Chemistry analyzers (for low-volume laboratories)

How the smaller chemistry analyzers stack up

Raymond D. Aller, MD

On pages 75–90 is CAP TODAY's lineup of chemistry analyzers for low-volume laboratories. For 18 analyzers manufactured by 11 vendors, we display a variety of data on what the instruments can do and how they work.

Some of what laboratories have to consider in selecting a small-scale chemistry analyzer is quite distinct from what they should consider in choosing the larger chemistry analyzers (which CAP TODAY will profile in the July issue). In the central, high-volume laboratory, expanding the menu handled on the large analyzer is advantageous. In the smaller (rapid response or clinic) laboratory, the opposite approach is appropriate. Wherever possible, limit the range of assays installed on your analyzers to those analytes that can have immediate impact on patient management. Less commonly ordered tests and those that produce results that are often redundant should be referred to the regional or core laboratory. For example, unless the practice specializes in liver disease, choose either AST or ALT for the local menu—but not both. Narrowing the menu will eliminate the costs associated with standardizing and controlling the quality of these less common or less essential analytes. Also, a limited menu will help clinicians focus their test choice on a few key analytes; they are less likely to order semi-redundant assays if they know these assays will entail longer turnaround times. Streamlining and minimizing the local test menu requires close cooperation with and the support of your clinical staff.

One characteristic not yet widespread in this class of analyzers is the

transmission of a standardized LOINC test code to identify each result. The accepted international standard for test codes, LOINC (www.regenstrief.org/loinc) facilitates plug-and-play connection of the instrument into the laboratory's information system. Once most instruments use these standard codes and LIS vendors build LOINC awareness into their instrument interface modules and test dictionaries, it will no longer be necessary to create a translation table every time a new laboratory instrument is installed. Indeed, it will become evermore feasible for users to install their own instrument interfaces from a library provided by LIS vendors. Incidentally, we can also hope LIS vendors will eventually charge far less than they do now for each instrument interface.

All of the information presented on pages 75–90 was supplied by the instrument vendors in response to CAP TODAY's questions. Verify key information for any analyzer you and your laboratory's staff may acquire. In addition, ask the vendors for a list of laboratories currently using the instrument. Call a few of these sites, and ask what the instrument's pros and cons are. Is it easy for technologists (other than the primary user) to use? Is downtime infrequent? Is the vendor's service organization responsive, and does it resolve instrument malfunctions rapidly?

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Part 1 of 9	Abaxis Inc. Ron Blasig ronblasig@abaxis.com	Abbott Laboratories Eric Perreault eric.perreault@abbott.com
	1320 Chesapeake Terrace	4A Crosby Dr.
	Sunnyvale, CA 94089 408-745-6804	Bedford, MA 01730 781-276-4797
See accompanying comments on previous page	www.abaxis.com	www.abbott.com
Name of instrument/first year sold in U.S.	Piccolo/1995	i-Stat Portable Clinical Analyzer/1995
.ist price No. units in clinical use in U.S./outside U.S.	\$11,250 400/200	\$7,900 6,700/2,500
Country where designed/manufactured/where reagents mftd.	U.S./U.S./U.S.	U.S./U.S./Canada
Operational type/reagent type	self-contained disc with multitest reag. panel	n/a/self-contained single-use cartridges-packages-slides
Sample handling system/model type Dimensions (H x W x D)/instrument footprint	disc loaded directly into instrument/benchtop 9.5 x 6 x 11.5 in./1 sq. ft.	n/a/handheld-portable 8.26 x 2.52 x 2.05 in./n/a
Tests available on instrument in U.S.	ALP, ALT, AST, GGT, amylase, albumin, total protein, bilirubin total, BUN, creatinine, calcium, cholesterol, glucose, uric acid, sodium, creatine kinase, potassium, TCO ₂	sodium, potassium, chloride, ionized calcium, BUN, glucose, creatinine, lactate, Hct, pH, pCO $_2$, pO $_2$, ACT $_c$, Calculated: Hb, TCO $_2$, HCO $_3$, BEecf, anion gap, SO $_2$
Tests cleared but not clinically released	chloride	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 none	ACT _k none
Research-use-only assays/tests in development	none/magnesium, phosphorus, triglycerides, HDL	none/PT, aPTT, CK-MB, myoglobin, troponin
User-defined methods implemented for what analytes	none	none
Methods supported/immunoassay methods No. of direct ion selective electrode channels	photometry/n/a n/a	potentiometry/n/a 10
must load separate reag. pack for ea. spec./no. diff. assays in pack	yes/6–12 analytes (chemistries) for 5 diff. chem./ elec. profiles; reag. self-contained with each disc	yes/1-7
separate reag. pack for each test run	no	yes
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	18 12	7 7
No. of user-definable (open) channels/no. active simultaneously	0/n/a	n/a/n/a
No. of different analytes for which system accommodates reag, containers onboard at once/tests per container set	6-12/self-contained disc with reagents 6-12	1 cartridge at a time, each up to 7 tests
Shortest/median onboard reag. stability/refrigerated onboard	1 yr/—/no	14 d at room temp./no
Multiple reag. configurations supported Reag. container placed directly on system for use	yes yes	no n/a
Instrument has same capabilities when 3rd-party reag. used	no	n/a
Reag. only cost per reportable result for standard chemistries/ therapeutic drugs/special analytes	\$1.33/n/a/n/a	\$3–\$9/n/a/n/a
Walkaway capacity in minutes/specimens/tests-assays	<15/1/12	approx. 2 min for any cartridge type
System is liquid or dry Jses disposable cuvettes/max. no. stored	reconstitutes onboard no/n/a	depends on component no/n/a
Jses disposable cuvettes/riax. no. stored Jses washable cuvettes/replacement frequency	no/n/a	no/n/a
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain	~100 µL no/no	95 μL no/no
Requires dedicated water system/water consumption	no/n/a	no/n/a
Noise generated Dedicated pediatric sample cup/dead volume	none no	none no
Primary tube sampling/pierces caps on primary tubes	no/n/a	no/n/a
Sample bar-code reading capability Reagent bar-code reading capability	no yes	no n/a
Bar code placement per NCCLS standard Auto2P	no	n/a
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection	yes n/a/yes/yes	no no/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	yes	yes
Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability	yes/yes yes/no	yes/yes no/no
Sample volume can be reduced/increased to rerun out-of-linear-	n/a/n/a	no/no
range high/low results Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/multipoint calibration supported	yes/yes	yes/no
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	self-calibrated onboard/disc n/a/no	each test/each test/n/a/n/a to start, insert cartridge/automatically powers down
Stat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TC02	15 min, 4 specimens	2 min, n/a 2 min, n/a
 Sodium, potassium, chloride, TCO2, glucose, urea, creatinine Album., bili. direct & total, AST, ALT, ALP 	15 min, 4 specimens 15 min, 4 specimens (total AST only, no phos.)	2 min, n/a n/a/n/a
Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC	n/a	n/a
Onboard real-time QC/support multiple QC lot nos. per analyte	per disc/yes yes/yes	24 hrs, longest interval: each new lot/yes yes/yes
QC results transferred automatically to LIS	yes	yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/no	optional add-on (\$23,000 including LIS interface, SW mftr:
nterfaces up and running in active user sites with	n/a	Abbott/Neon)/yes (addt'l cost) all systems
Bidirectional interface capability	no	yes (broadcast download & host query)
Test results transmitted to LIS as soon as chem. time complete	yes	yes
LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	yes no	yes yes
Lab can control analyzer remotely	no	no
nterface avail. (or will be) to automated specimen handling system	no	n/a
Modem servicing available/can diagnose own malfunctions/ determine malfunctioning component	no/no/no	yes/yes/yes
On-site time of svc. engineer/onboard error codes for troubleshooting	24 hr loaner/yes	replacement/yes
Mean time between failures/to repair failures	—/— daily: none_weekly: none_monthly: none	not determined
Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module	daily: none, weekly: none, monthly: none/_	daily: none, weekly: none, monthly: none n/a/n/a
Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes 1 yr warranty, >1 yr \$1,200	yes (depends on need)/yes \$300
Distinguishing features	compact chemistry system using a few drops of whole blood, serum,	handheld portable analyzer
g g	or plasma provides turnaround of results at point of care, including hands-on time, in 15 min	

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Mean time between failures/to repair failures not determined/24 hrs daily: none, weekly: none, monthly: none normal mintenance records/maint. training demo module raining provided with purchase/advanced oper. training avail. nouncal service contract cost (24 h/7 d) not determined/24 hrs daily: none, weekly: none, monthly: none n/a/n/a -/yes 4 d at vendor offices/yes inquire from vendor	Mean time between failures/to repair failures not determined/24 hrs daily: none, weekly: none, monthly: none nonboard maintenance records/maint. training demo module raining provided with purchase/advanced oper. training avail. nonboard maintenance records/maint. training demo module raining provided with purchase/advanced oper. training avail. nonboard maintenance records/maint. training demo module n/a/n/a -/yes 4 d at vendor offices/yes inquire from vendor		
Average time to complete maintenance by lab personnel daily: none, weekly: none, monthly: none nonthly: 30 min, weekly: 30 min, monthly: 30 min yes (includes audit trail of who replaced parts)/no yes (includes audit trail of who replaced parts)/no 4 d at vendor offices/yes inquire from vendor	Average time to complete maintenance by lab personnel daily: none, weekly: none, monthly: none daily: 3 min, weekly: 30 min, monthly: 30 min yes (includes audit trail of who replaced parts)/no yes (includes audit trail of who replaced parts)/no 4 d at vendor offices/yes inquire from vendor		
Onboard maintenance records/maint. training demo module n/a/n/a yes (includes audit trail of who replaced parts)/no Fraining provided with purchase/advanced oper. training avail. —/yes 4 d at vendor offices/yes Annual service contract cost (24 h/7 d) \$420 inquire from vendor	Onboard maintenance records/maint. training demo module n/a/n/a yes (includes audit trail of who replaced parts)/no Fraining provided with purchase/advanced oper. training avail. —/yes 4 d at vendor offices/yes Annual service contract cost (24 h/7 d) \$420 inquire from vendor		
raining provided with purchase/advanced oper. training avail. —/yes 4 d at vendor offices/yes Annual service contract cost (24 h/7 d) \$420 inquire from vendor	Training provided with purchase/advanced oper. training avail. —/yes 4 d at vendor offices/yes Annual service contract cost (24 h/7 d) \$420 inquire from vendor		
			4 d at vendor offices/yes
Distinguishing features handheld portable analyzer easy-to-use, multitasking software; closed-tube sampling	Distinguishing features handheld portable analyzer easy-to-use, multitasking software; closed-tube sampling		inquire from vendor
casy to assymmetration of social factoring software, crossed table sampling	Cusy to use, manuasking sortiface, closed-tube sumpling		easy-to-use, multitasking software: closed-tube sampling
		eld portable analyzer	
		t t	n/a n/a st interval: 24 hrs; longest interval: each new lot/yes s al add-on (\$45,000 including LIS interface, SW mftr: //Neon)/yes tems roadcast download & host query) ss/yes ement/yes termined/24 hrs none, weekly: none, monthly: none a

Part 3 of 9	Alfa Wassermann Inc. Monty Hatcher info@alfawassermannus.com	Awareness Technology Inc. C. Schneider ces@awaretech.com
	4 Henderson Drive West Caldwell, NJ 07006	P.O. Box 1679 Palm City, FL 34991
See accompanying comments on page 74	800-220-4488 alfawassermannus.com	561-283-6540 www.awaretech.com
lame of instrument/first year sold in U.S.	NExCT Clinical Chemistry System/1998	ChemWell/1999
.ist price No. units in clinical use in U.S./outside U.S.	\$39,900 90+/60+	\$25,000 2/140
Country where designed/manufactured/where reagents mftd. Description of the country where reagents mftd.	U.S./U.S./U.S. batch, random access, discrete, cont. random access, stat/closed reag. system with open reag. system channels	U.S./U.S./open system batch, random access/open reagent system
Sample handling system/model type Dimensions (H x W x D)/instrument footprint	ring with segments (15–30 samples/seg.)/benchtop 15.75 x 27.25 x 22.50 in. (analyzer only)/4.5 sq. ft. (full system)	rack/benchtop 16 x 34 x 20 in./—
Tests 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 ₂	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 cholester magnesium, inorganic phosphorus, total protein, triglyceride, urea (BUN), uric acid
Fests cleared but not clinically released Fests not available in U.S. but submitted for 510(k) clearance	none none	n/a Sigma Diagnostics assays include: albumin (bromcresol green & purple), alkaline phosphatase, ALT, AST, cholesterol, creatinine, gG
Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes	none none/none acetaminophen, alcohol, CRP, CK-MB, folate, fructosamine, HbA1c, lipase, salicylate, transferrin, B ₁₂	glucose, total protein, triglycerides, BUN, uric acid unlimited, open system any colorimetric (340–700 nm), open system/n/a all colorimetric end points and kinetic assays; open systems
Methods supported/immunoassay methods	photometry/CEDIA, turbidimetric, homogeneous, EIA	photometry/EIA-microplate format
No. of direct ion selective electrode channels • must load separate reag, pack for ea. spec./no. diff. assays in pack	0 (optional ISE interface)	n/a no
separate reag. pack for each test run	no	no
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	20 200	up to 27 unlimited
No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates	9/9 20/40–60 tests per bottle	unlimited/up to 27 27/assay dependent
reag. containers onboard at once/tests per container set Shortest/median onboard reag. stability/refrigerated onboard	120 hrs/30 d/no	n/a/n/a/no
Multiple reag. configurations supported Reag. container placed directly on system for use	yes yes	yes reagent dependent
nstrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/	yes \$.23/TBD/TBD	yes assay dependent
therapeutic drugs/special analytes Valkaway capacity in minutes/specimens/tests-assays	30/150/58	not limited/96/not limited
System is liquid or dry Jses disposable cuvettes/max. no. stored	liquid yes/58	liquid chemistry system yes/96
Jses washable cuvettes/replacement frequency	no/n/a	yes/weekly
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain	3 µL no/no	2 μL no/no
Requires dedicated water system/water consumption Noise generated	no/n/a	no/<1 L per hr 60 dB
Dedicated pediatric sample cup/dead volume Primary tube sampling/pierces caps on primary tubes	— yes/≤50 μL yes/yes	no no/no
Sample bar-code reading capability Reagent bar-code reading capability	yes, as sample is being aspirated (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination	yes/by handheld scanner as tubes are loaded onto instrument
Bar code placement per NCCLS standard Auto2P	yes no	no no
Onboard test auto inventory (determines volume in container) Weasures 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 Dilution of patient samples onboard/automatic rerun capability	no/no yes/yes	no/no yes/yes
Sample volume can be reduced/increased to rerun out-of-linear- range high/low results	yes/no	yes/no
Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported	yes no/yes	yes yes/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	n/a/30 d/TBD/TBD no/no	n/a/user defined/user defined yes/yes
Stat 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)	sodium and potassium not available
Sodium, potassium, chloride, TC02, glucose, urea, creatinine	<6 min (with offline ISE), 40 specimens (with offline ISE)	sodium and potassium not available
Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample	9 min, 21 specimens immediate response, as soon as 10 sec	5.5 min/28 15 sec.
low often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte	daily/yes yes/yes	user defined/yes yes/yes
C results transferred automatically to LIS	yes yes	no
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/no	onboard (Awareness Technology Inc.)/no
nterfaces up and running in active user sites with	Schuyler House, Antek, others	n/a
Bidirectional interface capability Fest results transmitted to LIS as soon as chem. time complete	yes (broadcast download) yes	no no
.IS interface operates simultaneously with running assays Jses LOINC to transmit orders & results	yes yes	n/a n/a
.ab can control analyzer remotely nterface avail. (or will be) to automated specimen handling system	no no	no no
Wodem servicing available/can diagnose own malfunctions/	no/yes/yes	yes/yes/yes
determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting	<24 hrs/yes	48 hrs in U.S./—
Mean time between failures/to repair failures	—/<1 hr	not specified/—
Average time to complete maintenance by lab personnel Onboard 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: <10 min, weekly: <30 min, monthly: <1 hr no/—
Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	4 d at vendor offices/yes inquire from vendor	2 d on-site, 3 d at vendor offices/yes \$4,000/yr
		ChemWell can also be programmed to perform ELISA assays in the

Part 4 of 9	Careside Inc. Grant Frazier gfrazier@careside.com 6100 Bristol Parkway Culver City, CA 90230 310-338-6767 ext. 124	Dade Behring Inc. 1717 Deerfield Deerfield, IL 60015 847-267-5300 www.dadebehring.com
See accompanying comments on page 74	www.careside.com	
Name of instrument/first year sold in U.S.	Careside Analyzer/1999	Dimension Xpand Integrated Chemistry System/2001
List price No. units in clinical use in U.S./outside U.S.	\$18,000 —/—	_ _/_
Country where designed/manufactured/where reagents mftd. Operational type/reagent type	U.S./U.S./U.S. random access, discrete/self-contained single-use cartridges	U.S./U.S./U.S. continuous random access/self-contained multi-use cartridges-
Sample handling system/model type	unit-of-use test cartridge/benchtop	pakages-slides & open reagent system sample segments/floor-standing
Dimensions (H x W x D)/instrument footprint	16 x 14 x 12 in./~1 sq. ft.	53 x 51 x 31/11
Tests available on instrument in U.S.	electrochemistry: anion gap, chloride, potassium, sodium; chemistry: A/G ratio, albumin, ALP, ALT, ALT/AST ratio, ammonia, amylase, AST, bilirubin direct & total, bilirubin indirect (calc.), BUN, BUN/creatinine ratio, calcium total, carbon dioxide, HDL-chol., LDL-chol. (calc.), chol. total, chol./HDL-chol. ratio, CK, CK-MB, % CK-MB, creatinine, GGT, globulin (calc.), glucose, LDH, magnesium, osmolality (calc.), phosphorus, total protein, triglycerides, uric acid, cholinesterase; hematology: hemoglobin, hematocrit (calc.); coagulation: prothrombin time	70-plus methods including TOM, immunoassys, plasma proteins, DAUs and general chemistry
Fests cleared but not clinically released Fests not available in U.S. but submitted for 510(k) clearance	none	n/a lithium, cyclosporin, early detect. PSA
Tests not available in U.S. but available in other countries	none	cyclosporin
Research-use-only assays/tests in development	none/ionized calcium, aPTT, fibrinogen, TT, digoxin, phenytoin, theoph.	n/a/HbaLC, Li, RF, T3, LDL, procainzmide
Jser-defined methods implemented for what analytes	none	n/a
Methods supported/immunoassay methods	photometry, potentiometry, optical transmission, reflectance/n/a	photometry, potentiometry, turbidimetric assays/Petinia, Emit, Acn
No. of direct ion selective electrode channels	3	mag. part. sep. 3
 must load separate reag. pack for ea. spec./no. diff. assays in pack separate reag. pack for each test run 	no/n/a 1 pack for 3 tests (Na, K, Cl)	no no
No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once	n/a total menu	47 75+
lo. of user-definable (open) channels/no. active simultaneously	0/n/a	10/10
lo. of different analytes for which system accommodates reag, containers onboard at once/tests per container set	n/a/n/a	47/480
Shortest/median onboard reag. stability/refrigerated onboard //ultiple reag. configurations supported	n/a/n/a/no	24 hrs/5 d/yes (2–8°C)
Reag. container placed directly on system for use	yes yes	no yes
nstrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/	n/a varies/n/a/n/a	yes n/a
therapeutic drugs/special analytes		
Valkaway capacity in minutes/specimens/tests-assays System is liquid or dry	12/1/8 dry	420/60/1,800 liquid & reconstitutes onboard
Jses disposable cuvettes/max. no. stored Jses washable cuvettes/replacement frequency	no/n/a no/n/a	yes/12,000 —/—
Minimum sample volume aspirated precisely at one time	n/a	2 μL
Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption	no/no no/none	yes/no yes/2 L per hr
Noise generated Dedicated pediatric sample cup/dead volume	<60 decibels no	<70 decibels no/30 µL with standard cup
Primary tube sampling/pierces caps on primary tubes	no/n/a	yes/no
Sample bar-code reading capability	no	yes/on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2P	yes n/a	yes yes
Onboard test auto inventory (determines volume in container)	n/a	yes
Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reag, for aspir. & analysis	n/a/yes/no n/a	yes/yes/no no
Hemolysis/turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-	no/no no/no	yes/yes yes/no
range high/low results Autocalibration or autocalibration alert	yes	yes
Calibrants stored onboard/multipoint calibration supported	no/no	no/yes
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	calibration verification every 6 mos/n/a/n/a no/no	2 hrs (auto)/90 d/60 d/60 d —/—
Stat time to completion of all analytes, throughput per hr. for:		
Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine	~10 min, 1 specimen (Na, K, Cl: 3–5 min) ~12 min, 1 specimen	2 min, 62 4 min, 62
Album., bili. direct & total, AST, ALT, ALP	~12 min, 1 specimen	8 min, 42
Fypical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC	immediate daily for electronic QC/yes	60 sec steady state, 2 min from standby daily/yes
Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	yes/yes yes	yes/— yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/yes Careside Connect DMS (addt'l cost)	onboard/no
nterfaces up and running in active user sites with	_	interfaces available for all major LIS vendors
Bidirectional interface capability Fest results transmitted to LIS as soon as chem. time complete	yes yes	yes (broadcast download & host query) yes
LIS interface operates simultaneously with running assays	yes	yes
Jses LOINC to transmit orders & results	yes	no no
ab can control analyzer remotely nterface avail. (or will be) to automated specimen handling system	yes no	no no
Modem servicing available/can diagnose own malfunctions/	no/yes/yes	yes/yes/yes
determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting	replacement/yes	situation dependent/yes
Mean time between failures/to repair failures Average time to complete maintenance by lab personnel	TBD/TBD daily: none, weekly: none, monthly: none	n/a/n/a daily: 5 min, weekly: n/a, monthly: 20 min
Onboard maintenance records/maint. training demo module	n/a/n/a	no/no
Fraining provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	yes/yes TBD	4 d at vendor offices/yes n/a
Distinguishing features	POC test device with the most comprehensive menu	specifically designed for low-volume testing laboratories; the analyzer performs the most requested chemistry and heterogeneo immunoassay tests on a single, easy-to-use instrument

Part 5 of 9	Elan Diagnostics 2 Thurber Blvd. Smithfield, RI 02917	Elan Diagnostics 2 Thurber Blvd. Smithfield, RI 02917
Con accompanying comments on page 74	401-233-3526 elandiagnostics.com	401-233-3526 elandiagnostics.com
See accompanying comments on page 74		
Name of instrument/first year sold in U.S. List price	Atac 6000 Chemistry System/1990	Atac 8000 Random Access Chemistry System/1995
No. units in clinical use in U.S./outside U.S.	_ _/_	_/_ _/_
Country where designed/manufactured/where reagents mftd. Operational type/reagent type	—/—/— discrete/open reagent system	—/—/— continuous random access/open reagent system
Sample handling system/model type Dimensions (H x W x D)/instrument footprint	sample wheel/benchtop 21 x 23 x 18.5 in./~3 sq. ft.	sample wheel/benchtop 19.5 x 39 x 20.5 in./5.5 sq. ft.
Tests available on instrument in U.S.	albumin, ALP, Apo A, Apo B, amylase, bilirubin direct & total, BUN, calcium, cholesterol, CPK, creatinine, fructosamine, GGT, glucose, AST, ALT, direct HDL, iron-total, phos., LDH, magnesium, total protein, triglycerides, uric acid, sodium, potassium, chloride-ISE	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, total iron, TIBC, LDH, magnesium, microalbumin, phosphorus, total protein, triglycerides, uric acid [CO ₂ , chloride, potassium, sodium—ISE]
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	none
Research-use-only assays/tests in development	none none/none	none none/none
User-defined methods implemented for what analytes	none	none
Methods supported/immunoassay methods	photometry, potentiometry/n/a	photometry, potentiometry/n/a
No. of direct ion selective electrode channels	3	4
must load separate reag. pack for ea. spec./no. diff. assays in pack separate reag. pack for each test run	no/n/a no	no/n/a no
No. of different measured assays onboard simultaneously	16	40
No. of different assays programmed, calibrated at once	16 48/16	40 320/40
No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates	16/30	40/150
reag. containers onboard at once/tests per container set		
Shortest/median onboard reag. stability/refrigerated onboard Multiple reag. configurations supported	6 hrs/2 d/no no	5 d/12 d/yes yes
Reag. container placed directly on system for use	no, requires operator prehandling/prep.	yes
Instrument has same capabilities when 3rd-party reag. used	no	yes
Reag. only cost per reportable result for standard chemistries/ therapeutic drugs/special analytes	-/-/-	_/_/_
Walkaway capacity in minutes/specimens/tests-assays	_/_/96	240+/50/1,200
System is liquid or dry Uses disposable cuvettes/max. no. stored	liquid yes/96	liquid no/n/a
Uses washable cuvettes/replacement frequency	no/n/a	yes/5 yrs
Minimum sample volume aspirated precisely at one time	2 μL	2 μL
Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption	no/no no/yes	yes/no no/yes
Noise generated	-	_
Dedicated pediatric sample cup/dead volume Primary tube sampling/pierces caps on primary tubes	no no/no	no yes/no
Sample bar-code reading capability	no	yes, on sample transport, shortly before sample is aspirated
Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2P	-	yes —
Onboard test auto inventory (determines volume in container)	no	yes
Measures no. tests remaining/short sample detection/clot detection	no/no/no	yes/yes/no
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/turbidity detection-quantitation	no no/no	yes —/—
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 Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	no/no 4 hrs/daily/n/a/n/a	no/yes 4 hrs/daily/n/a/n/a
Automatic shutdown/startup programmable	no/—	yes/yes
Stat time to completion of all analytics throughput nor he for		
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02	- ,-	60 sec, 60 specimens
Sodium, potassium, chloride, TC02, glucose, urea, creatinine	- ,-	6 min, 45 specimens
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
How often QC required/onboard SW capability to review QC	2 levels 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 yes
-	·	•
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/yes (addt'l cost)	onboard/yes (addt'l cost)
Interfaces up and running in active user sites with	Antek, Fletcher-Flora, Dynamedix, Schuyler House, Medcom, Costello,	Antek, Fletcher-Flora, Dynamedix, Schuyler House, Medcom, Costello,
	Psyche	Psyche
Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete	yes (host query) yes	yes (broadcast download & host query) yes
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders & results	no .	no
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	no no
Modem servicing available/can diagnose own malfunctions/	no/no/no	no/yes/yes
determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting	within 24 hrs/yes	within 24 hrs/yes
Mean time between failures/to repair failures	_/_	_/_
Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module	daily: 5 min, weekly: 15 min, monthly: 15 min no/—	daily: none, weekly: 15 min, monthly: 30 min yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/advanced oper. training avail.	no/— 5 d on site/no	yes (includes audit trail of who replaced parts)/yes 5 d on site, 5 d at vendor offices/yes
Annual service contract cost (24 h/7 d)	=	——————————————————————————————————————
Distinguishing features	batch mode with broad test menu; data management system; high level of flexibility & performance	475 tests/hr of general chemistry & ISE; reusable glass cuvettes, ensuring low reag. cost; onboard refrig.
		•

	Hemagen Diagnostics Inc.	Nova Biomedical Corp.
Part 6 of 9	Tricia Thurrell tthurrell@hemagen.com	Nova Sales Department
	9033 Red Branch Rd. Columbia, MD 21045	200 Prospect St. Waltham, MA 02454-9141
	800-436-2436	800-458-5813
See accompanying comments on page 74	www.hemagen.com	info@novabiomedical.com
Name of instrument/first year sold in U.S.	Analyst Benchtop Chemistry System/1986	Stat Profile M/1998
List price No. units in clinical use in U.S./outside U.S.	\$5,500 - \$9,900 —/—	\$55,750 —/—
Country where designed/manufactured/where reagents mftd.	France-U.S./U.S./U.S.	U.S./U.S./U.S.
Operational type/reagent type	batch/self-contained single-use cartridges-packages-slides, rotors —/benchtop	random access/self-contained multiuse packages stat sampling directly from sample container/benchtop
Sample handling system/model type Dimensions (H x W x D)/instrument footprint	8.5 x 25 x 13 in./2.25 sq. ft.	
· · · · · · · · · · · · · · · · · · ·	·	20.5 x 19.2 x 20.7 in./2.75 sq. ft.
Tests available on instrument in U.S.	ALP, GGT, GPT, Got, BUN, glucose, calcium, cholesterol, triglycerides, amylase, uric acid, total bilirubin, total protein, HDL-chol.	sodium, potassium, chloride, glucose, BUN, ionized magnesium, ionized calcium, lactate, Hct, hemoglobin, pH, pCO $_2$, pO $_2$, SO $_2$ %
Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance	none albumin, direct bilirubin, CO ₂ , potassium	none none
Tests not available in U.S. but available in other countries	none	none
Research-use-only assays/tests in development Jser-defined methods implemented for what analytes	none/T ₄ none	none/none none
<u> </u>	nhatamatru/n/a	natantiamatry antical reflectance/n/a
Methods supported/immunoassay methods No. of direct ion selective electrode channels	photometry/n/a n/a	potentiometry, optical, reflectance/n/a 12
must load separate reag. pack for ea. spec./no. diff. assays in pack separate reag. pack for each test run	yes/14 per rotor per patient	no/n/a
No. of different measured assays onboard simultaneously	<u>no</u>	no 14
No. of different assays programmed, calibrated at once	14	14
lo. of user-definable (open) channels/no. active simultaneously lo. of different analytes for which system accommodates	—/— 14/14	0/n/a 1/(@ 14,700 tests/mo): 6,300 tests
reag. containers onboard at once/tests per container set		
Shortest/median onboard reag. stability/refrigerated onboard Nultiple reag. configurations supported	—/—/no —	21 d/21 d/no n/a
Reag. container placed directly on system for use	yes	yes
nstrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/	no	n/a
teag. only cost per reportable result for standard chemistries/ therapeutic drugs/special analytes	—/—/—	standard chemistries: @35 sam/d: \$0.40 (14-test panel); bundled instr., reag., maint. cost: \$1.39 (14-test panel)
Valkaway capacity in minutes/specimens/tests-assays	10/1/14	n/a
system is liquid or dry Ises disposable cuvettes/max. no. stored	dry no (uses rotors)	n/a no/n/a
Ises washable cuvettes/replacement frequency	no/n/a	n/a
finimum sample volume aspirated precisely at one time upplied with UPS (backup power)/requires floor drain	10 μL & 80 μL	150 µL
Requires dedicated water system/water consumption	no/no no/n/a	no/no no/n/a
Voise generated		minimal
Dedicated pediatric sample cup/dead volume Primary tube sampling/pierces caps on primary tubes	no no/no	n/a yes/no
Sample bar-code reading capability	no	yes, by handheld scanner as tubes are loaded onto instrument (2 of
Reagent bar-code reading capability	yes	interl., UPC, Codabar, codes 39 & 128)/autodiscrimination alternate method
Bar code placement per NCCLS standard Auto2P	_	n/a
Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection	no no/no/no	yes yes/yes/yes
Automatic detection of adequate reag. for aspir. & analysis	no	yes/ yes/ yes
Hemolysis/turbidity detection-quantitation 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	no/no no/no
range high/low results		
Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported	no no/—	yes yes/n/a
ypical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse automatic shutdown/startup programmable	n/a/60 d/n/a/n/a no/no	2 hrs/2 hrs/n/a/n/a n/a/n/a
11. 0	110/110	IVA/IVA
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO2	_ ,_	75 sec, 35 specimens
Sodium, potassium, chloride, TC02, glucose, urea, creatinine	—, — 10 min, 6 specimens (glu, urea, crea)	75 sec, 35 specimens
Album., bili. direct & total, AST, ALT, ALP Sypical time delay from ordering stat test to aspir. of sample	10 min, 6 specimens	n/a 9 sec
low often QC required/onboard SW capability to review QC	 _/_	9 sec CLIA minimum/yes
Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	no/no	no/yes yes
ata mgmt. capability/instrument vendor supplies LIS interface	—/yes (included in price)	onboard & optional add-on (\$9,225; SW mftr: Nova)/no
. , ,		•
nterfaces up and running in active user sites with	in development	most LIS vendors incl. Cerner, Sunquest, HBO, Soft, others
Bidirectional interface capability	_	yes
est results transmitted to LIS as soon as chem. time complete IS interface operates simultaneously with running assays	_	yes no
lses LOINC to transmit orders & results	_	no
ab can control analyzer remotely nterface avail. (or will be) to automated specimen handling system		yes no
lodem servicing available/can diagnose own malfunctions/	no/yes/yes	yes/yes/yes
determine malfunctioning component		
On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures	most troubleshooting via phone/yes 14–16 mos/—	<8 business hrs/yes —/—
Average time to complete maintenance by lab personnel	daily: 2 min, weely: 15 min, monthly: 30 min	daily: <2 min, weekly: <5 min, monthly: <5 min
Onboard maintenance records/maint. training demo module Fraining provided with purchase/advanced oper. training avail.	no/—	no/no
training provided with hirchass/advanced open training avail	2 d on-site/yes \$1,000	3 d on-site/yes call for pricing
Annual service contract cost (24 h/7 d) Distinguishing features	uses only 90 µL of sample & requires <60 sec of prep work; minimal maintenance required	combines up to 14 onboard critical care tests; only combined bloo
Annual service contract cost (24 h/7 d)	uses only 90 µL of sample & requires <60 sec of prep work; minimal maintenance required	combines up to 14 onboard critical care tests; only combined bloo gas analyzer with BUN & iMg

	Nova Biomedical Corp. Nova Sales Department	Nova Biomedical Corp. Nova Sales Department
	200 Prospect St.	200 Prospect St.
	Waltham, MA 02454-9141	Waltham, MA 02454-9141
ee accompanying comments on page 74	800-458-5813 info@novabiomedical.com	800-458-5813 info@novabiomedical.com
ame of instrument/first year sold in U.S. st price	Stat Profile M7/1999 \$55,750	Nova 16/1995 \$22,500–\$25,500
o. units in clinical use in U.S./outside U.S.	_/_ US /US /US	_/_
ountry where designed/manufactured/where reagents mftd. perational type/reagent type	U.S./U.S./U.S random access/self-contained multiuse packages	U.S./U.S./U.S. batch, random access/self-contained multiuse packages
	stat sampling directly from sample container/benchtop	40-position tray, stat sampling directly from sample
ample handling system/model type mensions (H x W x D)/instrument footprint	20.5 x 19.2 x 20.7 in./2.75 sq. ft.	container/benchtop 20.5 x 19.2 x 20.7 in./2.75 sq. ft.
ests available on instrument in U.S.	sodium, potassium, chloride, glucose, BUN, creatinine, ionized	<u> </u>
ests available on instrument in 0.5.	calcium, lactate, Hct, hemoglobin, pH, pCO ₂ , pO ₂ , SO ₂ %	sodium, potassium, chloride, total CO ₂ , glucose, BUN, creatinine, I
ests cleared but not clinically released	none	none
ests not available in U.S. but submitted for 510(k) clearance	none	none
ests not available in U.S. but available in other countries esearch-use-only assays/tests in development	none none/none	none none/none
ser-defined methods implemented for what analytes	none	none
ethods supported/immunoassay methods	potentiometry, optical, reflectance/n/a	potentiometry/n/a
o. of direct ion selective electrode channels	12	8
 must load separate reag. pack for ea. spec./no. diff. assays in pack separate reag. pack for each test run 	no/n/a no	no/n/a no
o. of different measured assays onboard simultaneously	14	8
o. of different assays programmed, calibrated at once o. of user-definable (open) channels/no. active simultaneously	14 0/n/a	8 0/n/a
o. of different analytes for which system accommodates	1/(@14,700 tests/mo): 6,300 tests	1/(@ 8,000 tests/mo): 2,700 tests
reag. containers onboard at once/tests per container set nortest/median onboard reag. stability/refrigerated onboard	21 d/21 d/no	21 d/21 d/no
ultiple reag. configurations supported	n/a	n/a
eag. container placed directly on system for use	no, requires oper. prehandling/prep. (remove clip from sealed bag & mix)	no, requires prehandling (remove clip from sealed bag & mix)
strument has same capabilities when 3rd-party reag. used	n/a	n/a
eag. only cost per reportable result for standard chemistries/ therapeutic drugs/special analytes	standard chemistries: @35 sam/d: \$0.40 (14-test panel); bundled instr.; reag., maint. cost: \$1.39 (14-test panel)	standard chemistries: @25 sam/d: \$0.40 (8-test panel); bundled instr., reag., maint. cost per result: \$0.92 (8-test panel)
alkaway capacity in minutes/specimens/tests-assays	n/a	60 per tray/40 per tray/280 per tray
ystem is liquid or dry ses disposable cuvettes/max. no. stored	n/a	n/a
ses disposable cuvettes/max. no. stored ses washable cuvettes/replacement frequency	no/n/a n/a	no/n/a n/a/n/a
inimum sample volume aspirated precisely at one time	150 μL	385 μL
upplied with UPS (backup power)/requires floor drain equires dedicated water system/water consumption	no/no no/n/a	no/no no/n/a
pise generated	minimal	minimal
edicated pediatric sample cup/dead volume imary tube sampling/pierces caps on primary tubes	n/a yes/no	n/a yes/no
ample bar-code reading capability	yes, by handheld scanner as tubes are loaded onto instrument (2 of 5	yes, by handheld scanner as tubes are loaded onto instrument (2)
eagent bar-code reading capability	interl., UPC, Codabar, codes 39 & 128)/autodiscrimination alternate method	interl., UPC, Codabar, codes 39 & 128)/autodiscrimination alternate method
ar code placement per NCCLS standard Auto2P	n/a	n/a
nboard test auto inventory (determines volume in container)	yes	yes
easures no. tests remaining/short sample detection/clot detection utomatic detection of adequate reag. for aspir. & analysis	yes/yes/yes yes	no/yes/yes yes
emolysis/turbidity detection-quantitation	no/no	no/no
lution of patient samples onboard/automatic rerun capability ample volume can be reduced/increased to rerun out-of-linear-	no/no no/no	yes/yes no/no
range high/low results		
utocalibration or autocalibration alert alibrants stored onboard/multipoint calibration supported	yes yes/n/a	yes yes/n/a
pical 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
utomatic shutdown/startup programmable	n/a/n/a	n/a/n/a
at time to completion of all analytes, throughput per hr. for:	75 05 .	
 Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine 	75 sec, 35 specimens 75 sec, 35 specimens	90 sec, 39 specimens 90 sec, 39 specimens
Album., bili. direct & total, AST, ALT, ALP	n/a/n/a	n/a
rpical time delay from ordering stat test to aspir. of sample ow often QC required/onboard SW capability to review QC	9 sec CLIA minimum/yes	9 sec CLIA minimum/yes
nboard real-time QC/support multiple QC lot nos. per analyte	no/yes	no/yes
C results transferred automatically to LIS	yes	yes
ata 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
terfaces up and running in active user sites with	most LIS vendors including Cerner, Sunquest, HBO, Soft, others	most LIS vendors incl. Cerner, Sunquest, HBO, Soft, others
	most Lis vendors including certal, suriquest, fibu, soft, others	most Lis vendors men cerner, surrquest, ribo, sort, utilers
directional interface capability est results transmitted to LIS as soon as chem. time complete	yes	yes ves
S interface operates simultaneously with running assays	yes no	yes no
ses LOINC to transmit orders & results	no	no
b can control analyzer remotely terface avail. (or will be) to automated specimen handling system	yes	yes
	no	no maturatura
odem servicing available/can diagnose own malfunctions/ determine malfunctioning component	yes/yes/yes	no/yes/yes
n-site time of svc. engineer/onboard error codes for troubleshooting	<8 business hrs/yes	<8 business hrs/yes
ean time between failures/to repair failures verage time to complete maintenance by lab personnel	—/— daily: <2 min, weekly: <5 min, monthly: <5 min	—/— daily: <2 min, weekly: <5 min, monthly: <5 min
nboard maintenance records/maint. training demo module	no/no	no/no
aining provided with purchase/advanced oper. training avail.	3 d on-site/yes call for pricing	2 d on-site/yes call for pricing
nnual service contract cost (24 h/7 d)		
· · ·	first & only analyzer to offer Chem 7 & blood gases: can interface	the only whole blood analyzer for creatinine & TCO2 available: can
nnual service contract cost (24 h/7 d) stinguishing 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 $\& {\rm TCO_2}$ available; car analyze whole blood, serum, plasma, urine, CSF, $\&$ dialysate

Part 8 of 9	Ortho-Clinical Diagnostics Distributor Sales Support Center	Roche Diagnostics Corp.
		9115 Hague Rd.
	1001 U.S. Highway 202	Indianapolis, IN 46250
	Raritan, NJ 08869 800-457-7848	800-428-5074 www.us.labsystems.roche.com
See accompanying comments on page 74	orthoclinical.com	www.us.iubsystems.rocite.com
Name of instrument/first year sold in U.S.	Vitros DT60-II Analyzer/1993	Cobas Integra 400/1999
List price	-	\$165,000
No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd.	15,000 units worldwide U.S./U.S./U.S.	>1,200 Switzerland/Switzerland/U.S. & Germany
Operational type/reagent type	batch, random access, discrete, self-contained single-use cartridges- packages-slides	continuous random access/self-contained multiuse cartridges
Sample handling system/model type	—/benchtop	rack/benchtop
Dimensions (H x W x D)/instrument footprint	6.75 x 18.75 x 13.75/1.8 sq. ft.	30 x 53 x 26 in./9.6 sq. ft.
Tests available on instrument in U.S.	ammonia, cholesterol, HDL-chol., neonatal bilirubin, total protein, amylase, creatinine, lactate, phosphorus, triglycerides, BUN/urea, glucose, magnesium, total bilirubin, uric acid, albumin, AST, CK, GGT, lipase, ALP, calcium, iron, lithium, ALT, cholinesterase, LDH, theophylline, CO ₂ , sodium, potassium, chloride, urine, creatinine, CK-MB	$\alpha\text{-}1\text{-}acid glycoprot.}, \alpha\text{-}1\text{-}antitryp.}, alb. I, apo A & B, antistrepto0, A' III, complement C3c & C4, cerul., CRP latex, ferr., hapt., IgA/G/M, myo., prealb., RF, transferr., amph., barb., benz., coca., ethanol, LSD, meth., methaq., opia., PCP, PPX, S barb., S benz., THC, ACPP, ALP, ALT, \alpha\text{-}amy. pancreatic, AP, AST, cholinest. & Che-D, CK-MB, \gamma\text{-} glutamyltrans., LDH, lipase, alb., bil direct & total, Ca., chol., CO2, creat., fructosam., gluc., HbA1c, HDL direct, iron, lact., LDL direct, Mg, ammon., phos., TP, TPU-C, trig., UA, UIBC, urea, Na, K, CI, Li, acet., amik., carb., CSA, dig., digit., gent., lido., NAPA, pheno., pheny. prim., proc., quin., sali., theo., tobra., valp. acid, vanc., T4, T-up, D-dimer, soluble transferrin receptor$
Tests cleared but not clinically released 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	none cyclosporine, lipoprotein A
Research-use-only assays/tests in development User-defined methods implemented for what analytes	none/none none	none/homocysteine, cyclosporine 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	4	4
 must load separate reag. pack for ea. spec./no. diff. assays in pack separate reag. pack for each test run 	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 No. of user-definable (open) channels/no. active simultaneously	1 none	up to 999 0/0
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 Reag. container placed directly on system for use	no no	yes yes
Instrument has same capabilities when 3rd-party reag, used	n/a	no
Reag. only cost per reportable result for standard chemistries/ therapeutic drugs/special analytes	n/a/n/a/n/a	_/_/_
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, reconst. onboard yes/1,500
Uses washable cuvettes/replacement frequency	no/n/a	no/n/a
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain	10 μL no/no	1 μL no/no
Requires dedicated water system/water consumption	no/none	no/2 L maximum
Noise generated Dedicated pediatric sample cup/dead volume	— n/a	_ _
Primary tube sampling/pierces caps on primary tubes Sample bar-code reading capability	no/no	Yes/no yes (2 of 5 interl., Codabar, codes 39 & 128)/autodiscrimination
Reagent bar-code reading capability	no yes	yes
Bar code placement per NCCLS standard Auto2P 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/no (not necessary due to sampling method)
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/turbidity detection-quantitation	yes —/—	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 Calibrants stored onboard/multipoint calibration supported	no no tros	yes weekee
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse	no/yes 6 mos/6 mos/6 mos/n/a	yes/yes 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 Sodium, potassium, chloride, TC02, glucose, urea, creatinine	100 tests per hr 100 tests per hr	-, - -, -
Album., bili. direct & total, AST, ALT, ALP	100 tests per hr	_,'_
Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC	none 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 Interfaces up and running in active user sites with	—/no —	onboard/yes (addt'l cost) 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 yes	yes yes
Uses LOINC to transmit orders & results	_	_
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	yes/yes/yes
determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting	—/yes	_/ _
Mean time between failures/to repair failures	<u> </u>	_/ _
Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module	daily: 5 min, weekly: 5 min, monthly: none no/no	daily: none, weekly: 5 min, monthly: none yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/advanced oper. training avail.	1 d on-site/—	5 d 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 indicating direct LDL, HbA1c, and lithium

Part 9 of 9	Roche Diagnostics Corp. 9115 Hague Rd.	Roche Diagnostics Corp. 9115 Hague Rd.
	Indianapolis, IN 46250 800-428-5074	Indianapolis, IN 46250 800-428-5074
Soo accompanying comments on page 74	www.us.labsystems.roche.com	www.us.labsystems.roche.com
See accompanying comments on page 74 Name of instrument/first year sold in U.S.	Roche Hitachi 912/1997	Cobas Mira Plus CC/1992
ist price	\$159,000	\$50,000
No. units in clinical use in U.S./outside U.S. Country where designed/manufactured/where reagents mftd.	>1,100 Japan-U.S./Japan-U.S./U.SGermany	2,500/12,500 Switzerland/Switzerland/Germany-U.S.
Operational type/reagent type Sample handling system/model type	continuous random access/open reagent system disk/floor-standing	random access/open reagent system rack/benchtop
Dimensions (H x W x D)/instrument footprint	46 x 40 x 30 in./8.3 sq. ft.	26 x 29 x 23 in./4.63 sq. ft.
Tests available on instrument in U.S.	alb., ALP, ALT, ammonia, amy. total & panc., AST, bili. total & direct, BUN, Ca, cholest., cholinest., CK, CK-MB, CO ₂ , crea., fruct., GGT, glu.,	ACP, alb., alk. phos., ALT, amy., amm., Apo A1 & B, AST, bili. direct total, BUN, Ca., chol., CK, CO ₂ , crea., alcohol, iron TIBC, GGT, HDL
	HDL direct, iron, lact., LD, LD-1, LDL direct, lipase, Mg, phos., TIBC	direct, HDL, glu., LDH, LDL direct, Mg, phosphorus, TP, triglycerides
	(calc.), NAPA, procainamide, TP, trig., T ₄ , T-up, UIBC, UA, Na, K, Cl, α-1-antitryp., ASLO, β-2-microgl., C3c, C4, ceru., CRP, ferr., fol., hapt.,	UA, fruct., HbA1c, amph., barb., benz., THC, coca., methad., methaq- opia., PCP, propoxy., dig., acetamin., salic, Na, K, Cl by ISE
	HbA1c, IgA/E/G/M, microalb., myo., prealb., RF, transferrin, B ₁₂ , carb., dig., gent., pheno., pheny., salicy., theo., tobra., valp. acid,	
	alcohol, amph., barb., benz., coca., methad., opia., PCP, propoxy.,	
	THC. Also CSF and urine chemistries, D-dimer, soluble transferrin receptor	
Fests cleared but not clinically released Fests not available in U.S. but submitted for 510(k) clearance	none none	none none
Tests not available in U.S. but available in other countries	kappa/lambda light chains, %CDT, α -1-glycoprotein, Apo A1, Apo B, α -1-microgl., cyclos., lipoprotein (a)	none
Research-use-only assays/tests in development Jser-defined methods implemented for what analytes	none/homocysteine	none/information to be released at test launch
<u> </u>	none photometry potentiametry/turbidimetric latey particle enhanced	none
Methods supported/immunoassay methods	photometry, potentiometry/turbidimetric, latex particle enhanced, CEDIA	photometry, potentiometry/n/a
No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack	3 no/n/a	3 no/n/a
separate reag. pack for each test run of different measured assays onboard simultaneously	no 35 tests plus applications for urine & CSF	no max. 30
No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously	68 65/65	104 + profiles & ratios 104 + profiles & ratios/max. 30
No. of different analytes for which system accommodates	35/100–500	max. 30/40–50
reag. containers onboard at once/tests per container set Shortest/median onboard reag. stability/refrigerated onboard	—/30 d/yes (2–12° C)	6-8 hrs/30 d/yes (10-14° below ambient)
Multiple reag. configurations supported Reag. container placed directly on system for use	yes yes	yes yes, but requires some operator prehandling/prep.
nstrument has same capabilities when 3rd-party reag. used Reag. only cost per reportable result for standard chemistries/	no —/—/—	no —/—/—
therapeutic drugs/special analytes		
Nalkaway capacity in minutes/specimens/tests-assays System is liquid or dry	408/70/2,450 liquid	max. 120 min/90/depends on test vol. liquid
Jses disposable cuvettes/max. no. stored Jses washable cuvettes/replacement frequency	no/n/a yes/monthly (120 stored on instrument)	yes/— no/n/a
Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain	2 µL no/yes	1 μL no/no
Requires dedicated water system/water consumption loise generated	yes/30 L ≤65 decibels	no/4 L daily ≤62 decibels
Dedicated pediatric sample cup/dead volume	yes/—	no
Primary tube sampling/pierces caps on primary tubes Sample bar-code reading capability	yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5	yes/no yes, as soon as tubes loaded & start key activated (2 of 5 interl.,
Reagent bar-code reading capability	interl., Codabar, codes 39 & 128)/autodiscrimination yes	Codabar, codes 39 & 128)/autodiscrimination no
Bar code placement per NCCLS standard Auto2P Onboard test auto inventory (determines volume in container)	yes yes	no
Measures no. tests remaining/short sample detection/clot detection	yes/yes/no (not necessary due to sampling method)	no/yes/no
Automatic detection of adequate reag. for aspir. & analysis Hemolysis/turbidity detection-quantitation	yes yes/yes	yes no/no
Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-	yes/yes yes/yes	yes/yes yes/yes
range high/low results Autocalibration or autocalibration alert	yes	
Calibrants stored onboard/multipoint calibration supported	yes/yes	yes yes/yes word br/20, 60 d/ _ /n/a
Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	24 hrs/lot change (every 6 mos)/3–5 d/56 d yes/—	every hr/30–60 d/—/n/a no/no
Stat time to completion of all analytes, throughput per hr. for:		
 Sodium, potassium, chloride, TC02 Sodium, potassium, chloride, TC02, glucose, urea, creatinine 	3.5 min, 180 specimens 5.5 min, 90 specimens	4 min, 15 specimens 7 min, 9 specimens
Album., bili. direct & total, AST, ALT, ALP Sypical time delay from ordering stat test to aspir. of sample	10.5 min, 60 specimens 30 sec	7.5 min, 8 specimens none
How often QC required/onboard SW capability to review QC	24 hrs/yes	8 hrs, longest interval: daily/yes
Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	yes/yes yes	yes/no yes
Data mgmt. capability/instrument vendor supplies LIS interface	onboard/yes (addt'l cost)	onboard & optional add-on (\$5,000, SW mftr: Antek, Fletcher
nterfaces up and running in active user sites with	all major LIS vendors	Flora)/no —
Bidirectional interface capability	yes (host query)	yes
Fest results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays	yes yes	yes yes
Jses LOINC to transmit orders & results	100	<u> </u>
ab can control analyzer remotely nterface avail. (or will be) to automated specimen handling system	no yes (CLAS)	yes (limited) no
Modem servicing available/can diagnose own malfunctions/	no/yes/yes	no/—/—
determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting	—/yes	24 hrs/yes
	daily: —, weekly: —, monthly: —	4 mos/2 hrs daily: 10 min, weekly: 10 min, monthly: 5 min
Mean time between failures/to repair failures		
Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module	yes (includes audit trail of who replaced parts)/yes	no/no
Mean time between failures/to repair failures Average time to complete maintenance by lab personnel		no/no 4 d at vendor offices/no approx. \$9,000
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 (includes audit trail of who replaced parts)/yes	4 d at vendor offices/no