luca	no no/—
Calibrants stored onboard/multipoint calibration supported Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	no/yes 4 hrs/14 days/n/a/n/a yes/yes	n/a/60 days/n/a/n/a no/no
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02	60 sec 60 specimens	
<ul> <li>Sodium, potassium, chloride, TCO2, glucose, urea, creatinine</li> </ul>	60 sec, 60 specimens 6 min, 45 specimens	—, — 10 min, 6 specimens (glu, urea, crea)
Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	7 min, 36 patients with specified panel 20 sec	10 min, 6 specimens
How often QC required/onboard SW capability to review QC	2 levels daily/yes	
Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	yes/yes	no/no —
	•	han (included in mine)
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/yes (addt'l cost)	—/yes (included in price)
nterfaces up and running in active user sites with	Fletcher-Flora	in development
Bidirectional interface capability	yes (broadcast download & host query)	-
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays	yes yes	_
Uses LOINC to transmit orders & results	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/	no/yes/yes	no/yes/yes
determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting	within 24 hrs/yes	most troubleshooting via phone/yes
Mean time between failures/to repair failures Average time to complete maintenance by lab personnel	—/— daily: none; weekly: 15 min; monthly: 30 min	14–16 mos/— daily: 2 min; weekly: 15 min; monthly: 30 min
Onboard maintenance records/maintenance by lab personner 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, 5 days on-site/yes —	no/— 1 day on-site/yes \$650
Distinguishing features	475 tests/hr of general chemistry & ISE; reusable glass cuvettes,	uses only 90 µL of sample & requires <60 sec of prep work; minima maintenance required; offered with sodium, potassium, and chlorid
	ensuring low reag. cost; onboard refrigeration; includes LIS	maintenance required; offered with sodium, potassium, and chlorid ISE units

Part 9 of 12	Landmark Scientific Inc. Valerie Brady vbrady@landmarkscientific.com	Nova Biomedical Corp. Nova Sales Department 200 Departs
	101-B Creek Ridge Rd. Greensboro, NC 27406	200 Prospect St. Waltham, MA 02454-9141
	336-373-0274	800-458-5813
ee accompanying comments on page 60	www.landmarkscientific.com	info@novabiomedical.com
ame of instrument/first year sold in U.S.	AGII Chemistry System (w/ISE)/1998	Stat Profile M/1998
ist price o. units in clinical use in U.S./outside U.S.	\$31,527 39/225	\$55,750 —/—
ountry where designed/manufactured/where reagents mftd.	U.S./U.K./U.S.	—/— U.S./U.S./U.S.
perational type/reagent type	batch, random access/open reagent system	random access/self-contained multiuse packages
ample handling system/model type imensions in inches (H x W x D)/instrument footprint	wheel/benchtop 24 x 24 x 14/4 sq ft	stat sampling directly from sample container/benchtop 20.5 x 19.2 x 20.7/2.75 sq ft
· · · ·		
ests available on instrument in U.S.	albumin, alk. phos., ALT, AST, amylase, total/direct bilirubin, BUN, calcium, cholesterol, creatinine, CO <sub>2</sub> , CK/CPK, CRP, GGTP, HDL	sodium, potassium, chloride, glucose, BUN, ionized magnesium, ionized calcium, lactate, Hct, hemoglobin, pH, pCO <sub>2</sub> , pO <sub>2</sub> , SO <sub>2</sub> %
	cholesterol, total iron, LDH, LDL direct, magnesium, phosphorus,	· · · · · · · · · · · · · · · · · · ·
	total protein, triglycerides, uric acid; w/ISE: sodium, potassium, chloride	
	chorac	
ests cleared but not clinically released ests not available in U.S. but submitted for 510(k) clearance	n/a n/a	none
ests not available in U.S. but available in other countries	open system	none
esearch-use-only assays/tests in development	n/a/thyroid (T <sub>3</sub> , T <sub>4</sub> , T-uptake, TSH), auto HDL	none/none
ser-defined methods implemented for what analytes	n/a	none
lethods supported/immunoassay methods	photometry/n/a	potentiometry, optical, reflectance/n/a
<ul> <li>of direct ion selective electrode channels</li> <li>must load separate reag. pack for ea. spec./no. diff. assays in pack</li> </ul>	none no	12 no/n/a
<ul> <li>separate reag. pack for each test run</li> <li>of different measured assays onboard simultaneously</li> </ul>	yes 16	no 14
p. of different assays programmed, calibrated at once	16	14
o. of user-definable (open) channels/no. active simultaneously	unlimited/16	0/n/a 14/(@ 14 700 tosts/ma): 6 200 tosts
<ul> <li>of different analytes for which system accommodates reag. containers onboard at once/tests per container set</li> </ul>	16/average 600–1,000 per kit	14/(@ 14,700 tests/mo): 6,300 tests
hortest/median onboard reag. stability/refrigerated onboard	2 hrs/7days/no	21 days/21 days/no
Iultiple reag. configurations supported eag. container placed directly on system for use	yes requires operator prehandling, preparation	n/a ves
strument has same capabilities when 3rd-party reag. used	yes	yes n/a
eag. only cost per reportable result for standard chemistries/	\$0.02 to \$0.52/n/a/—	standard chemistries: @35 sam/d: \$0.40 (14-test panel); bundled
therapeutic drugs/special analytes /alkaway capacity in minutes/specimens/tests-assays	10 min/38/38	instr., reag., maint. cost: \$1.39 (14-test panel) n/a
ystem is liquid or dry	either liquid or powder	n/a
ses disposable cuvettes/max. no. stored	NO	no/n/a
ses washable cuvettes/replacement frequency linimum sample volume aspirated precisely at one time	yes/after 10 uses 2 μL	n/a 150 μL
upplied with UPS (backup power)/requires floor drain	yes/no	no/no
equires dedicated water system/water consumption in L per hour oise generated in decibels	no/0.25 L per hr ~35	no/n/a minimal
edicated pediatric sample cup/dead volume	no	n/a
rimary tube sampling/pierces caps on primary tubes	no/no	yes/no
ample bar-code reading capability	no	yes, by handheld scanner as tubes are loaded onto instrument (2 o 5 interl., UPC, Codabar, codes 39 & 128)/autodiscrimination
eagent bar-code reading capability	no	alternate method
ar-code placement per NCCLS standard Auto2A nboard test auto inventory (determines volume in container)	no	n/a
leasures no. tests remaining/short sample detection/clot detection	no no/no/no	yes yes/yes/yes
utomatic detection of adequate reag. for aspir. & analysis	no	yes
emolysis/turbidity detection-quantitation ilution of patient samples onboard/automatic rerun capability	no/no no/no	no/no no/no
ample volume can be reduced/increased to rerun out-of-linear-	no/no	no/no
range high/low results utocalibration or autocalibration alert	20	Voc
alibrants stored onboard/multipoint calibration supported	no no/no	yes yes/n/a
ypical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	ISE separate unit/n/a/n/a/n/a	2 hrs/2 hrs/n/a/n/a n/a/n/a
utomatic shutdown/startup programmable	no/no	1/ 0/1// 0
tat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2	30 sec, 180	75 sec, 35 specimens
<ul> <li>Sodium, potassium, chloride, TCO2</li> <li>Sodium, potassium, chloride, TCO2, glucose, urea, creatinine</li> </ul>	30 sec, 180 13 min, 50	75 sec, 35 specimens 75 sec, 35 specimens
Album., bili. direct & total, AST, ALT, ALP	15 min, 35	n/a
ypical time delay from ordering stat test to aspir. of sample ow often QC required/onboard SW capability to review QC	<30 sec shortest interval: each rotor; longest: 1 8-hr shift/yes	9 sec CLIA minimum/yes
nboard real-time QC/support multiple QC lot nos. per analyte	n/a/yes	no/yes
C results transferred automatically to LIS	yes	yes
ata mgmt. capability/instrument vendor supplies LIS interface	onboard/no (additional)	onboard & optional add-on (\$9,225; SW mftr.: Nova)/no
terfaces up and running in active user sites with	LahDag LahDak	most LIS vendors including Cerner, Sunquest, HBO, Soft, others
tterfaces up and running in active user sites with	LabDaq, LabPak	most Lis venuors menuumy cerner, sunquest, HDU, SUI, others
idirectional interface capability	yes	yes
est results transmitted to LIS as soon as chem. time complete IS interface operates simultaneously with running assays	yes yes	yes no
ses LOINC to transmit orders & results		no
ab can control analyzer remotely	no	yes
nterface avail. (or will be) to automated specimen handling system	no	no
lodem servicing available/can diagnose own malfunctions/ determine malfunctioning component	no/no/no	yes/yes
determine malfunctioning component n-site time of svc. engineer/onboard error codes for troubleshooting	24–48 hrs/no	<8 business hrs/yes
lean time between failures/to repair failures	once every 27 months/2 hrs	_/_
verage time to complete maintenance by lab personnel nboard maintenance records/maint. training demo module	daily: 5 min; weekly: 5 min; monthly: 30 min no/no	daily: <2 min; weekly: <5 min; monthly: <5 min no/no
	3 days at vendor offices/yes	3 days on-site/yes
raining provided with purchase/advanced oper. training avail.	Cap service agreement—no service fee if not needed, no more than \$4,200 per year with reagent agreement	call for pricing
raining provided with purchase/advanced oper. training avail. nnual service contract cost (24 h/7 d)	Tradition and the second secon	
nnual service contract cost (24 h/7 d)		and the second state of th
	cost per test; Cap service agreement, long-term mean time between	combines up to 14 onboard critical care tests; only combined bloo gas analyzer with BUN & iMg
nnual service contract cost (24 h/7 d)	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	
nnual service contract cost (24 h/7 d)	cost per test; Cap service agreement, long-term mean time between failures; reusable rotors; user friendly; true Windows-based	

Part 10 of 12	Nova Biomedical Corp.	Nova Biomedical Corp.
	Nova Sales Department	Nova Sales Department
	200 Prospect St.	200 Prospect St.
	Waltham, MA 02454-9141	Waltham, MA 02454-9141
See accompanying comments on page 60	800-458-5813 info@novabiomedical.com	800-458-5813 info@novabiomedical.com
See accompanying comments on page oo	ากษะกองสมเอกเล่นเปล่า.com	
Name of instrument/first year sold in U.S.	Stat Profile M7/1999	Nova 16/1995
List price	\$55,750	\$22,500-\$25,500
No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd.	—/— U.S./U.S./U.S	—/— U.S./U.S./U.S.
Operational type/reagent type	random access/self-contained multiuse packages	batch, random access/self-contained multiuse packages
Sample handling system/model type	stat sampling directly from sample container/benchtop	40-position tray, stat sampling directly from sample
		container/benchtop
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	sodium, potassium, chloride, total CO2, glucose, BUN, creatinine, Hct
	calcium, lactate, Hct, hemoglobin, pH, pCO <sub>2</sub> , pO <sub>2</sub> , SO <sub>2</sub> %	
Tests cleared but not clinically released	none	none
Tests not available in U.S. but submitted for 510(k) clearance	none	none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays/tests in development	none/none	none/none
User-defined methods implemented for what analytes	none	none
Methods supported/immunoassay methods	potentiometry, optical, reflectance/n/a	potentiometry/n/a
No. of direct ion selective electrode channels	12	8
<ul> <li>must load separate reag. pack for ea. spec./no. diff. assays in pack</li> </ul>	no/n/a	no/n/a
separate reag. pack for each test run	no	no
No. of different measured assays onboard simultaneously	14	8
No. of different assays programmed, calibrated at once	14	8
No. of user-definable (open) channels/no. active simultaneously	0/n/a	0/n/a
No. of different analytes for which system accommodates	14/(@14,700 tests/mo): 6,300 tests	8/(@ 8,000 tests/mo): 2,700 tests
reag. containers onboard at once/tests per container set	21 days/21 days/20	21 days/21 days/no
Shortest/median onboard reag. stability/refrigerated onboard Multiple reag. configurations supported	21 days/21 days/no n/a	21 days/21 days/no n/a
Reag. container placed directly on system for use	no, requires oper. prehandling/prep. (remove clip from sealed bag &	no, requires prehandling (remove clip from sealed bag & mix)
	mix)	
Instrument has same capabilities when 3rd-party reag. used	n/a	n/a
Reag. only cost per reportable result for standard chemistries/	standard chemistries: @35 sam/d: \$0.40 (14-test panel); bundled	standard chemistries: @25 sam/d: \$0.40 (8-test panel); bundled
therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays	instr.; reag., maint. cost: \$1.39 (14-test panel)	instr., reag., maint. cost per result: \$0.92 (8-test panel)
System is liquid or dry	n/a n/a	60 per tray/40 per tray/280 per tray n/a
Uses disposable cuvettes/max. no. stored	no/n/a	no/n/a
Uses washable cuvettes/replacement frequency	n/a	n/a/n/a
Minimum sample volume aspirated precisely at one time	150 µL	385 µL
Supplied with UPS (backup power)/requires floor drain	no/no	no/no
Requires dedicated water system/water consumption in L per hour Noise generated in decibels	no/n/a minimal	no/n/a minimal
Dedicated pediatric sample cup/dead volume	n/a	n/a
Primary tube sampling/pierces caps on primary tubes	yes/no	yes/no
Sample bar-code reading capability	yes, by handheld scanner as tubes are loaded onto instrument (2 of	yes, by handheld scanner as tubes are loaded onto instrument (2 of
	5 interl., UPC, Codabar, codes 39 & 128)/autodiscrimination	5 interl., UPC, Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	alternate method	alternate method
Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container)	n/a yes	n/a yes
Measures no. tests remaining/short sample detection/clot detection	yes/yes/yes	no/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard/automatic rerun capability	no/no	yes/yes
Sample volume can be reduced/increased to rerun out-of-linear- range high/low results	no/no	no/no
Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/multipoint calibration supported	yes/n/a	yes/n/a
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	2 hrs/2 hrs/n/a/n/a	2 hrs/2 hrs/n/a/n/a
Automatic shutdown/startup programmable	n/a/n/a	n/a/n/a
Stat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TCO2	75 sec, 35 specimens	90 sec, 39 specimens
<ul> <li>Sodium, potassium, chloride, TCO2, glucose, urea, creatinine</li> </ul>	75 sec, 35 specimens	90 sec, 39 specimens
<ul> <li>Album., bili. direct &amp; total, AST, ALT, ALP</li> </ul>	n/a/n/a	n/a
Typical time delay from ordering stat test to aspir. of sample	9 sec	9 sec
How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte	CLIA minimum/yes no/yes	CLIA minimum/yes no/yes
QC results transferred automatically to LIS	yes	yes
	•	•
Data mgmt. capability/instrument vendor supplies LIS interface	onboard & optional add-on (\$9,225, SW mftr.: Nova)/no	onboard & optional add-on (\$9,225, SW mftr: Nova)/no
Interfaces up and running in active user sites with	most LIS vendors including Corner Sunguest UPO. Soft others	most LIS vendors including Cerner Sunguest UPO. Soft others
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	yes	yes
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays	no	no
Uses LOINC to transmit orders & results	no	no

Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	yes no	yes no
Modem servicing available/can diagnose own malfunctions/ determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes/yes <8 business hrs/yes —/— 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 <sub>2</sub> available; can analyze whole blood, serum, plasma, urine, CSF, & dialysate

Part 11 of 12 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 Tests available on instrument in U.S.	Ortho-Clinical Diagnostics Distributor Sales Support Center 1001 U.S. Highway 202 Raritan, NJ 08869 800-457-7848 orthoclinical.com Vitros DT60-II Analyzer/1993 — 15,000 units worldwide U.S./U.S./U.S. batch, random access, discrete/self-contained single-use car- tridges-packages-slides —/benchtop 6.75 x 18.75 x 13.75/1.8 sq ft ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN/urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH,	Roche Diagnostics Corp.9115 Hague Rd.Indianapolis, IN 46250800-428-5074www.us.labsystems.roche.comCobas Integra 400 Plus/1999\$175,000>2,000Switzerland/Switzerland/U.S. & Germany continuous random access/self-contained multiuse cartridgesrack/benchtop 30 x 53 x 26/9.6 sq ft $\alpha$ -1-acid glycoprot., $\alpha$ -1-antitryp., alb. I, apo A & B, antistrepto0,
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	orthoclinical.com Vitros DT60-II Analyzer/1993 	Cobas Integra 400 Plus/1999 \$175,000 >2,000 Switzerland/Switzerland/U.S. & Germany continuous random access/self-contained multiuse cartridges rack/benchtop 30 x 53 x 26/9.6 sq ft
Name of instrument/first year sold in U.S. List price No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd. Operational type/reagent type Sample handling system/model type Dimensions in inches (H x W x D)/instrument footprint	Vitros DT60-II Analyzer/1993 — 15,000 units worldwide U.S./U.S./U.S. batch, random access, discrete/self-contained single-use car- tridges-packages-slides —/benchtop 6.75 x 18.75 x 13.75/1.8 sq ft ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN/urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH,	\$175,000 >2,000 Switzerland/Switzerland/U.S. & Germany continuous random access/self-contained multiuse cartridges rack/benchtop 30 x 53 x 26/9.6 sq ft
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	<ul> <li>15,000 units worldwide U.S./U.S./U.S.</li> <li>batch, random access, discrete/self-contained single-use car- tridges-packages-slides —/benchtop</li> <li>6.75 x 18.75 x 13.75/1.8 sq ft</li> <li>ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN/urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH,</li> </ul>	\$175,000 >2,000 Switzerland/Switzerland/U.S. & Germany continuous random access/self-contained multiuse cartridges rack/benchtop 30 x 53 x 26/9.6 sq ft
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	U.S./U.S./U.S. batch, random access, discrete/self-contained single-use car- tridges-packages-slides —/benchtop 6.75 x 18.75 x 13.75/1.8 sq ft ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN/urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH,	>2,000 Switzerland/Switzerland/U.S. & Germany continuous random access/self-contained multiuse cartridges rack/benchtop 30 x 53 x 26/9.6 sq ft
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	U.S./U.S./U.S. batch, random access, discrete/self-contained single-use car- tridges-packages-slides —/benchtop 6.75 x 18.75 x 13.75/1.8 sq ft ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN/urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH,	Switzerland/Switzerland/U.S. & Germany continuous random access/self-contained multiuse cartridges rack/benchtop 30 x 53 x 26/9.6 sq ft
Operational type/reagent type Sample handling system/model type Dimensions in inches (H x W x D)/instrument footprint	batch, random access, discrete/self-contained single-use car- tridges-packages-slides —/benchtop 6.75 x 18.75 x 13.75/1.8 sq ft ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN/urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH,	continuous random access/self-contained multiuse cartridges rack/benchtop 30 x 53 x 26/9.6 sq ft
Dimensions in inches (H x W x D)/instrument footprint	-/benchtop 6.75 x 18.75 x 13.75/1.8 sq ft ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN/urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH,	30 x 53 x 26/9.6 sq ft
Dimensions in inches (H x W x D)/instrument footprint	6.75 x 18.75 x 13.75/1.8 sq ft ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN/urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH,	30 x 53 x 26/9.6 sq ft
· · · ·	ammonia, cholesterol, HDL chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN/urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH,	•
Tests available on instrument in U.S.	amylase, creatinine, lactate, phosphorus, triglycerides, BUN/urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH,	$\alpha$ -1-acid glycoprot, $\alpha$ -1-antitryp all I and A & B antistrepto -0
Tests cleared but not clinically released	theophylline, CO <sub>2</sub> , sodium, potassium, chloride, urine creatinine, CK-MB	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, $\alpha$ -amy. pancreatic, AP, AST, cholinest. & Che-D, CK-MB, $\gamma$ - glutamyltrans., LDH, lipase, alb., bil direct & total, Ca., chol., CO <sub>2</sub> , creat., fructosam., gluc., HbA1c, HDL direct, iron, lact., LDL direct, Mg, ammon., phos., TP, TPU-C, trig., UA, UIBC, urea, Na, K, CI, Li, acet., amik., carb., CSA, dig., digit., gent., lido., NAPA, pheno., pheny., prim., proc., quin., sali., theo., tobra., valp. acid, vanc., T <sub>4</sub> , T- up, D-dimer, soluble transferrin receptor, cyclosporine 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	lipoprotein A
Research-use-only assays/tests in development User-defined methods implemented for what analytes	none/none	none/homocysteine, lipoprotein A caffeine
oser-denned methods implemented for what analytes	none	
Methods supported/immunoassay methods	potentiometry, dry slide technology/n/a	photometry, potentiometry, fluorescence polarization/turbidimetric,
		latex particle enhanced
No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack	4 ves/1	4 no/n/a
<ul> <li>must load separate reag. pack for ea. spec./no. diff. assays in pack</li> <li>separate reag. pack for each test run</li> </ul>	yes/1 yes	no/n/a no
No. of different measured assays onboard simultaneously	n/a	36 tests plus applications for urine & CSF
No. of different assays programmed, calibrated at once	1	up to 999
No. of user-definable (open) channels/no. active simultaneously	none n/a/n/a	0/0 36/50_800 tosts
No. of different analytes for which system accommodates reag. containers onboard at once/tests per container set	n/a/n/a	36/50–800 tests
Shortest/median onboard reag. stability/refrigerated onboard	n/a/no	2 weeks/8–12 weeks/yes (12° C)
Multiple reag. configurations supported	no	yes
Reag. container placed directly on system for use	no p/a	yes
Instrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/	n/a n/a/n/a/n/a	no //
therapeutic drugs/special analytes		
Walkaway capacity in minutes/specimens/tests-assays	n/a/n/a/n/a	176/90/1,808
System is liquid or dry Uses disposable cuvettes/max. no. stored	dry no/n/a	liquid
Uses washable cuvettes/replacement frequency	no/n/a	yes/1,500 no/n/a
Minimum sample volume aspirated precisely at one time	10 µL	1μL
Supplied with UPS (backup power)/requires floor drain	no/no	no/no
Requires dedicated water system/water consumption in L per hour	no/none	no/2 L maximum
Noise generated in decibels Dedicated pediatric sample cup/dead volume	— n/a	-
Primary tube sampling/pierces caps on primary tubes	no/no	yes/no
Sample bar-code reading capability	no	yes (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	yes	yes
Bar-code placement per NCCLS standard Auto2A Onboard test auto inventory (determines volume in container)	— n/a	yes
Measures no. tests remaining/short sample detection/clot detection	n/a/yes/yes	yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	
Hemolysis/turbidity detection-quantitation		no/no
Dilution of patient samples onboard/automatic rerun capability	no/no	yes/yes
Sample volume can be reduced/increased to rerun out-of-linear- range high/low results	no/no	yes/yes
Autocalibration or autocalibration alert	no	yes
Calibrants stored onboard/multipoint calibration supported	no/yes	yes/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	6 mos/6 mos/6 mos/n/a	5 hrs/once per lot/each lot & 12 weeks/each lot & 12 weeks
Automatic shutdown/startup programmable	no/no	yes/yes
Stat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TC02	100 tests per hr	369 tests per hr
Sodium, potassium, chloride, TCO2, glucose, urea, creatinine     Album bili direct & total AST ALT ALD	100 tests per hr	369 tests per he
Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	100 tests per hr none	250 tests per hr none
How often QC required/onboard SW capability to review QC	every 24 hrs/no	24 hrs/yes
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/yes (addt'l cost)
Interfaces up and running in active user sites with		all major LIS vendors
Bidirectional interface capability	no	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays	yes vos	yes
Uses LOINC to transmit orders & results	yes —	yes —
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	yes —
Modem servicing available/can diagnose own malfunctions/	no/yes/yes	yes/yes/
determine malfunctioning component		
On-site time of svc. engineer/onboard error codes for troubleshooting	—/yes	—/yes
Mean time between failures/to repair failures Average time to complete maintenance by lab personnel	 daily: 5 min; weekly: 5 min; monthly: none	—/— daily: none; weekly: 5 min; monthly: none
Onboard maintenance records/maint. training demo module	no/no	yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/advanced oper. training avail.	1 day on-site/—	5 days at vendor offices/yes
Annual service contract cost (24 h/7 d)	-	-
Distinguishing features	disposable tips eliminate sample carryover; random access testing so chemistries can be run in any order, with no reag. prep.; indiv. packaged test slides elim. waste & facilitate rapid analysis; dry slide technology minimizes the effects of common interferences to provide precise, accurate results; wide ranges allow for fewer dilutions & repeats	unique reagent cassette eliminates reagent preparation; multiple tube sizes, microcups, and sample types on a single rack; menu consolidates testing including direct LDL, HbA1c, and lithium

ics Corp. 46250	Roche Diagnostics Corp. 9115 Hague Rd. Indianapolis, IN 46250
ms.roche.com	800-428-5074 www.us.labsystems.roche.com
12/1997	Cobas Mira Plus CC/1992
12/1997	\$50,000
	2,500/12,500
an-U.S./U.SGermany lom access/open reagent system	Switzerland/Switzerland/Germany-U.S. random access/open reagent system
ling	rack/benchtop
sq ft	26 x 29 x 23/4.63 sq ft
mmonia, amy. total & panc., AST, bili. total & direct,	ACP, alb., alk. phos., ALT, amy., amm., Apo A1 & B, AST, bili. direct &
t., cholinest., CK, CK-MB, CO <sub>2</sub> , crea., fruct., GGT, glu.,	total, BUN, Ca., chol., CK, CO <sub>2</sub> , crea., alcohol, iron TIBC, GGT, HDL
lact., LD, LD-1, LDL direct, lipase, Mg, phos., TIBC	direct, HDL, glu., LDH, LDL direct, Mg, phosphorus, TP, triglycerides,
ocainamide, TP, trig., T <sub>4</sub> , T-up, UIBC, UA, Na, K, CI, SLO, B-2-microgl., C3c, C4, ceru., CRP, ferr., fol.,	UA, fruct., HbA1c, amph., barb., benz., THC, coca., methad., methaq. opia., PCP, propoxy., dig., acetamin., salic, Na, K, CI by ISE
A/E/G/M, microalb., myo., prealb., RF, transferrin,	
gent., pheno., pheny., salicy., theo., tobra.,	
ol, amph., barb., benz., coca., methad., opia., PCP, Iso CSF and urine chemistries, D-dimer, soluble	
ptor	
	none
ight chains, %CDT, $lpha$ -1-glycoprotein, Apo A1, Apo B,	none
clos., lipoprotein A	
eine	none/information to be released at test launch none
entiometry/turbidimetric, latex particle enhanced,	photometry, potentiometry/n/a
	3
	no/n/a
nlications for uring & CSE	no max. 30
plications for urine & CSF	max. 30 104 + profiles & ratios
	104 + profiles & ratios/max. 30
	max. 30/40–50
(2–12°C)	6–8 hrs/30 days/yes (10–14° below ambient)
	yes
	yes, but requires some operator prehandling/prep.
	_/_/_/
	may 120 min/00/depende on test val
	max. 120 min/90/depends on test vol. liquid
	yes/—
0 stored on instrument)	no/n/a
	1 μL no/no
	no/4 L daily
	≤62 no
	yes/no
ransport, shortly before sample is aspirated (2 of 5	yes, as soon as tubes loaded & start key activated (2 of 5 interl.,
codes 39 & 128)/autodiscrimination	Codabar, codes 39 & 128)/autodiscrimination no
	—
necessary due to sampling method)	no no/wos/no
necessary due to sampling methody	no/yes/no yes
	no/no
	yes/yes yes/yes
	yesi yes
	yes
je (every 6 mos)/3–5 days/56 days	yes/yes every hr/30–60 days/—/n/a
, , , , , , , , , , , , , , , , , , ,	no/no
cimens	4 min, 15 specimens
imens	7 min, 9 specimens
cimens	7.5 min, 8 specimens none
	8 hrs, longest interval: daily/yes
	yes/no
	yes
ldt'l cost)	onboard & optional add-on (\$5,000, SW mftr: Antek, Fletcher
orders	Flora)/no
ndors	
	yes
	yes
	yes
	vec (limited)
	yes (limited) no
	no/—/—
	24 hrs/yes 4 mos/2 hrs
y: —; monthly: —	4 mos/2 hrs daily: 10 min; weekly: 10 min; monthly: 5 min
dit trail of who replaced parts)/yes	no/no
r offices/yes	4 days at vendor offices/no approx. \$9,000
	level detection of the sample & reag.; user friendliness of entire system
, mashi open system dependability and throughput	555011
	software with easy stat function provides instant stat ne Hitachi open system dependability and throughput