

## 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](http://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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## Chemistry analyzers (for low-volume laboratories)

Part 1 of 9	Abaxis Inc. Ron Blasig ronblasig@abaxis.com 1320 Chesapeake Terrace Sunnyvale, CA 94089 408-745-6804 www.abaxis.com	Abbott Laboratories Eric Perreault eric.perreault@abbott.com 4A Crosby Dr. Bedford, MA 01730 781-276-4797 www.abbott.com
See accompanying comments on previous page		
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 \$11,250 400/200 U.S./U.S./U.S. self-contained disc with multitest reag. panel	i-Stat Portable Clinical Analyzer/1995 \$7,900 6,700/2,500 U.S./U.S./Canada 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 <sub>2</sub>	sodium, potassium, chloride, ionized calcium, BUN, glucose, 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> , BE <sub>ecf</sub> , anion gap, SO <sub>2</sub>
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	chloride none none none/magnesium, phosphorus, triglycerides, HDL none	none ACT <sub>k</sub> none none/PT, aPTT, CK-MB, myoglobin, troponin none
Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reag. pack for ea. spec./no. diff. assays in pack • separate reag. pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated 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 Auto2P Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reagent for aspir. & analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calib. frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable	potentiometry/n/a 10 yes/1-7 yes 7 7 n/a/n/a 1 cartridge at a time, each up to 7 tests 14 d at room temp./no no n/a n/a \$3-\$9/n/a/n/a approx. 2 min for any cartridge type depends on component no/n/a no/n/a 95 µL no/no no/n/a no no no/n/a no yes n/a yes yes yes/yes yes/no n/a/n/a yes yes/yes self-calibrated onboard/disc n/a/no	
Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO <sub>2</sub> • Sodium, potassium, chloride, TCO <sub>2</sub> , glucose, urea, creatinine • Album., bili. direct & total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS	15 min, 4 specimens 15 min, 4 specimens 15 min, 4 specimens (total AST only, no phos.) n/a per disc/yes yes/yes yes	2 min, n/a 2 min, n/a n/a/n/a n/a 24 hrs, longest interval: each new lot/yes yes/yes yes
Data mgmt. capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders & results	onboard/no n/a no yes yes no	optional add-on (\$23,000 including LIS interface, SW mfr: Abbott/Neon)/yes (add'l cost) all systems yes (broadcast download & host query) yes yes yes
Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system	no no	no n/a
Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)	no/no/no 24 hr loaner/yes —/— daily: none, weekly: none, monthly: none —/— yes/yes 1 yr warranty, >1 yr \$1,200	yes/yes/yes replacement/yes not determined daily: none, weekly: none, monthly: none n/a/n/a yes (depends on need)/yes \$300
Distinguishing features	compact chemistry system using a few drops of whole blood, serum, or plasma provides turnaround of results at point of care, including hands-on time, in 15 min	handheld portable analyzer

## Chemistry analyzers (for low-volume laboratories)

<p><b>Part 2 of 9</b></p> <p><i>See accompanying comments on page 74</i></p>	<p><b>Abbott Laboratories</b>  Eric Perreault eric.perreault@abbott.com  4A Crosby Drive  Bedford, MA 01730  781-276-4797  www.abbott.com</p>	<p><b>Alfa Wassermann Inc.</b>  Monty Hatcher info@alfawassermann.com  4 Henderson Drive  West Caldwell, NJ 07006  800-220-4488  alfawassermann.com</p>
<p>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</p>	<p>i-Stat 1/2000  \$8,500  75/—  U.S./U.S./Canada  —/self-contained single-use cartridges-packages-slides</p>	<p>Ace Clinical Chemistry System/1993  \$69,900  900+/500+  U.S./U.S./U.S.  batch, random access, discrete, cont. random access, stat/closed reagent system with open reagent system channels  ring with segments (15–30 samples/seg.)/benchtop  15.75 x 27.25 x 22.50 in. (analyzer only)/8 sq. ft. (full system)</p>
<p>Tests available on instrument in U.S.</p> <p>Tests cleared but not clinically released  Tests not available in U.S. but submitted for 510(k) clearance  Tests not available in U.S. but available in other countries  Research-use-only assays/tests in development  User-defined methods implemented for what analytes</p>	<p>sodium, potassium, chloride, ionized calcium, BUN, glucose, 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></p> <p>none  ACT<sub>k</sub>  none  none/PT, aPTT, CK-MB, myoglobin, troponin  none</p>	<p>albumin, bilirubin direct &amp; total, calcium, creatinine, glucose, inorganic phosphorus, iron, magnesium, total protein, BUN, uric acid, ALP, ALT, amylase, AST, CK, gamma-GT, LDH, cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, sodium, potassium, chloride, CO<sub>2</sub>, digoxin, T<sub>4</sub>, T-uptake</p> <p>none  none  special proteins  none/none  acetaminophen, alcohol, cortisol, CRP, CK-MB, folate, fructosamine, HbA<sub>1c</sub>, lipase, salicylate, transferrin, B<sub>12</sub>, amphetamine, barbiturate, benzodiazepine, THC, cocaine, opiate, PCP</p>
<p>Methods supported/immunoassay methods  No. of direct ion selective electrode channels  • must load separate reagent pack for ea. spec./no. diff. assays in pack  • separate reagent pack for each test run  No. of different measured assays onboard simultaneously  No. of different assays programmed, calibrated at once  No. of user-definable (open) channels/no. active simultaneously  No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set  Shortest/median onboard reagent stability/refrigerated onboard  Multiple reagent configurations supported  Reagent container placed directly on system for use  Instrument has same capabilities when 3rd-party reagent used  Reagent only cost per reportable result for standard chemistries/therapeutic drugs/special analytes  Walkaway capacity in minutes/specimens/tests-assays  System is liquid or dry  Uses disposable cuvettes/max. no. stored  Uses washable cuvettes/replacement frequency  Minimum sample volume aspirated precisely at one time  Supplied with UPS (backup power)/requires floor drain  Requires dedicated water system/water consumption  Noise generated  Dedicated pediatric sample cup/dead volume  Primary tube sampling/pierces caps on primary tubes  Sample bar-code reading capability</p> <p>Reagent bar-code reading capability  Bar code placement per NCCLS standard Auto2P  Onboard test auto inventory (determines volume in container)  Measures no. tests remaining/short sample detection/clot detection  Automatic detection of adequate reagent for aspir. &amp; 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</p>	<p>potentiometry/—  10  yes/up to 16  yes  11  up to 16  n/a/n/a  n/a/1 cartridge at a time, each up to 16 tests</p> <p>—/14 d/no  no  n/a  n/a  \$3-\$9/—/—</p> <p>2 min/1/up to 16  —  no  no  65 µL  no/no  no/n/a  none  no  no/no  yes/patient, operator, identification (2 of 5 interleaved, UPC, Codabar codes 39 &amp; 128)  yes  yes  n/a  n/a/yes/yes  yes  yes/yes  no/no  no/no  yes  yes/no  each test/each test/—/—  yes/yes</p>	<p>photometry, potentiometry/CEDIA, turbidimetric, homogeneous, EIA  3  no/n/a  no  43  200  18/18  40/100–150 tests per bottle</p> <p>120 hrs/30 d/yes (10–14°C)  yes  yes  yes  \$.16/\$3.50/\$3.50</p> <p>150/150/450  liquid  yes/248  no/n/a  3 µL  yes/no  no/n/a  —  yes/≤50 µL  yes/yes  yes, as sample is being aspirated (2 of 5 interl., Codabar, codes 39 &amp; 128)/autodiscrimination  yes  no  yes  yes/yes/no  yes  no/no  yes/yes  yes/no  yes  no/yes  3 hrs/30 d/45 d with 48 hr updates/TBD  n/a/n/a</p>
<p>Stat time to completion of all analytes, throughput per hr. for:  • Sodium, potassium, chloride, TCO<sub>2</sub>  • Sodium, potassium, chloride, TCO<sub>2</sub>, glucose, urea, creatinine  • Albumin, bili. direct &amp; total, AST, ALT, ALP  Typical time delay from ordering stat test to aspir. of sample  How often QC required/onboard SW capability to review QC  Onboard real-time QC/support multiple QC lot nos. per analyte  QC results transferred automatically to LIS</p>	<p>2 min, n/a  2 min, n/a  n/a, —  n/a  shortest interval: 24 hrs; longest interval: each new lot/yes  yes/yes  yes</p>	<p>3.5 min, 32 specimens  &lt;6 min, 25 specimens  9 min, 21 specimens  immediate response, as soon as 10 sec  daily/yes  yes/yes  yes</p>
<p>Data mgmt. capability/instrument vendor supplies LIS interface  Interfaces up and running in active user sites with  Bidirectional interface capability  Test results transmitted to LIS as soon as chem. time complete  LIS interface operates simultaneously with running assays  Uses LOINC to transmit orders &amp; results</p>	<p>optional add-on (\$45,000 including LIS interface, SW mftr: Abbott/Neon)/yes  all systems</p> <p>yes (broadcast download &amp; host query)  yes  yes  yes</p>	<p>onboard/no  Schuyler House, Antek, others</p> <p>yes (broadcast download)  yes  yes  yes</p>
<p>Lab can control analyzer remotely  Interface avail. (or will be) to automated specimen handling system</p>	<p>yes  n/a</p>	<p>no  no</p>
<p>Modem servicing available/can diagnose own malfunctions/determine malfunctioning component  On-site time of svc. engineer/onboard error codes for troubleshooting  Mean time between failures/to repair failures  Average time to complete maintenance by lab personnel  Onboard maintenance records/maint. training demo module  Training provided with purchase/advanced oper. training avail.  Annual service contract cost (24 h/7 d)</p>	<p>yes/yes/yes  replacement/yes  not determined/24 hrs  daily: none, weekly: none, monthly: none  n/a/n/a  —/yes  \$420</p>	<p>no/yes/yes  &lt;24 hrs/yes  —/&lt;1 hr  daily: 3 min, weekly: 30 min, monthly: 30 min  yes (includes audit trail of who replaced parts)/no  4 d at vendor offices/yes  inquire from vendor</p>
<p>Distinguishing features</p>	<p>handheld portable analyzer</p>	<p>easy-to-use, multitasking software; closed-tube sampling</p>

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

## Chemistry analyzers (for low-volume laboratories)

<p><b>Part 3 of 9</b></p> <p>See accompanying comments on page 74</p>	<p>Alfa Wassermann Inc. Monty Hatcher info@alfawassermannus.com 4 Henderson Drive West Caldwell, NJ 07006 800-220-4488 alfawassermannus.com</p>	<p>Awareness Technology Inc. C. Schneider ces@awaretech.com P.O. Box 1679 Palm City, FL 34991 561-283-6540 www.awaretech.com</p>
<p>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</p>	<p>NExCT Clinical Chemistry System/1998 \$39,900 90+ /60+ U.S./U.S./U.S. batch, random access, discrete, cont. random access, stat/closed reag. system with open reag. system channels ring with segments (15-30 samples/seg.)/benchtop 15.75 x 27.25 x 22.50 in. (analyzer only)/4.5 sq. ft. (full system)</p>	<p>ChemWell/1999 \$25,000 2/140 U.S./U.S./open system batch, random access/open reagent system</p>
<p>Sample handling system/model type Dimensions (H x W x D)/instrument footprint</p>	<p>rack/benchtop 16 x 34 x 20 in./—</p>	<p>rack/benchtop 16 x 34 x 20 in./—</p>
<p>Tests available on instrument in U.S.</p>	<p>albumin, bilirubin direct &amp; total, calcium, creatinine, glucose, in. phosphorus, iron, magnesium, total protein, BUN, uric acid, ALP, ALT, amylase, AST, CK, gamma-GT, LDH, cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, CO<sub>2</sub></p>	<p>unlimited, open system; Pointe Scientific reagents have been FDA cleared and given CLIA moderate complexity and include: ALT, albumin, amylase, AST, bilirubin direct &amp; total, calcium, cholesterol enzymatic, CK, CK-MB, creatinine, GGT, glucose (hexokinase), glucose (oxidase), iron/TIBC, lactate dehydrogenase, LDL cholesterol, magnesium, inorganic phosphorus, total protein, triglyceride, urea (BUN), uric acid</p>
<p>Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance</p>	<p>none none</p>	<p>n/a Sigma Diagnostics assays include: albumin (bromocresol green &amp; purple), alkaline phosphatase, ALT, AST, cholesterol, creatinine, gGT, glucose, total protein, triglycerides, BUN, uric acid</p>
<p>Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes</p>	<p>none none/none acetaminophen, alcohol, CRP, CK-MB, folate, fructosamine, HbA1c, lipase, salicylate, transferrin, B<sub>12</sub></p>	<p>unlimited, open system any colorimetric (340-700 nm), open system/n/a all colorimetric end points and kinetic assays; open systems</p>
<p>Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reagent pack for ea. spec./no. diff. assays in pack • separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated Dedicated pediatric sample cup/dead volume Primary tube sampling/pierces caps on primary tubes Sample bar-code reading capability</p>	<p>photometry/CEDIA, turbidimetric, homogeneous, EIA 0 (optional ISE interface) no/n/a no 20 200 9/9 20/40-60 tests per bottle 120 hrs/30 d/no yes yes yes \$.23/TBD/TBD 30/150/58 liquid yes/58 no/n/a 3 µL no/no no/n/a — yes/≤50 µL yes/yes yes, as sample is being aspirated (2 of 5 interl., Codabar, codes 39 &amp; 128)/autodiscrimination yes no yes yes/yes/no yes no/no yes/yes yes/no yes no/yes n/a/30 d/TBD/TBD no/no</p>	<p>photometry/EIA-microplate format n/a no no up to 27 unlimited unlimited/up to 27 27/assay dependent n/a/n/a/no yes reagent dependent yes assay dependent not limited/96/not limited liquid chemistry system yes/96 yes/weekly 2 µL no/no no/&lt;1 L per hr 60 dB no no/no yes/by handheld scanner as tubes are loaded onto instrument</p>
<p>Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2P Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reagent for aspir. &amp; 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</p>	<p>yes no yes yes/yes/no yes no/no yes/yes yes/no yes no/yes n/a/30 d/TBD/TBD no/no</p>	<p>no no yes yes/yes/no yes no/no yes/yes yes/no yes yes/yes n/a/user defined/user defined/user defined yes/yes</p>
<p>Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO<sub>2</sub> • Sodium, potassium, chloride, TCO<sub>2</sub>, glucose, urea, creatinine • Album., bili. direct &amp; total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS</p>	<p>3.5 min (with offline ISE), 55 specimens (with offline ISE) &lt;6 min (with offline ISE), 40 specimens (with offline ISE) 9 min, 21 specimens immediate response, as soon as 10 sec daily/yes yes/yes yes</p>	<p>sodium and potassium not available sodium and potassium not available 5.5 min/28 15 sec. user defined/yes yes/yes no</p>
<p>Data mgmt. capability/instrument vendor supplies LIS interface</p>	<p>onboard/no</p>	<p>onboard (Awareness Technology Inc.)/no</p>
<p>Interfaces up and running in active user sites with</p>	<p>Schuyler House, Antek, others</p>	<p>n/a</p>
<p>Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders &amp; results</p>	<p>yes (broadcast download) yes yes yes</p>	<p>no no n/a n/a</p>
<p>Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system</p>	<p>no no</p>	<p>no no</p>
<p>Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)</p>	<p>no/yes/yes &lt;24 hrs/yes —/&lt;1 hr daily: 2 min, weekly: 1 min, monthly: 30 min yes (includes audit trail of who replaced parts)/no 4 d at vendor offices/yes inquire from vendor</p>	<p>yes/yes/yes 48 hrs in U.S./— not specified/— daily: &lt;10 min, weekly: &lt;30 min, monthly: &lt;1 hr no/— 2 d on-site, 3 d at vendor offices/yes \$4,000/yr</p>
<p>Distinguishing features</p>	<p>easy-to-use, multitasking software; closed-tube sampling</p>	<p>ChemWell can also be programmed to perform ELISA assays in the microwell format</p>

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## Chemistry analyzers (for low-volume laboratories)

<p><b>Part 4 of 9</b></p> <p>See accompanying comments on page 74</p>	<p>Careside Inc. Grant Frazier gfrazier@careside.com 6100 Bristol Parkway Culver City, CA 90230 310-338-6767 ext. 124 www.careside.com</p>	<p>Dade Behring Inc. 1717 Deerfield Deerfield, IL 60015 847-267-5300 www.dadebehring.com</p>
<p>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</p> <p>Sample handling system/model type Dimensions (H x W x D)/instrument footprint</p>	<p>Careside Analyzer/1999 \$18,000 —/— U.S./U.S./U.S. random access, discrete/self-contained single-use cartridges</p> <p>unit-of-use test cartridge/benchtop 16 x 14 x 12 in./~1 sq. ft.</p>	<p>Dimension Xpand Integrated Chemistry System/2001 — —/— U.S./U.S./U.S. continuous random access/self-contained multi-use cartridges-packages-slides &amp; open reagent system sample segments/floor-standing 53 x 51 x 31/11</p>
<p>Tests available on instrument in U.S.</p> <p>Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development</p> <p>User-defined methods implemented for what analytes</p>	<p>electrochemistry: anion gap, chloride, potassium, sodium; chemistry: A/G ratio, albumin, ALP, ALT, ALT/AST ratio, ammonia, amylase, AST, bilirubin direct &amp; total, bilirubin indirect (calc.), BUN, BUN/creatinine ratio, calcium total, carbon dioxide, HDL-cholesterol, LDL-cholesterol (calc.), cholesterol, total, cholesterol/HDL-cholesterol 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</p> <p>— none none none/ionized calcium, aPTT, fibrinogen, TT, digoxin, phenytoin, theoph. none</p>	<p>70-plus methods including TOM, immunoassays, plasma proteins, DAUs and general chemistry</p> <p>n/a lithium, cyclosporin, early detect. PSA cyclosporin n/a/Hba1C, Li, RF, T3, LDL, procainzamide n/a</p>
<p>Methods supported/immunoassay methods</p> <p>No. of direct ion selective electrode channels • must load separate reagent pack for ea. spec./no. diff. assays in pack • separate reagent pack for each test run</p> <p>No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set</p> <p>Shortest/median onboard reagent stability/refrigerated onboard</p> <p>Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/therapeutic drugs/special analytes</p> <p>Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated</p> <p>Dedicated pediatric sample cup/dead volume Primary tube sampling/pierces caps on primary tubes Sample bar-code reading capability</p> <p>Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2P Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reagent for aspir. &amp; 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</p>	<p>photometry, potentiometry, optical transmission, reflectance/n/a</p> <p>3 no/n/a 1 pack for 3 tests (Na, K, Cl) n/a total menu 0/n/a n/a/n/a</p> <p>n/a/n/a/no yes yes n/a varies/n/a/n/a</p> <p>12/1/8 dry no/n/a no/n/a n/a no/no no/none &lt;60 decibels no no/n/a no</p> <p>yes n/a n/a n/a/yes/no n/a yes/yes no/no no/no yes no/no calibration verification every 6 mos/n/a/n/a/n/a no/no</p>	<p>photometry, potentiometry, turbidimetric assays/Petinia, Emit, Acmia, mag. part. sep. 3 no no 47 75+ 10/10 47/480</p> <p>24 hrs/5 d/yes (2–8°C) no yes yes n/a</p> <p>420/60/1,800 liquid &amp; reconstitutes onboard yes/12,000 —/— 2 µL yes/no yes/2 L per hr &lt;70 decibels no/30 µL with standard cup yes/no yes/on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 39 &amp; 128)/autodiscrimination yes yes yes yes/yes/no no no/no yes/yes yes/no</p> <p>yes no/yes 2 hrs (auto)/90 d/60 d/60 d —/—</p>
<p>Stat time to completion of all analytes, throughput per hr. for:</p> <ul style="list-style-type: none"> <li>• Sodium, potassium, chloride, TCO<sub>2</sub></li> <li>• Sodium, potassium, chloride, TCO<sub>2</sub>, glucose, urea, creatinine</li> <li>• Album., bili. direct &amp; total, AST, ALT, ALP</li> </ul> <p>Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS</p>	<p>~10 min, 1 specimen (Na, K, Cl: 3–5 min) ~12 min, 1 specimen ~12 min, 1 specimen immediate daily for electronic QC/yes yes/yes yes</p>	<p>2 min, 62 4 min, 62 8 min, 42 60 sec steady state, 2 min from standby daily/yes yes/— yes</p>
<p>Data mgmt. capability/instrument vendor supplies LIS interface</p> <p>Interfaces up and running in active user sites with</p> <p>Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders &amp; results</p>	<p>onboard/yes Careside Connect DMS (add'l cost)</p> <p>—</p> <p>yes yes yes yes</p>	<p>onboard/no</p> <p>interfaces available for all major LIS vendors</p> <p>yes (broadcast download &amp; host query) yes yes no</p>
<p>Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system</p>	<p>yes no</p>	<p>no no</p>
<p>Modem servicing available/can diagnose own malfunctions/determine malfunctioning component</p> <p>On-site time of svc. engineer/onboard error codes for troubleshooting</p> <p>Mean time between failures/to repair failures</p> <p>Average time to complete maintenance by lab personnel</p> <p>Onboard maintenance records/maint. training demo module</p> <p>Training provided with purchase/advanced oper. training avail.</p> <p>Annual service contract cost (24 h/7 d)</p>	<p>no/yes/yes</p> <p>replacement/yes TBD/TBD daily: none, weekly: none, monthly: none n/a/n/a yes/yes TBD</p>	<p>yes/yes/yes</p> <p>situation dependent/yes n/a/n/a daily: 5 min, weekly: n/a, monthly: 20 min no/no 4 d at vendor offices/yes n/a</p>
<p>Distinguishing features</p>	<p>POC test device with the most comprehensive menu</p>	<p>specifically designed for low-volume testing laboratories; the analyzer performs the most requested chemistry and heterogeneous immunoassay tests on a single, easy-to-use instrument</p>

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

## Chemistry analyzers (for low-volume laboratories)

<p><i>Part 5 of 9</i></p> <p><i>See accompanying comments on page 74</i></p>	<p>Elan Diagnostics 2 Thurber Blvd. Smithfield, RI 02917 401-233-3526 elandiagnostics.com</p>	<p>Elan Diagnostics 2 Thurber Blvd. Smithfield, RI 02917 401-233-3526 elandiagnostics.com</p>
<p>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</p>	<p>Atac 6000 Chemistry System/1990 — —/— —/—/— discrete/open reagent system</p>	<p>Atac 8000 Random Access Chemistry System/1995 — —/— —/—/— continuous random access/open reagent system</p>
<p>Sample handling system/model type Dimensions (H x W x D)/instrument footprint</p>	<p>sample wheel/benchtop 21 x 23 x 18.5 in./~3 sq. ft.</p>	<p>sample wheel/benchtop 19.5 x 39 x 20.5 in./5.5 sq. ft.</p>
<p>Tests available on instrument in U.S.</p>	<p>albumin, ALP, Apo A, Apo B, amylase, bilirubin direct &amp; 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</p>	<p>albumin, ALP, amylase, Apo A1, Apo B, , bilirubin direct &amp; 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<sub>2</sub>, chloride, potassium, sodium—ISE]</p>
<p>Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes</p>	<p>none none none none/none none</p>	<p>none none none none/none none</p>
<p>Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reagent pack for ea. spec./no. diff. assays in pack • separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated 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 Auto2P Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reagent for aspir. &amp; analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calibration frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable</p>	<p>photometry, potentiometry/n/a 3 no/n/a no 16 16 48/16 16/30 6 hrs/2 d/no no no, requires operator prehandling/prep. no —/—/— —/—/96 liquid yes/96 no/n/a 2 µL no/no no/yes — no no/no no no no/no no/no no no 4 hrs/daily/n/a/n/a no/—</p>	<p>photometry, potentiometry/n/a 4 no/n/a no 40 40 320/40 40/150 5 d/12 d/yes yes yes yes —/—/— 240+/50/1,200 liquid no/n/a yes/5 yrs 2 µL yes/no no/yes — no yes/no yes, on sample transport, shortly before sample is aspirated yes — yes yes/yes/no yes —/— yes/yes yes/yes yes no/yes 4 hrs/daily/n/a/n/a yes/yes</p>
<p>Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Album., bili. direct &amp; total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS</p>	<p>—, — —, — —, — — 2 levels daily/yes yes/yes yes</p>	<p>60 sec, 60 specimens 6 min, 45 specimens 7 min, 36 patients with specified panel 20 sec 2 levels daily/yes yes/yes yes</p>
<p>Data mgmt. capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders &amp; results</p>	<p>onboard/yes (add'l cost) Antek, Fletcher-Flora, Dynamedix, Schuyler House, Medcom, Costello, Psyche yes (host query) yes yes no</p>	<p>onboard/yes (add'l cost) Antek, Fletcher-Flora, Dynamedix, Schuyler House, Medcom, Costello, Psyche yes (broadcast download &amp; host query) yes yes no</p>
<p>Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system</p>	<p>no no</p>	<p>no no</p>
<p>Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)</p>	<p>no/no/no within 24 hrs/yes —/— daily: 5 min, weekly: 15 min, monthly: 15 min no/— 5 d on site/no —</p>	<p>no/yes/yes within 24 hrs/yes —/— daily: none, weekly: 15 min, monthly: 30 min yes (includes audit trail of who replaced parts)/yes 5 d on site, 5 d at vendor offices/yes —</p>
<p>Distinguishing features</p>	<p>batch mode with broad test menu; data management system; high level of flexibility &amp; performance</p>	<p>475 tests/hr of general chemistry &amp; ISE; reusable glass cuvettes, ensuring low reagent cost; onboard refrigeration.</p>

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

## Chemistry analyzers (for low-volume laboratories)

<p><i>Part 6 of 9</i></p> <p><i>See accompanying comments on page 74</i></p>	<p>Hemagen Diagnostics Inc. Tricia Thurrell tthurrell@hemagen.com 9033 Red Branch Rd. Columbia, MD 21045 800-436-2436 www.hemagen.com</p>	<p>Nova Biomedical Corp. Nova Sales Department 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 info@novabiomedical.com</p>
<p>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</p>	<p>Analyst Benchtop Chemistry System/1986 \$5,500-\$9,900 —/— France-U.S./U.S./U.S. batch/self-contained single-use cartridges-packages-slides, rotors —/benchtop</p>	<p>Stat Profile M/1998 \$55,750 —/— U.S./U.S./U.S. random access/self-contained multiuse packages stat sampling directly from sample container/benchtop</p>
<p>Sample handling system/model type Dimensions (H x W x D)/instrument footprint</p>	<p>8.5 x 25 x 13 in./2.25 sq. ft.</p>	<p>20.5 x 19.2 x 20.7 in./2.75 sq. ft.</p>
<p>Tests available on instrument in U.S.</p>	<p>ALP, GGT, GPT, Got, BUN, glucose, calcium, cholesterol, triglycerides, amylase, uric acid, total bilirubin, total protein, HDL-chol.</p>	<p>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>%</p>
<p>Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes</p>	<p>none albumin, direct bilirubin, CO<sub>2</sub>, potassium none none/T<sub>4</sub> none</p>	<p>none none none none/none none</p>
<p>Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reagent pack for ea. spec./no. diff. assays in pack • separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated Dedicated pediatric sample cup/dead volume Primary tube sampling/pierces caps on primary tubes Sample bar-code reading capability</p>	<p>photometry/n/a n/a yes/14 per rotor per patient no — 14 —/— 14/14 —/—/no — yes no —/—/— 10/1/14 dry no (uses rotors) no/n/a 10 µL &amp; 80 µL no/no no/n/a — no no/no no no no/no no/no no/no no no/— n/a/60 d/n/a/n/a no/no</p>	<p>potentiometry, optical, reflectance/n/a 12 no/n/a no 14 14 0/n/a 1/(@ 14,700 tests/mo): 6,300 tests 21 d/21 d/no n/a yes n/a standard chemistries: @35 sam/d: \$0.40 (14-test panel); bundled instr., reagent, maint. cost: \$1.39 (14-test panel) n/a n/a no/n/a n/a 150 µL no/no no/n/a minimal n/a yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interl., UPC, Codabar, codes 39 &amp; 128)/autodiscrimination alternate method n/a yes yes/yes/yes yes no/no no/no no/no yes yes/n/a 2 hrs/2 hrs/n/a/n/a n/a/n/a</p>
<p>Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO<sub>2</sub> • Sodium, potassium, chloride, TCO<sub>2</sub>, glucose, urea, creatinine • Album., bill. direct &amp; total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS</p>	<p>—, — 10 min, 6 specimens (glu, urea, crea) 10 min, 6 specimens — —/— no/no —</p>	<p>75 sec, 35 specimens 75 sec, 35 specimens n/a 9 sec CLIA minimum/yes no/yes yes</p>
<p>Data mgmt. capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders &amp; results</p>	<p>—/yes (included in price) in development — — — —</p>	<p>onboard &amp; optional add-on (\$9,225; SW mfr: Nova)/no most LIS vendors incl. Cerner, Sunquest, HBO, Soft, others yes yes no no</p>
<p>Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system</p>	<p>— —</p>	<p>yes no</p>
<p>Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)</p>	<p>no/yes/yes most troubleshooting via phone/yes 14-16 mos/— daily: 2 min, weekly: 15 min, monthly: 30 min no/— 2 d on-site/yes \$1,000</p>	<p>yes/yes/yes &lt;8 business hrs/yes —/— daily: &lt;2 min, weekly: &lt;5 min, monthly: &lt;5 min no/no 3 d on-site/yes call for pricing</p>
<p>Distinguishing features</p>	<p>uses only 90 µL of sample &amp; requires &lt;60 sec of prep work; minimal maintenance required</p>	<p>combines up to 14 onboard critical care tests; only combined blood gas analyzer with BUN &amp; iMg</p>

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

## Chemistry analyzers (for low-volume laboratories)

<p><i>Part 7 of 9</i></p> <p><i>See accompanying comments on page 74</i></p>	<p>Nova Biomedical Corp. Nova Sales Department 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 info@novabiomedical.com</p>	<p>Nova Biomedical Corp. Nova Sales Department 200 Prospect St. Waltham, MA 02454-9141 800-458-5813 info@novabiomedical.com</p>
<p>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</p>	<p>Stat Profile M7/1999 \$55,750 —/— U.S./U.S./U.S. random access/self-contained multiuse packages stat sampling directly from sample container/benchtop</p>	<p>Nova 16/1995 \$22,500–\$25,500 —/— U.S./U.S./U.S. batch, random access/self-contained multiuse packages 40-position tray, stat sampling directly from sample container/benchtop</p>
<p>Sample handling system/model type Dimensions (H x W x D)/instrument footprint</p>	<p>20.5 x 19.2 x 20.7 in./2.75 sq. ft.</p>	<p>20.5 x 19.2 x 20.7 in./2.75 sq. ft.</p>
<p>Tests available on instrument in U.S.</p>	<p>sodium, potassium, chloride, glucose, BUN, creatinine, ionized calcium, lactate, Hct, hemoglobin, pH, pCO<sub>2</sub>, pO<sub>2</sub>, SO<sub>2</sub>%</p>	<p>sodium, potassium, chloride, total CO<sub>2</sub>, glucose, BUN, creatinine, Hct</p>
<p>Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes</p>	<p>none none none none/none none</p>	<p>none none none none/none none</p>
<p>Methods supported/immunoassay methods No. of direct ion selective electrode channels • must load separate reagent pack for ea. spec./no. diff. assays in pack • separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use</p> <p>Instrument has same capabilities when 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated Dedicated pediatric sample cup/dead volume Primary tube sampling/pierces caps on primary tubes Sample bar-code reading capability</p> <p>Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2P Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reagent for aspir. &amp; analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calibration frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable</p>	<p>potentiometry, optical, reflectance/n/a 12 no/n/a no 14 14 0/n/a 1/(@14,700 tests/mo): 6,300 tests 21 d/21 d/no n/a no, requires oper. prehandling/prep. (remove clip from sealed bag &amp; mix) n/a standard chemistries: @35 sam/d: \$0.40 (14-test panel); bundled instr.; reagent, maint. cost: \$1.39 (14-test panel) n/a n/a no/n/a n/a 150 µL no/no no/n/a minimal n/a yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interl., UPC, Codabar, codes 39 &amp; 128)/autodiscrimination alternate method n/a yes yes/yes/yes yes no/no no/no no/no yes yes/n/a 2 hrs/2 hrs/n/a/n/a n/a/n/a</p>	<p>potentiometry/n/a 8 no/n/a no 8 8 0/n/a 1/(@ 8,000 tests/mo): 2,700 tests 21 d/21 d/no n/a no, requires prehandling (remove clip from sealed bag &amp; mix) n/a standard chemistries: @25 sam/d: \$0.40 (8-test panel); bundled instr., reagent, maint. cost per result: \$0.92 (8-test panel) 60 per tray/40 per tray/280 per tray n/a no/n/a n/a/n/a 385 µL no/no no/n/a minimal n/a yes/no yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interl., UPC, Codabar, codes 39 &amp; 128)/autodiscrimination alternate method n/a yes no/yes/yes yes no/no yes/yes no/no yes yes/n/a 2 hrs/2 hrs/n/a/n/a n/a/n/a</p>
<p>Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO<sub>2</sub> • Sodium, potassium, chloride, TCO<sub>2</sub>, glucose, urea, creatinine • Album., bili. direct &amp; total, AST, ALT, ALP Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS</p>	<p>75 sec, 35 specimens 75 sec, 35 specimens n/a/n/a 9 sec CLIA minimum/yes no/yes yes</p>	<p>90 sec, 39 specimens 90 sec, 39 specimens n/a 9 sec CLIA minimum/yes no/yes yes</p>
<p>Data mgmt. capability/instrument vendor supplies LIS interface</p>	<p>onboard &amp; optional add-on (\$9,225, SW mfr.: Nova)/no</p>	<p>onboard &amp; optional add-on (\$9,225, SW mfr.: Nova)/no</p>
<p>Interfaces up and running in active user sites with</p>	<p>most LIS vendors including Cerner, Sunquest, HBO, Soft, others</p>	<p>most LIS vendors incl. Cerner, Sunquest, HBO, Soft, others</p>
<p>Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders &amp; results</p>	<p>yes yes no no</p>	<p>yes yes no no</p>
<p>Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system</p>	<p>yes no</p>	<p>yes no</p>
<p>Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)</p>	<p>yes/yes/yes &lt;8 business hrs/yes —/— daily: &lt;2 min, weekly: &lt;5 min, monthly: &lt;5 min no/no 3 d on-site/yes call for pricing</p>	<p>no/yes/yes &lt;8 business hrs/yes —/— daily: &lt;2 min, weekly: &lt;5 min, monthly: &lt;5 min no/no 2 d on-site/yes call for pricing</p>
<p>Distinguishing features</p>	<p>first &amp; only analyzer to offer Chem 7 &amp; blood gases; can interface with Sysmex Kx 4500 hematology analyzer through Nova data manager</p>	<p>the only whole blood analyzer for creatinine &amp; TCO<sub>2</sub> available; can analyze whole blood, serum, plasma, urine, CSF, &amp; dialysate</p>

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## Chemistry analyzers (for low-volume laboratories)

<p><i>Part 8 of 9</i></p> <p><i>See accompanying comments on page 74</i></p>	<p>Ortho-Clinical Diagnostics Distributor Sales Support Center 1001 U.S. Highway 202 Raritan, NJ 08869 800-457-7848 orthoclinical.com</p>	<p>Roche Diagnostics Corp. 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.us.labsystems.roche.com</p>
<p>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</p>	<p>Vitros DT60-II Analyzer/1993 — 15,000 units worldwide U.S./U.S./U.S. batch, random access, discrete, self-contained single-use cartridges- packages-slides —/benchtop 6.75 x 18.75 x 13.75/1.8 sq. ft.</p>	<p>Cobas Integra 400/1999 \$165,000 &gt;1,200 Switzerland/Switzerland/U.S. &amp; Germany continuous random access/self-contained multiuse cartridges</p>
<p>Sample handling system/model type Dimensions (H x W x D)/instrument footprint</p>	<p>—/benchtop 6.75 x 18.75 x 13.75/1.8 sq. ft.</p>	<p>rack/benchtop 30 x 53 x 26 in./9.6 sq. ft.</p>
<p>Tests available on instrument in U.S.</p>	<p>ammonia, cholesterol, HDL-cholesterol, 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<sub>2</sub>, sodium, potassium, chloride, urine, creatinine, CK-MB</p>	<p>α-1-acid glycoprotein, α-1-antitrypsin, albumin, apo A &amp; B, antistreptolysin-O, AT III, complement C3c &amp; C4, ceruloplasmin, CRP latex, ferritin, IgA/G/M, myoglobin, prealbumin, RF, transferrin, amphetamine, barbiturate, benzoin, cocaine, ethanol, LSD, methamphetamine, opiates, PCP, PPH, S barbital, S benzoin, THC, ACPP, ALP, ALT, α-amylase, pancreatic amylase, AP, AST, cholinesterase &amp; Che-D, CK-MB, γ-glutamyltransferase, LDH, lipase, albumin, bilirubin direct &amp; total, calcium, cholesterol, CO<sub>2</sub>, creatinine, fructosamine, glucose, HbA1c, HDL direct, iron, lactate, LDL direct, Mg, ammonium, phosphate, TP, TPU-C, triglyceride, UA, UIBC, urea, Na, K, Cl, Li, acetaminophen, amikacin, carbimazole, digoxin, digitoxin, gentamicin, lidozine, NAPA, phenolphthalein, primidone, procainamide, salicylate, theophylline, tobramycin, valproic acid, vancocin, T<sub>4</sub>, T-up, D-dimer, soluble transferrin receptor</p>
<p>Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries Research-use-only assays/tests in development User-defined methods implemented for what analytes</p>	<p>none none none none/none none</p>	<p>none none cyclosporine, lipoprotein A none/homocysteine, cyclosporine none</p>
<p>Methods supported/immunoassay methods</p>	<p>potentiometry, dry slide technology/n/a</p>	<p>photometry, potentiometry, fluorescence polarization/turbidimetric, latex particle enhanced</p>
<p>No. of direct ion selective electrode channels • must load separate reagent pack for ea. spec./no. diff. assays in pack • separate reagent pack for each test run No. of different measured assays onboard simultaneously No. of different assays programmed, calibrated at once No. of user-definable (open) channels/no. active simultaneously No. of different analytes for which system accommodates reagent containers onboard at once/tests per container set Shortest/median onboard reagent stability/refrigerated onboard Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when 3rd-party reagent used Reagent only cost per reportable result for standard chemistries/therapeutic drugs/special analytes Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated 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 Auto2P Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reagent for aspirate &amp; analysis Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard/automatic rerun capability Sample volume can be reduced/increased to rerun out-of-linear-range high/low results Autocalibration or autocalibration alert Calibrants stored onboard/multipoint calibration supported Typical calibration frequency for ISE/metabolites/ther. drugs/drugs of abuse Automatic shutdown/startup programmable</p>	<p>4 yes/1 yes n/a 1 none n/a/n/a n/a/no no no n/a n/a/n/a/n/a n/a/n/a/n/a dry no/n/a no/n/a 10 µL no/no no/none — n/a no/no no yes — n/a n/a/yes/yes yes —/— no/no no no no/yes 6 mos/6 mos/6 mos/n/a no/no</p>	<p>4 no/n/a no 36 tests plus applications for urine &amp; CSF up to 999 0/0 36/50–800 tests 2 weeks/8–12 weeks/yes (12° C) yes yes no —/—/— 176/90/1,808 liquid, reconst. onboard yes/1,500 no/n/a 1 µL no/no no/2 L maximum — — Yes/no yes (2 of 5 interl., Codabar, codes 39 &amp; 128)/autodiscrimination yes — yes yes/yes/no (not necessary due to sampling method) — no/no yes/yes yes/yes — yes yes/yes 5 hrs/once per lot/each lot &amp; 12 weeks/each lot &amp; 12 weeks yes/yes</p>
<p>Stat time to completion of all analytes, throughput per hr. for: • Sodium, potassium, chloride, TCO<sub>2</sub> • Sodium, potassium, chloride, TCO<sub>2</sub>, glucose, urea, creatinine • Albumin, bili. direct &amp; total, AST, ALT, ALP Typical time delay from ordering stat test to aspirate of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS</p>	<p>100 tests per hr 100 tests per hr 100 tests per hr none every 24 hrs/no no/no —</p>	<p>—, — —, — —, — — 24 hrs/yes yes/yes yes</p>
<p>Data mgmt. capability/instrument vendor supplies LIS interface Interfaces up and running in active user sites with Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders &amp; results</p>	<p>—/no — no yes yes —</p>	<p>onboard/yes (add'l cost) all major LIS vendors yes (broadcast download &amp; host query) yes yes —</p>
<p>Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system</p>	<p>no no</p>	<p>— —</p>
<p>Modem servicing available/can diagnose own malfunctions/determine malfunctioning component On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)</p>	<p>no/yes/yes —/yes — daily: 5 min, weekly: 5 min, monthly: none no/no 1 d on-site/— —</p>	<p>yes/yes/yes —/— —/— daily: none, weekly: 5 min, monthly: none yes (includes audit trail of who replaced parts)/yes 5 d at vendor offices/yes —</p>
<p>Distinguishing features</p>	<p>disposable tips eliminate sample carryover; random access testing so chemistries can be run in any order, with no reagent prep.; indiv. packaged test slides elim. waste &amp; facilitate rapid analysis; dry slide technology minimizes the effects of common interferences to provide precise, accurate results; wide ranges allow for fewer dilutions &amp; repeats</p>	<p>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</p>

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## Chemistry analyzers (for low-volume laboratories)

<p><i>Part 9 of 9</i></p> <p><i>See accompanying comments on page 74</i></p>	<p>Roche Diagnostics Corp. 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.us.labsystems.roche.com</p>	<p>Roche Diagnostics Corp. 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.us.labsystems.roche.com</p>
<p>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 (H x W x D)/instrument footprint</p>	<p>Roche Hitachi 912/1997 \$159,000 &gt;1,100 Japan-U.S./Japan-U.S./U.S.-Germany continuous random access/open reagent system disk/floor-standing 46 x 40 x 30 in./8.3 sq. ft.</p>	<p>Cobas Mira Plus CC/1992 \$50,000 2,500/12,500 Switzerland/Switzerland/Germany-U.S. random access/open reagent system rack/benchttop 26 x 29 x 23 in./4.63 sq. ft.</p>
<p>Tests available on instrument in U.S.</p> <p>Tests cleared but not clinically released Tests not available in U.S. but submitted for 510(k) clearance Tests not available in U.S. but available in other countries</p> <p>Research-use-only assays/tests in development User-defined methods implemented for what analytes</p>	<p>alb., ALP, ALT, ammonia, amy. total &amp; panc., AST, bili. total &amp; direct, BUN, Ca, cholest., cholinest., CK, CK-MB, CO<sub>2</sub>, crea., fruct., GGT, glu., HDL direct, iron, lact., LD, LD-1, LDL direct, lipase, Mg, phos., TIBC (calc.), NAPA, procainamide, TP, trig., T<sub>4</sub>, T-up, UIBC, UA, Na, K, Cl, <math>\alpha</math>-1-antitryp., ASLO, B-2-microgl., C3c, C4, ceru., CRP, ferr., fol., hapt., HbA1c, IgA/E/G/M, microalb., myo., prealb., RF, transferrin, B<sub>12</sub>, 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</p> <p>none none kappa/lambda light chains, %CDT, <math>\alpha</math>-1-glycoprotein, Apo A1, Apo B, <math>\alpha</math>-1-microgl., cyclos., lipoprotein (a) none/homocysteine none</p>	<p>ACP, alb., alk. phos., ALT, amy., amm., Apo A1 &amp; B, AST, bili. direct &amp; total, BUN, Ca., chol., CK, CO<sub>2</sub>, crea., alcohol, iron TIBC, GGT, HDL direct, HDL, glu., LDH, LDL direct, Mg, phosphorus, TP, triglycerides, UA, fruct., HbA1c, amph., barb., benz., THC, coca., methad., methaq., opia., PCP, propoxy., dig., acetamin., salic, Na, K, Cl by ISE</p> <p>none none none none/information to be released at test launch none</p>
<p>Methods supported/immunoassay methods</p> <p>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</p> <p>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</p> <p>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</p> <p>Walkaway capacity in minutes/specimens/tests-assays System is liquid or dry Uses disposable cuvettes/max. no. stored Uses washable cuvettes/replacement frequency Minimum sample volume aspirated precisely at one time Supplied with UPS (backup power)/requires floor drain Requires dedicated water system/water consumption Noise generated Dedicated pediatric sample cup/dead volume Primary tube sampling/pierces caps on primary tubes Sample bar-code reading capability</p> <p>Reagent bar-code reading capability Bar code placement per NCCLS standard Auto2P Onboard test auto inventory (determines volume in container) Measures no. tests remaining/short sample detection/clot detection Automatic detection of adequate reag. for aspir. &amp; 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</p>	<p>photometry, potentiometry/turbidimetric, latex particle enhanced, CEDIA</p> <p>3 no/n/a no 35 tests plus applications for urine &amp; CSF 68 65/65 35/100-500</p> <p>—/30 d/yes (2-12° C) yes yes no —/—/—</p> <p>408/70/2,450 liquid no/n/a yes/monthly (120 stored on instrument) 2 <math>\mu</math>L no/yes yes/30 L <math>\leq</math>65 decibels yes/— yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 &amp; 128)/autodiscrimination yes yes yes yes/yes/no (not necessary due to sampling method) yes yes/yes yes/yes yes yes/yes 24 hrs/lot change (every 6 mos)/3-5 d/56 d yes/—</p>	<p>photometry, potentiometry/n/a</p> <p>3 no/n/a no max. 30 104 + profiles &amp; ratios 104 + profiles &amp; ratios/max. 30 max. 30/40-50</p> <p>6-8 hrs/30 d/yes (10-14° below ambient) yes yes, but requires some operator prehandling/prep. no —/—/—</p> <p>max. 120 min/90/depends on test vol. liquid yes/— no/n/a 1 <math>\mu</math>L no/no no/4 L daily <math>\leq</math>62 decibels no yes/no yes, as soon as tubes loaded &amp; start key activated (2 of 5 interl., Codabar, codes 39 &amp; 128)/autodiscrimination no — no no/yes/no yes no/no yes/yes yes/yes yes yes/yes every hr/30-60 d/—/n/a no/no</p>
<p>Stat time to completion of all analytes, throughput per hr. for:</p> <ul style="list-style-type: none"> <li>• Sodium, potassium, chloride, TCO<sub>2</sub></li> <li>• Sodium, potassium, chloride, TCO<sub>2</sub>, glucose, urea, creatinine</li> <li>• Album., bili. direct &amp; total, AST, ALT, ALP</li> </ul> <p>Typical time delay from ordering stat test to aspir. of sample How often QC required/onboard SW capability to review QC Onboard real-time QC/support multiple QC lot nos. per analyte QC results transferred automatically to LIS</p>	<p>3.5 min, 180 specimens 5.5 min, 90 specimens 10.5 min, 60 specimens 30 sec 24 hrs/yes yes/yes yes</p>	<p>4 min, 15 specimens 7 min, 9 specimens 7.5 min, 8 specimens none 8 hrs, longest interval: daily/yes yes/no yes</p>
<p>Data mgmt. capability/instrument vendor supplies LIS interface</p> <p>Interfaces up and running in active user sites with</p> <p>Bidirectional interface capability Test results transmitted to LIS as soon as chem. time complete LIS interface operates simultaneously with running assays Uses LOINC to transmit orders &amp; results</p>	<p>onboard/yes (add'l cost)</p> <p>all major LIS vendors</p> <p>yes (host query) yes yes no</p>	<p>onboard &amp; optional add-on (\$5,000, SW mfr: Antek, Fletcher Flora)/no</p> <p>—</p> <p>yes yes yes —</p>
<p>Lab can control analyzer remotely Interface avail. (or will be) to automated specimen handling system</p>	<p>no yes (CLAS)</p>	<p>yes (limited) no</p>
<p>Modem servicing available/can diagnose own malfunctions/determine malfunctioning component</p> <p>On-site time of svc. engineer/onboard error codes for troubleshooting Mean time between failures/to repair failures Average time to complete maintenance by lab personnel Onboard maintenance records/maint. training demo module Training provided with purchase/advanced oper. training avail. Annual service contract cost (24 h/7 d)</p>	<p>no/yes/yes</p> <p>—/yes —/— daily: —, weekly: —, monthly: — yes (includes audit trail of who replaced parts)/yes 5 d at vendor offices/yes —</p>	<p>no/—/—</p> <p>24 hrs/yes 4 mos/2 hrs daily: 10 min, weekly: 10 min, monthly: 5 min no/no 4 d at vendor offices/no approx. \$9,000</p>
<p>Distinguishing features</p>	<p>sophisticated software with easy stat function provides instant stat selection; Roche Hitachi open system dependability and throughput</p>	<p>level detection of the sample &amp; reag.; user friendliness of entire system</p>

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