

Low-volume analyzers: growing menus, more consolidation

Brendan Dabkowski

It's not an oxymoron, but the desire to obtain larger test menus from simplified product offerings is akin to wanting jumbo shrimp.

Yet enhanced test menus and greater consolidation are on the horizon for the low-volume chemistry/immunoassay analyzers marketplace, according to the makers of such instruments. Alfa Wassermann Diagnostic Technologies anticipates that customers will be asking for expanded assay menus that provide full disease-state profiling on a single workstation, says Trip Trepagnier, vice president of marketing and business development. Roche Diagnostics marketing manager Adam Sterle agrees that customers will demand "greater breadth and depth of menu." Adds Bruno Borganti, AMS Diagnostics' vice president of North American operations: "Certainly the ability to run more types of tests on the same platform" is desirable, as are analyzers that are "simple in design but with no limitation on sample-loading capacity."

New to Alfa Wassermann's assay menu is no-pretreatment HbA1c, which, Trepagnier says, requires no manual pretreatment steps, has 30-

day onboard stability, and is available on the ACE, ACE Alera, and ACE Axcel clinical chemistry systems.

Alfa Wassermann launched in August the ACE Axcel clinical chemistry system. Built-in Internet connectivity allows the analyzer to link with electronic health records using any laboratory information system. Designed for physician office labs, the analyzer performs up to 285 tests per hour with photometric and potentiometric technologies and runs any combination of single tests, panels, or profiles from a comprehensive test menu.

Another system launched in August was AMS Diagnostics' Liasys 450 clinical chemistry analyzer,

which can perform 450 tests per hour, has a test cycle of 13 seconds, has an onboard capacity of 72 assays, and provides a full test menu, including testing for drugs of abuse. The system has a service interface that allows operators to "save and send pertinent files and information to the service organization via e-mail," Borganti says.

Also in this month's product guide is the Liasys 330 clinical chemistry system, which performs 330 tests per hour. Next year, Borganti says, AMS will introduce a 650-test-per-hour chemistry system in benchtop and floor-model configurations.

EliTech Clinical Systems will soon release updated Selectra TouchPro software for its Selectra

Letters

EMR donations

The article in the August issue titled "On EMR donations, steer clear of troubled waters" contains valuable advice on laboratory compliance with federal law when making these donations. However, the article exclusively focuses on the federal

aspect of this issue and does not mention important state law applicability. The federal safe harbor for electronic health record donations does not preempt or displace state anti-kickback law and regulations. The CAP, working with state pathology societies, has obtained attorney general or agency clarifications on the application of state anti-kickback law to these donations.

In response to our efforts, five states (New York, New Jersey, Pennsylvania, Missouri, and West Virginia) have issued formal guidance to the clinical laboratory community on the application of their respective state anti-kickback law to these donations. Notwithstanding the federal safe harbor, these state opinions can limit or prohibit the donation of the EHR as delineated. The text of the state opinions elicited to date can be found on the CAP advocacy Web site in the State Advocacy section. As of this writing, other CAP-state pathology society requests for state clarification are pending and may be issued.

The CAP has long advocated with the Office of Inspector General for Health and Human Services and others at the federal level for the removal of pathologists and laboratories as protected EMR donors under the federal EHR safe harbor currently scheduled to sunset on Dec. 31, 2013. The CAP continues to advocate along these lines regardless of the scheduled sunset.

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See, Test and Treat program

On Aug. 18, I and colleagues provided services through the CAP Foundation's See, Test and Treat program at a health fair at the Nhân Hòa Comprehensive Health Care Clinic in Garden Grove, Calif., which more than 700 people attended. We could not have done our

work alone. A grant from the CAP Foundation and donations from Pathology Inc. laboratory in Torrance, Calif., Hologic, Qiagen USA, CooperSurgical, and others made it possible for us to provide in one day cervical cancer screening to 168 women. Fifty-three women were screened for breast cancer; the See, Test and Treat grant helped fund the purchase of mammogram supplies. This took place in Orange County, one of the richest counties in the U.S., yet as the turnout shows, many are without insurance and access to basic care. Many women at Nhân Hòa clinic had never before had a Pap test; others hadn't had one in five years or more. Of the 141 Vietnamese women tested for cervical cancer, abnormal results were found in 14. That's a 10 percent abnormal rate in our Vietnamese community, where cancer is considered a death sentence and a punishment and is a taboo subject. See, Test and Treat is helping to clear up some of the misinformation and begin in this community a much-needed dialogue about cancer.

See, Test and Treat at this time is in only a handful of cities, but the hope is that it will spread. At the CAP '12 annual meeting last month, the program in Minneapolis was recognized for its accomplishments. Several pathologists at the meeting were inspired by the success of the Minneapolis See, Test and Treat, and the ones at Nhân Hòa and in Boston and Houston, and are planning to do volunteer work with an existing program or to start one of their own. We can help prevent cancer and perhaps change cultural attitudes one Pap test at a time.

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Chemistry analyzers (for low-volume laboratories)

Pro S and Selectra Pro M benchtop systems, both of which were launched last year. The software will enable the analyzers to anticipate worklists for calibrations and controls, meaning that if an analyzer is configured to perform QC measurements once per day, the system will display the list of tests for which controls should be run. "The operator can load and run the quality control tests as suggested or override the list of tests by deselecting it," says Abe Gutman, EliTech's North American vice president of marketing and sales. Other software enhancements will be additional reporting capabilities and the ability to import and export data for further analysis.

Both Selectra Pro analyzers offer icon-driven operator touchscreens, positive sample identification, and automated reagent programming and tracking, Gutman says. The Pro M typically processes 180 tests per hour, while the Pro S typically processes 140 tests per hour. Both products received FDA clearance for creatine-kinase testing in August. And the company has "multiple new tests in development, including iron and hsCRP [high-sensitivity C-reactive protein]," Gutman adds.

New to the product guide, but available since 2008, is Mindray North America's BS-200 benchtop chemistry analyzer for small- to medium-volume labs. The BS-200 runs general chemistry and drugs-of-abuse tests, says Peggy Chan, Mindray's North America regional marketing manager of in vitro diagnostic products. It performs up to 200 tests per hour or up to 330 tests per hour with ion-selective electrodes. The system has a built-in bar-code scanner, refrigerated reagent and sample compartments, and a bi-directional LIS interface.

At MedTest Dx, the focus is on chemistry testing for physician pain management centers as well as physician office labs. "Our number-one arena where we're selling is in the pain management centers and group practices that are doing pain management," says Dennis Boyle, vice president of sales and corporate development. The company continues to offer its Poly-Chem 90, 180, and 400 systems, as well as the SpotChem EZ analyzer. MedTest Dx is also a third-party reagent supplier, Boyle adds.

New to Roche Diagnostics' Cobas c 311 analyzer are oral fluid drugs-of-abuse tests for amphetamines, cocaine, opiates, PCP, and methamphetamines. "Workstation consolidation and complete menus are key criteria for small hospital labs," Sterle says.

And finally, Beckman Coulter Diagnostics continues to offer, for small- to medium-volume labs, its AU480 chemistry system, which has an onboard capacity of 76 assays and performs up to 400 tests per hour, or up to 800 with electrolytes, says senior marketing manager Stephen Ishii.

CAP TODAY's guide to chemistry/immunoassay analyzers for low-volume labs includes products from the aforementioned manufacturers and from Abaxis, Abbott Point of Care, Awareness Technology, Carolina Liquid Chemistries, Horiba Medical, Medica Corp., Nova Biomedical, Randox Laboratories, Siemens Healthcare Diagnostics, and Vital Diagnostics. Companies supplied the information listed. Readers interested in a particular product should confirm that it has the stated features and capabilities.

Brendan Dabkowski is CAP TODAY associate editor.

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See captodayonline.com/productguides for an interactive version of guide		
Name of instrument/First year sold in U.S./List price No. of units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Reagents manufactured Operational type/Reagent type	Piccolo Xpress/2006/16,500 2,500/4,000 U.S./U.S./U.S. discrete/self-contained single-use cartridges-packages-slides	i-Stat 1 analyzer/2000/— 30,000+ worldwide U.S./U.S./Canada —/self-contained single-use cartridges packages-slides
Sample handling system/Model type	disk loaded directly into instrument/ benchtop	—/handheld
Dimensions in inches (H × W × D)/Instrument footprint	12.75 × 6 × 8/<1 square foot	9.25 × 3.0 × 2.85/<1 square foot
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, others	tropinin I, CK-MB, lactate, BUN, creatinine, glucose, ionized calcium, sodium, potassium, chloride, hematocrit, pH, PCO ₂ , PO ₂ , TC0 ₂ , ACTc, ACTk, others
Research-use-only assays/Tests in development Analytes for which user-defined methods have been implemented	— —	— —
Methods supported/Immunoassay methods	photometry, enzymatic/—	potentiometry, amperometric, conductometric/—
No. of direct-ion selective electrode channels	0 (system is enzymatic)	10
• Must load separate reagent pack for each specimen	yes	no (unit-use cartridge based)
• Separate reagent pack for each test run	no	yes
No. of different measured assays onboard simultaneously	CLIA-waived CMP has 14 analytes	—
• No. of different assays programmed and calibrated at once	14	18
• No. of user-definable (open) channels/No. active simultaneously	0/—	—
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	29/up to 14	—/unit use
• Shortest/Median onboard reagent stability/Refrigerated onboard	—/—/yes (0°–8°C)	—/14 days/no
• Multiple reagent configurations supported	yes	no
Reagent container placed directly on system for use	yes	—
Instrument has same capabilities when third-party reagent used	—	—
Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays	30 seconds hands-on; 12 minutes to printed result/1/up to 29 available analytes in menu, up to 14 per reagent disk	2/1/up to 18
System is liquid chemistry, dry chemistry, or reconstituted onboard	liquid reconstitutes onboard	—
• Uses disposable cuvettes/Maximum No. stored	no/28 cuvettes per reagent disk	no/—
• Uses washable cuvettes/Replacement frequency	no/—	no/—
Minimum sample volume aspirated precisely at one time	requires 80–100 µL of whole blood, serum, or plasma	16 µL
System supplied with UPS (backup power)/Requires floor drain	yes/no	no/no
Requires dedicated water system/Water consumption in L per hour	no/—	no/—
Noise generated in decibels	none	none
Dedicated pediatric sample cup/Dead volume	no/—	no/—
Primary tube sampling/Pierces caps on primary tubes	no/no	no/no
Sample bar-code reading capability/Autodiscrimination	Intelligent Quality Control system automatically reads bar code on disk/—	yes (reads operator, cartridge, and patient bar code)/yes
• Reagent bar-code reading capability	yes	yes
Onboard test auto inventory (determines volume in container)	—	—
• Measures No. of tests remaining/Short sample detection/Clot detection	—/yes/yes	—/yes/yes
• Automatic detection of adequate reagent for aspiration and analysis	yes	yes
• Hemolysis/Turbidity detection-quantitation	yes/yes	no/no
Dilution of patient samples onboard/Automatic rerun capability	yes/no	no/no
• Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	—/—	no/no
Autocalibration or autocalibration alert	yes	yes
• Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes
Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	self-calibrated onboard/self-calibrated onboard/—/—	each test/each test/—/—
Automatic shutdown/Startup programmable	yes/yes	yes/yes
Stat time to completion of all analytes/throughput per hour for:		
• Sodium, potassium, chloride, TC0 ₂	30 seconds hands-on, 10–12 minutes to printed result/2–14 tests per disk	2 minutes/—
• Sodium, potassium, chloride, TC0 ₂ , glucose, urea, creatinine	30 seconds hands-on, 10–12 minutes to printed result, 2–14 tests per disk	2 minutes/—
• Albumin, direct and total bilirubin, AST, ALT, ALP	30 seconds hands-on, 10–12 minutes to printed result, 2–14 tests per disk	—
Typical time delay from ordering stat test to aspiration of sample	none	none
Frequency of QC required/Onboard SW capability to review QC	shortest: automatic QC onboard with every run; longest: external high/low QC required monthly, according to CLIA guidelines/yes	shortest interval: 24 hours; longest interval: each new lot or reagent/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-management capability/Instrument vendor supplies LIS interface	onboard/no	optional add-on (<\$30,000, SW manufacturer: Abbott Point of Care)/yes (additional cost)
• LISs with which system interfaces in active user sites	many	all systems
Bidirectional interface capability	yes (broadcast download and host query)	yes (broadcast download and host query)
LIS interface operates simultaneously with running assays	yes	yes
Uses LOINC to transmit orders and results	yes	yes
• How labs get LOINC codes for reagent kits	Web site, package insert, e-mail query	customized on site
Lab can control analyzer remotely	yes	yes
Modem servicing available/System can diagnose own malfunctions	yes/yes	yes/yes
On-site time of service engineer/Onboard error codes for troubleshooting	not necessary, 24-hour RMA turnaround of loaner instruments/yes	replacement within 24 hours/yes
• Mean time between failures/To repair failures	none/replacement within 24 hours	not determined/replacement within 24 hours
Onboard maintenance records/Maintenance training demo module	yes/yes	—
Training provided with purchase/Advanced operator training	1–2 hours (supplemented by free Web-cast)/yes	—/yes
Annual service contract cost (24 hours/7 days)	1-year warranty standard; 3 years often free through distribution partners; \$1,195 for additional years	based on volume
Distinguishing features (supplied by company)	comprehensive CLIA-waived menu of tests; 15 disks (11 CLIA-waived) represent commonly ordered chemistry panels; works with three simple steps; intranet connectivity extends reach to the point of care, while maintaining centralized control of test data	handheld portable analyzer; unit use system can perform chemistry, blood gas, cardiac marker, and coagulation tests with two drops of whole blood or plasma

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Chemistry analyzers (for low-volume laboratories)

Part 2 of 10 <i>See captodayonline.com/productguides for an interactive version of guide</i>	Alfa Wassermann Diagnostic Technologies LLC Lauren DiPrima ldiprima@alfawassermannus.com 4 Henderson Dr., West Caldwell, NJ 07006 800-220-4488 www.alfawassermannus.com	Alfa Wassermann Diagnostic Technologies LLC Lauren DiPrima ldiprima@alfawassermannus.com 4 Henderson Dr., West Caldwell, NJ 07006 800-220-4488 www.alfawassermannus.com	AMS Diagnostics, LLC Bruno Borganti bb@amsdiagnostics.com 141 N. Main Street, Suite B, Summerville, SC 29483 866-419-7839 www.amsdiagnostics.com
Name of instrument/First year sold in U.S./List price No. of units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Reagents manufactured Operational type/Reagent type Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	ACE/1993; ACE Alera Clinical Chemistry System/2004— 1,300/800+ U.S./U.S./U.S. batch, random access, discrete, continuous random access/stat and closed reagent system with open reagent system channel ring with up to 5 segments (15 samples per segment)/benchtop	ACE Axccl/2012/\$59,995 — U.S./U.S./U.S. batch, random access, discrete, continuous random access/stat closed reagent system with open reagent system channel ring with up to 5 segments (15 samples per segment)/benchtop	LIASYS (330)/2009/\$45,000 68/\$1,682 Europe-U.S./Europe-U.S./Europe-U.S. batch, random access, discrete, continuous random access/— 5 sliding racks for primary tubes from 10–16 mm diameter, from 40–100 mm height, short cups 1 mL, short cups 3 mL, conical/benchtop 16.5 × 39.3 × 25.6/6.78 square feet
Tests available on instrument in U.S. Research-use-only assays/Tests in development Analytes for which user-defined methods have been implemented	urine applications (creatinine, urea, calcium, phospho- rous), albumin, gamma GT, bilirubin direct and total, calcium, creatinine, glucose, HbA1c, phosphorus, total iron, magnesium, total protein, BUN, uric acid, others —/enzymatic creatinine, hsCRP open-channel bottles are available for user-derived or third-party reagents	ALT, ALB, ALP, AMY, AST, DBILI, TBILI, BUN, Ca, CO2, CI, CHOL, CK, CREAT, Ferritin, GGT, GLU, HbA1c, HDL, PHOS, IRON, LDH, LIPASE, LDL, Mg, K, TP, Na, direct TIBC, T4, TRIG, T uptake, UA —/Apo A1, Apo B, Lp(a), microalbumin, transferrin, urine applications (creatinine, urea, calcium, phosphorus), enzymatic creatinine, hsCRP open-channel bottles are available for user-derived or third-party reagents	general chemistries, electrolytes, enzyme assays, lipid assays, HbA1c, lipase, microalbumin, microprotein, DOA, others dedicated research software available —
Methods supported/Immunoassay methods No. of direct-ion selective electrode channels <ul style="list-style-type: none"> • Must load separate reagent pack for each specimen • Separate reagent pack for each test run No. of different measured assays onboard simultaneously <ul style="list-style-type: none"> • No. of different assays programmed and 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 <ul style="list-style-type: none"> • Shortest/Median onboard reagent stability/Refrigerated onboard • Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when third-party reagent used Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays System is liquid chemistry, dry chemistry, or reconstituted onboard <ul style="list-style-type: none"> • Uses disposable cuvettes/Maximum No. stored • Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time System supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination <ul style="list-style-type: none"> • Reagent bar-code reading capability Onboard test auto inventory (determines volume in container) <ul style="list-style-type: none"> • Measures No. of tests remaining/Short sample detection/Clot detection • Automatic detection of adequate reagent for aspiration and analysis • Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard Automatic rerun capability <ul style="list-style-type: none"> • Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert <ul style="list-style-type: none"> • Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown/Startup programmable	photometry, potentiometry (ion-selective electrode), turbidimetric homogeneous EIA 3 no no 40 200 15/15 40/30–250 tests per bottle 5 days/30 days/yes (10°–14°C) yes yes yes 75/75/248 liquid yes/248 no/— 3 µL no/no no/— 55 no/— yes/yes yes, as sample is being aspirated (2 of 5 interleaved, UPC, Codabar, code 39, code 128 set B and C)/yes yes, proprietary dot coding yes/yes/no yes — yes yes/no yes no/yes 3 hours/30 days/45 days with 48-hour updates/— —	photometry, potentiometry (ion-selective electrode), turbidimetric homogeneous EIA 3 no no 40 200 15/15 40/30–250 tests per bottle 120 hours/30 days/yes (10°–14°C) yes yes yes 75/75/248 liquid yes/248 no/— 3 µL no/no no/— 55 no/— yes/yes yes (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes yes yes/yes/no yes no/no yes yes yes/no yes no/yes 3 hours/30 days/45 days with 48-hour updates/— no/no	photometry, potentiometry (ion-selective electrode)/turbidimetry 3 no no 36 36 200/36 36/250–400 7 days/20 days/yes (2°–8°C) yes yes yes 240/64/36 liquid no/60 yes/40,000 tests 2 µL no/no no/0.5 45 no/50 µL yes/no yes/yes yes yes yes/yes/yes yes yes/yes yes yes yes/yes autocalibrate/14 days/14 days/14 days yes/yes
Stat time to completion of all analytes/throughput per hour for: <ul style="list-style-type: none"> • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct and total bilirubin, AST, ALT, ALP Typical time delay from ordering stat test to aspiration of sample Frequency of 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	4 minutes/35 specimens 7 minutes/20 specimens 10 minutes/12 specimens immediate response, as soon as 10 seconds daily/yes yes/yes yes	4 minutes/35 specimens 7 minutes/20 specimens 10 minutes/12 specimens immediate response, as soon as 10 seconds daily/yes yes/yes yes	2 minutes, 3 seconds/150 specimen 5 minutes, 6 second/35 specimens 8 minutes, 4 seconds/144 specimens 4 seconds 8–24 hours/yes yes/yes yes
Data-management capability/Instrument vendor supplies LIS interface <ul style="list-style-type: none"> • LISs with which system interfaces in active user sites Bidirectional interface capability LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results <ul style="list-style-type: none"> • How labs get LOINC codes for reagent kits 	onboard/no Antek, Apex, LabPak, Schuyler House, others yes (host query) yes no —	onboard/no Apex Healthcare yes (host query) yes no —	onboard/yes, included Antek, Fletcher, Flora, others yes (broadcast download and host query) yes no —
Lab can control analyzer remotely	no	no	yes
Modem servicing available/System can diagnose own malfunctions	no/yes	yes/yes	yes/yes
On-site time of service engineer/Onboard error codes for troubleshooting <ul style="list-style-type: none"> • Mean time between failures/To repair failures Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced operator training Annual service contract cost (24 hours/7 days)	24 hours/yes 8 months/1 hour yes/no 4.5 days at manufacturer's facility/yes several programs available	24 hours/yes 8 months/1 hour yes (includes audit trail)/no 4.5 days at manufacturer's facility/yes several programs available	24 hours/yes 11.5 months/30 minutes no/— 5 days on site, 1 day at vendor offices/yes \$7,500 warranty extension
Distinguishing features (supplied by company)	closed-tube sampling; stat interrupt capability; onboard sample and reagent refrigeration; onboard reagent inventory management; ready-to-use reagents; integrated ISE module; self-contained analyzer; no external water source or waste drainage	closed-tube sampling; stat interrupt capability; onboard sample and reagent refrigeration; onboard reagent inventory management; ready-to-use reagents; integrated ISE module; self-contained analyzer; no external water source or waste drainage; Internet connectivity allows for technical support, remote access, and laboratory integration	monitors cuvette cleanliness, flags its replace- ment; cuvettes can change immediately; displays all system and patient tests status on first screen; at-a-glance interface design saves time running chemistry panels; precision data comparison; runs three reagent methods; suitable for more esoteric testing in development; automatic samples predilu- tion, postdilution, and post-concentration

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Part 3 of 10 <i>See captodayonline.com/productguides for an interactive version of guide</i>	AMS Diagnostics, LLC Bruno Borganti bb@amsdiagnostics.com 141 N Main Street Suite B, Summerville, SC 29843 843-277-1642 www.amsdiagnostics.com	Awareness Technology Jamie Ristaino info@awaretech.com 1935 S.W. Martin Highway, Palm City, FL 34990 772-283-6540 www.awaretech.com	Awareness Technology Jamie Ristaino info@awaretech.com 1935 S.W. Martin Highway, Palm City, FL 34990 772-283-6540 www.awaretech.com
Name of instrument/First year sold in U.S./List price No. of units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Reagents manufactured Operational type/Reagent type	LIASYS 450 Clinical Chemistry System/2012/\$55,000 8/197 Europe, U.S./Europe U.S./— batch, random access, discrete, continuous random access/AMS Diagnostics, dedicated reagents	ChemWell-T/2010/\$12,500 5/550 U.S./U.S./open system batch, random access, continuous random access/ open reagent system	Stat Fax 4500/2009/\$2,895 200/2,800 U.S./U.S./open system —/open reagent system
Sample handling system/Model type	4 rotating racks with 16 universal positions each, plus 8 stationary positions	custom-configurable rack/benchtop	tube, cuvette, or flowcell/benchtop
Dimensions in inches (H × W × D)/Instrument footprint	19.7 × 35.4 × 27.6/6.78 square feet	20 × 21 × 16/3 square feet	5 × 9 × 13.5/<1 square feet
Tests available on instrument in U.S.	general chemistries, electrolytes, enzyme assays, lipid assays, specialty assays including microalbumin, CRP, Homocysteine, ApoB and Lp(a)	open system	open system
Research-use-only assays/Tests in development Analytes for which user-defined methods have been implemented	dedicated research software available —	— —	— —
Methods supported/Immunoassay methods	photometry, potentiometry (ion-selective electrode)/immunoturbidimetry	photometry	photometry
No. of direct-ion selective electrode channels	3	—	—
• Must load separate reagent pack for each specimen	no	—	—
• Separate reagent pack for each test run	no	—	—
No. of different measured assays onboard simultaneously	64	40	—
• No. of different assays programmed and calibrated at once	64	—	1
• No. of user-definable (open) channels/No. active simultaneously	12/12	PC-based	120/1
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	72/600	variable/—	—
• Shortest/Median onboard reagent stability/Refrigerated onboard	7 days/20 days/yes (2°–8°C)	—/—/yes (9°–12°C below ambient)	—/no
• Multiple reagent configurations supported	yes	yes	—
Reagent container placed directly on system for use	yes	yes	—
Instrument has same capabilities when third-party reagent used	yes	yes	yes
Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays	240/72/64	—/—/40	—
System is liquid chemistry, dry chemistry, or reconstituted onboard	liquid	liquid	liquid
• Uses disposable cuvettes/Maximum No. stored	no/80	yes/40	yes/12
• Uses washable cuvettes/Replacement frequency	yes/40,000 tests	yes/variable	yes/supplier-dependent
Minimum sample volume aspirated precisely at one time	2 µL	2 µL	250 µL
System supplied with UPS (backup power)/Requires floor drain	yes/no	no/no	no/no
Requires dedicated water system/Water consumption in L per hour	no/50 µL	no/—	no/—
Noise generated in decibels	<45	—	<45
Dedicated pediatric sample cup/Dead volume	no/—	no/—	no/—
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no	—
Sample bar-code reading capability/Autodiscrimination	yes (2 of 5 interleaved, UPC, Codabar, code 39, code 128)/yes	no/no	no/—
• Reagent bar-code reading capability	yes	no	—
Onboard test auto inventory (determines volume in container)	yes	yes	—
• Measures No. of tests remaining/Short sample detection/Clot detection	yes/yes/yes	—/yes/no	—
• Automatic detection of adequate reagent for aspiration and analysis	yes	yes	—
• Hemolysis/Turbidity detection-quantitation	yes/yes	no/no	—
Dilution of patient samples onboard	yes	yes	—
Automatic rerun capability	yes	—	—
• Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	yes/yes	yes/yes	—
Autocalibration or autocalibration alert	yes	yes	no
• Calibrants stored onboard/Multipoint calibration supported	yes/yes	no/yes	—/yes
Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	autocalibrate/14days/14days/14 days	—	—
Automatic shutdown/Startup programmable	yes/yes	no/no	no/no
Stat time to completion of all analytes/throughput per hour for:			
• Sodium, potassium, chloride, TC02	2 minutes, 3 seconds/150 specimens	—	—
• Sodium, potassium, chloride, TC02, glucose, urea, creatinine	4 minutes, 20 seconds/300 specimens	—	—
• Albumin, direct and total bilirubin, AST, ALT, ALP	6 minutes, 45 seconds/300 specimens	—	—
Typical time delay from ordering stat test to aspiration of sample	4 seconds	—	—
Frequency of QC required/Onboard SW capability to review QC	8-24 hours/yes	—/yes	—
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	yes/yes	—
QC results transferred automatically to LIS	yes	yes	—
Data-management capability/Instrument vendor supplies LIS interface	onboard/no	onboard/—	no/no
• LISs with which system interfaces in active user sites	Labdaq, Fletcher Flora, Antech standard ASTM protocol	—	—
Bidirectional interface capability	yes (broadcast download and host query)	yes	no
LIS interface operates simultaneously with running assays	yes	yes	—
Uses LOINC to transmit orders and results	no	no	—
• How labs get LOINC codes for reagent kits	no	—	—
Lab can control analyzer remotely	yes	no	no
Modem servicing available/System can diagnose own malfunctions	yes/yes	yes/yes	—
On-site time of service engineer/Onboard error codes for troubleshooting	24 hours/yes	—/yes	—/yes
• Mean time between failures/To repair failures	11 months/30 minutes	—	—
Onboard maintenance records/Maintenance training demo module	no/no	yes/no	—
Training provided with purchase/Advanced operator training	5 days on site/yes	—/yes	—
Annual service contract cost (24 hours/7days)	\$7,500 warranty extension	varies per distributor	—
Distinguishing features (supplied by company)	operator can take snapshot of instrument error(s) and e-mail them to service department directly from analyzer workstation, with automatically gathered pertinent files for immediate diagnosis; one robotic arm style system for all aspiration and fluidic functions; simple design for less moving parts; washing system with low deionized water consumption	versatile open system, runs biochemistry and turbidimetric assays; universal rack for reagent containers, controls, and calibrators for regular, stat, and pediatric samples; user decides which ones and how many rack positions to allocate for each; compact, economical instrument designed to bring automation to lower-throughput labs, and for use as a backup to larger systems	cost-effective with long-life IAD filters; self-prompting touchscreen with mouse-compatible interface for easy selections and entries; optional built-in flowcell for reduced sample volumes; includes built-in flowcell for reduced sample volumes

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Chemistry analyzers (for low-volume laboratories)

Part 4 of 10 <i>See captodayonline.com/productguides for an interactive version of guide</i>	Beckman Coulter, Inc. Stephen Ishii scishii@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 800-526-3821 www.beckmancoulter.com	Carolina Liquid Chemistries Patricia Shugart contactsales@carolinachemistries.com 391 Technology Way, Suite 2, Winston Salem, NC 27101 877-722-8910 www.carolinachemistries.com	Carolina Liquid Chemistries Patricia Shugart contactsales@carolinachemistries.com 391 Technology Way, Suite 2, Winston Salem, NC 27101 877-722-8910 www.carolinachemistries.com
Name of instrument/First year sold in U.S./List price No. of units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Reagents manufactured Operational type/Reagent type	AU480 Clinical System/2009/— >235/800 Japan/Japan/Ireland continuous random access/open reagent system	BioLis 24i/2008/\$60,000 >200/3,000 Japan/Japan/U.S. batch, random access, continuous random access/ open reagent system	CLC 480/FDA cleared/\$75,000 >3,000 worldwide Japan/Japan/U.S. batch, random access, discrete, continuous random access/self-contained single-use cartridges-pack- ages-slides, open reagent system sample ring/benchtop
Sample handling system/Model type	continuous loading rack feeder holds up to 80 samples, while 22 samples are accommodated via stat turntable/floor-standing	sample ring/benchtop	sample ring/benchtop
Dimensions in inches (H × W × D)/Instrument footprint	47.5 × 57.1 × 30/11.9 square feet	20 × 31 × 25/5 square feet	31.5 × 26.5 × 20.5/5 square feet
Tests available on instrument in U.S.	>125 tests, including complete general chemistry, proteins/serology (including reformulated ferritin assay), thyroid, esoterics (including lithium), TDM (including methotrexate), DAT panels (including oxycodone; multiple cutoffs, qualitative, and semi- quantitative methods available for most assays)	100, GlycoMark, fentanyl, tramadol	>80 different chemistries, including drugs of abuse (fentanyl and tramadol) and adulterants; reads at 10 different wavelengths between 340 and 800 nm
Research-use-only assays/Tests in development Analytes for which user-defined methods have been implemented	—/HbA1c (fully automated) total open system, unlimited	—/vitamin D —	vitamin D/vitamin D application —
Methods supported/Immunoassay methods	photometry, potentiometry (ion-selective electrode), homogenous EIA, turbidimetry, latex agglutination/—	photometry, potentiometry/—	photometry, potentiometry, ISE
No. of direct-ion selective electrode channels • Must load separate reagent pack for each specimen • Separate reagent pack for each test run No. of different measured assays onboard simultaneously • No. of different assays programmed and 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 third-party reagent used Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests—assays System is liquid chemistry, dry chemistry, or reconstituted onboard • Uses disposable cuvettes/Maximum No. stored • Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one µL System supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	3 electrodes, indirect method no no 63 63 60/all up to 60 different assays/50–1,500 (per vial) 5 days/30 days/yes (4°–12°C) yes yes yes varies/up to 102/varies liquid no/— yes/permanent 1 µL no (optional)/yes (no with optional water pump) yes/20 average peak consumption <60 no/— yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interl., Codabar, codes 39 and 128)/yes yes yes yes/yes/yes yes yes/yes yes yes yes/yes yes yes/yes 1 day/30 days/14 days/14–20 days yes/yes	3 no no 39 39 39/39 39/3 × 300 7 days/14 days/yes (2°–8°C) yes yes yes 4 hours/40/39 liquid no/— yes/— — yes/no yes, water system provided with instrument/— — yes/30 µL yes/no yes (on sample transport, shortly before sample is aspirated, codes 39 and 128)/yes yes yes yes/yes/yes yes yes/yes yes yes yes/yes no yes/yes 24 hours/14 days/4–7 days/7 days yes/yes	3 no no 39 39 39/39 39/3 × 300 7 days/14 days/yes (<10°C) yes yes yes 4 hours/40/39 liquid no/— yes/annual or as needed 3 µL no/no yes/3.5 <60 yes/30 µL yes/no yes (on sample transport, shortly before sample is aspirated, codes 39 and 128, ITF, NW-7)/yes yes yes yes/yes/yes yes yes/yes yes yes yes/no no yes/yes 24 hours/14 days/4–7 days/7 days yes/yes
Stat time to completion of all analytes/throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct and total bilirubin, AST, ALT, ALP Typical time delay from ordering stat test to aspiration of sample Frequency of 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	<9 minutes (includes TC02)/200 specimens <9 minutes (includes photometric assays)/ 80 specimens <9 minutes/67 specimens <2 minutes per CLIA and laboratory's decision/yes yes/yes yes	12 minutes/160 specimens 1 hour/60 specimens 14 minutes/240 specimens 5 minutes 8–24 hours/yes yes/yes yes	12 minutes/160 specimens 1 hour/60 specimens 14 minutes/240 specimens 5 minutes 8–24 hours/yes yes/yes yes
Data-management capability/Instrument vendor supplies LIS interface • LISs with which system interfaces in active user sites	onboard/no (optional) all common interfaces, including Cerner, Antrim, CCA, Chemware, Dawning Technology, ADAC, Dynamic Healthcare, Antek, Siemens, McKesson (Data Innovations), CPSI, Meditech, Misys, Citation, SCC	onboard/yes (additional cost) Fletcher Flora, Lab Track, and several other common systems	onboard/yes (additional cost) Lab Track, Lab DAQ, Fletcher Flora, Orchard, and other systems
Bidirectional interface capability LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results • How labs get LOINC codes for reagent kits	yes (broadcast download and host query) yes no —	yes (broadcast download and host query) yes — —	yes (broadcast download and host query) yes yes by contacting technical support
Lab can control analyzer remotely	yes	no	yes
Modem servicing available/System can diagnose own malfunctions	yes/yes	no/yes	yes/no
On-site time of service engineer/Onboard error codes for troubleshooting • Mean time between failures/To repair failures Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced operator training Annual service contract cost (24 hours/7 days)	<24 hours/yes average two calls per year/<24 hours yes/yes 3–5 days on site, 5 days at vendor offices/yes contract-dependent	24 hours/yes — yes (includes audit trail)/no 5 days on site/yes —	24 hours/yes — — installation on site, 3.5 days at vendor offices/yes \$8,500
Distinguishing features (supplied by company)	standardization across the AU family of chemistry systems from low end to ultra-high test volumes— AU680, AU2700, AU5400 and AU5800; test menu of 130 methods provides standardized results for improved patient management and streamlined operation	water system eliminates need to purchase, ship, and store cubes of water; HbA1c performed directly onboard with results equivalent to HPLC, separate HbA1c analyzer is not needed; small size, large menu, 39 onboard chemistries; runs general and special chemistries from CMPs to D-dimer, cystatin C, insulin, more	comprehensive test menu; cost-effective water sys- tem eliminates need for daily cuvette changes and costs associated with cuvette wash solutions; runs drugs of abuse in a qualitative or semiquantitative mode, providing a number in ng/mL

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Chemistry analyzers (for low-volume laboratories)

Part 5 of 10 <i>See captodayonline.com/productguides for an interactive version of guide</i>	ELITech Clinical Systems Patrice Babineau elitechNA@elitechgroup.com 101 College Road East, Princeton, NJ 08540 609-216-7360 www.elitechgroup.com	ELITech Clinical Systems Patrice Babineau elitechNA@elitechgroup.com 101 College Road East, Princeton, NJ 08540 609-216-7360 www.elitechgroup.com	HORIBA Medical Jim Knowles jim.knowles@horiba.com 34 Bunsen Drive, Irvine, CA 92618 888-903-5001, ext. 4553 www.horiba.com/us/en
Name of instrument/First year sold in U.S./List price No. of units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Reagents manufactured Operational type/Reagent type	Selectra ProM Chemistry System/2012/\$62,500 —/448 Netherlands/Netherlands/France continuous random access, discrete, random access, batch/self-contained multi-use cartridges-packages-slides	Selectra ProS Chemistry System/2012/\$52,500 —/285 Netherlands/Netherlands/France continuous random access, discrete, random access, batch/self-contained multi-use cartridges-packages-slides	Pentra C200/2012/\$56,433 >10/>200 Japan/France/U.S. batch, random access, continuous random access/self-contained single-use cartridges-packages, open reagent system
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	ring/benchtop 30 × 48 × 24.4/8.1 square feet	ring/benchtop 30 × 32.5 × 24/5.4 square feet	rack/benchtop 22.5 × 29.8 × 28.6/4.5 square feet
Tests available on instrument in U.S.	albumin, ALT-GPT, ALKP, AST-GOT, bilirubin (direct and total), BUN, calcium, carbon dioxide, chloride cholesterol, cholesterol (HDL and LDL), CK, creatinine, glucose, GGT, hemoglobin A1c, LDH, phosphorus, potassium, sodium, total protein, triglycerides, uric acid	albumin, ALT-GPT, ALKP, AST-GOT, bilirubin (direct and total), BUN, calcium, carbon dioxide, chloride cholesterol, cholesterol (HDL and LDL), CK, creatinine, glucose, GGT, hemoglobin A1c, LDH, phosphorus, potassium, sodium, total protein, triglycerides, uric acid	albumin, ALT, ALP, amylase, AST, bilirubin (direct and total), BUN, calcium, carbon dioxide, chloride, cholesterol, CRP, creatinine, direct HDL, direct LDL, glucose HK, GGT, HbA1c, iron, LDH, magnesium, microalbumin, Na, K, amylase, phosphorus, total protein, more
Research-use-only assays/Tests in development	—/TxB cardio, hyaluronic acid, D-dimer, TIMP-1, PIIINC, amylase*, iron*, TIBC*, magnesium*, multi-range CRP, microprotein*	—/TxB cardio, hyaluronic acid, D-dimer, TIMP-1, PIIINC, amylase*, iron*, TIBC*, magnesium*, multi-range CRP, microprotein*	—/DAUs, TDMs
Analytes for which user-defined methods have been implemented	APO A1, APO B, CRP*, haptoglobin, IgA*, IgG*, IgM*, microalbumin*, microprotein*, orosomucoid, prealbumin*, transferrin*	APO A1, APO B, CRP*, haptoglobin, IgA*, IgG*, IgM*, microalbumin*, microprotein*, orosomucoid, prealbumin*, transferrin*	—
Methods supported/Immunoassay methods	photometry, potentiometry/turbidimetric homogeneous, EIA	photometry, potentiometry/turbidimetric homogeneous, EIA	photometry, potentiometry (ion-selective electrode), turbidimetric/—
No. of direct-ion selective electrode channels • Must load separate reagent pack for each specimen • Separate reagent pack for each test run	4 no no	4 no no	3 no no
No. of different measured assays onboard simultaneously • No. of different assays programmed and calibrated at once • No. of user-definable (open) channels/No. active simultaneously	36 96 10/10	34 90 10/10	18 with ISE's 35 5/5
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	36/34–83 24 hours/28 days/yes (10°C) yes	34/34–83 24 hours/28 days/yes (10°C) yes	18/100 to 400 8 hours/30 days/yes (8°–15°C) yes
Reagent container placed directly on system for use Instrument has same capabilities when third-party reagent used Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays	yes yes 240/62/720	yes yes 120/25/285	yes yes 2 hours/15 samples/—
System is liquid chemistry, dry chemistry, or reconstituted onboard • Uses disposable cuvettes/Maximum No. stored • Uses washable cuvettes/Replacement frequency	liquid no/48 in semi-disposable rotor yes/10,000 tests	liquid no/48 in semi-disposable rotor yes/10,000 tests	liquid yes/192 no/—
Minimum sample volume aspirated precisely at one time System supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour Noise generated in decibels	1 µL yes/no no/up to 0.5 62	1 µL yes/no no/up to 0.9 62	2 µL no/no no/2.1 <65
Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	yes/100 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 4, 11, 39, 93, and 128)/yes	yes/100 µL yes/no yes, on sample transport, shortly before sample is aspirated (2 of 5 interleaved, Codabar, codes 4, 11, 39, 93, and 128)/yes	no/small biocups yes/no yes/yes
• Reagent bar-code reading capability Onboard test auto inventory (determines volume in container) • Measures No. of tests remaining/Short sample detection/Clot detection	yes yes yes/yes/no	yes yes yes/yes/no	yes yes yes/yes/yes
• Automatic detection of adequate reagent for aspiration and analysis • Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard Automatic rerun capability • Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	yes no/no yes yes yes/no	yes no/no yes yes yes/no	yes yes/yes yes yes yes/yes
Autocalibration or autocalibration alert • Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	yes no/yes 4–8 hours/28 days/—/—	yes no/yes 4–8 hours/28 days/—/—	yes yes/yes 8 hours for ISE/14 days/—/—
Automatic shutdown/Startup programmable	yes/yes	yes/yes	no/yes
Stat time to completion of all analytes/throughput per hour for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Albumin, direct and total bilirubin, AST, ALT, ALP Typical time delay from ordering stat test to aspiration of sample	5 minutes/66 specimens 12 minutes/33 specimens 14 minutes/22 specimens 3 minutes	5 minutes/66 specimens 12 minutes/22 specimens 14 minutes/12 specimens 3 minutes	<5 minutes/— 7.5 minutes/35 specimens <11 minutes/23 specimens 3 minutes
Frequency of 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	0.5–1 day/yes yes/no yes	0.5–1 day/yes yes/no yes	8 hours/yes yes/yes yes
Data-management capability/Instrument vendor supplies LIS interface • LISs with which system interfaces in active user sites	onboard/no LabDaQ, SchuyLab	onboard/no LabDaQ, SchuyLab	onboard/no Antek, Fletcher Flora, Meditech, Orchard, Schuyler House, Sunquest, Technidata
Bidirectional interface capability LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results • How labs get LOINC codes for reagent kits	yes broadcast download and host query no —	yes broadcast download and host query no —	yes yes no —
Lab can control analyzer remotely	yes	yes	no
Modem servicing available/System can diagnose own malfunctions	no/yes	no/yes	yes/yes
On-site time of service engineer/Onboard error codes for troubleshooting • Mean time between failures/To repair failures Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced operator training Annual service contract cost (24 hours/7 days)	24 hours/yes 10–12 months/1 hour yes/yes 3 days on site/yes \$4,200 (M-F, 9 AM–5 PM)	24 hours/yes 12–14 months/1 hour yes/yes 3 days on site/yes \$3,500 (M-F, 9 AM–5 PM)	<24 hours/yes —/24 hours yes/yes 3.5 days onsite only/yes —
Distinguishing features (supplied by company)	TouchPro software with smart icons guides the operator through daily workflow, including configurable daily checklists; ELITech ProServe remote-assist diagnostics and internet-based training; combination of onboard PSID, host-query LIS, and configurable result checks provide autoverification, improved walk-away, and error reduction; liquid-stable, ready-to-use reagents	TouchPro software with smart icons guides the operator through daily workflow, including configurable daily checklists; ELITech ProServe remote-assist diagnostics and internet-based training; combination of onboard PSID, host-query LIS, and configurable result checks provide autoverification, improved walk-away, and error reduction; liquid-stable, ready-to-use reagents	benchtop design; runs more than 15 assays with room for 18 onboard tests; user-friendly, color-coded touchscreen validation station; high throughput (360 tests per hour); crash protection; auto rerun, autocalibration, autodilution; most reagents in plug-and-play cassettes

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

*available outside North America

*available outside North America

Chemistry analyzers (for low-volume laboratories)

Part 6 of 10	HORIBA Medical	Medica Corp.	MedTest DX
<p><i>See captodayonline.com/productguides for an interactive version of guide</i></p>	<p>Jim Knowles jim.knowles@horiba.com 34 Bunsen Drive, Irvine, CA 92618 888-903-5001 www.horiba.com/us/en/medical</p>	<p>Raymond Morrill rmorrill@medicacorp.com 5 Oak Park Drive, Bedford, MA 01730 800-777-5983 www.medicacorp.com</p>	<p>Dennis Boyle dboyle@medtestdx.com 510 Furnace Dock Road, Cortlandt Manor, NY 10567 866.540.2715 www.medtestdx.com</p>
<p>Name of instrument/First year sold in U.S./List price No. of units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Reagents manufactured Operational type/Reagent type</p>	<p>ABX Pentra 400/2006/\$99,142 176/1,003 France/France/France and U.S. batch, random access, discrete, continuous random access/self-contained single-use cartridges-packages, open reagent system</p>	<p>Easy RA/2009/— >60/>200 U.S./U.S./U.S. batch, random access, discrete, continuous random access/self-contained multi-use cartridges-packages-slides</p>	<p>Poly-Chem/2002/\$58,500 150+ /— Japan/Japan/U.S. batch, random access/open reagent system</p>
<p>Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint</p>	<p>rack/benchtop 25 × 40 × 28/7.7 square feet</p>	<p>two sample rings (up to 48 samples)/benchtop 15 × 40 × 26/7.2 square feet</p>	<p>rack/benchtop 22 × 30 × 24/—</p>
<p>Tests available on instrument in U.S.</p>	<p>albumin, calcium, sodium, alk phos, ALT, carbon dioxide, glucose (PAP), lipase, total protein, chloride, glucose (hexokinase), magnesium, triglycerides, amylase, cholesterol, iron, myoglobin, uric acid, total bilirubin, creatinine, lactic acid, more</p>	<p>albumin, ALK, ALT, amylase, AST, calcium, chloride, chol, trig, HDL, LDL, creatinine (serum and urine), GGT, glucose-trinder, total iron, LDH, lithium, magnesium, phosphorus, Na, K, Cl, total protein, microalbumin, HbA1c, drugs of abuse (DAUs), more</p>	<p>DOA including amphetamines, barbituates, benzodiazepine, cocaine, cannabinoid, EDDP, ethanol, MDMA, methadone, albumin, ALK, ALT, amylase, apolipoprotein A and B, AST, direct and total bilirubin, calcium, cholesterol, CO2, creatinine, CRP and FR CRP, fructosamine, gamma GT, glucose, HDL, HgbA1c, IGM, iron, LDH, LDL, lipase, LpA, magnesium, phosphorus, prealbumin, rheumatoid factor, total protein, triglycerides, urea, more</p>
<p>Research-use-only assays/Tests in development Analytes for which user-defined methods have been implemented</p>	<p>—/TDMs, DAUs apolipoprotein A1, apolipoprotein B, beta 2, microglobulin, ferritin, fructosamine, more</p>	<p>—/lipase, TIBC, CKMB, full range CRP, IgG, IgA, IgM creatinine (jaffe)</p>	<p>APOA11, APOE, APOC11, APOC111/— glutamine, glutamate, lactate, ammonia</p>
<p>Methods supported/Immunoassay methods</p>	<p>photometry, potentiometry (ion-selective electrode), turbidimetric/—</p>	<p>photometry, potentiometry, turbidimetric immunoassay, enzymatic immunoassay</p>	<p>photometry, RISE</p>
<p>No. of direct-ion selective electrode channels</p>	3	4	3
<p>• Must load separate reagent pack for each specimen</p>	no	no	no
<p>• Separate reagent pack for each test run</p>	no	no	no
<p>No. of different measured assays onboard simultaneously</p>	55	28	43
<p>• No. of different assays programmed and calibrated at once</p>	55	140	43
<p>• No. of user-definable (open) channels/No. active simultaneously</p>	15/15	6/6	60/60
<p>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</p>	55/100 to 400	28/80–250	40/200
<p>• Shortest/Median onboard reagent stability/Refrigerated onboard</p>	8 hours/30 days/yes (2°–8°C)	168 hours/30 days/yes (8°C)	4 hours/28 days/yes (8°C)
<p>• Multiple reagent configurations supported</p>	yes	yes	yes
<p>Reagent container placed directly on system for use</p>	yes	yes	yes
<p>Instrument has same capabilities when third-party reagent used</p>	yes	no	no
<p>Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays</p>	2 hours/60/—	36/24/28	18 to first result/40/1,000
<p>System is liquid chemistry, dry chemistry, or reconstituted onboard</p>	liquid	liquid	liquid
<p>• Uses disposable cuvettes/Maximum No. stored</p>	yes/432	yes/72	no/—
<p>• Uses washable cuvettes/Replacement frequency</p>	no/—	no/—	yes/50,000 tests
<p>Minimum sample volume aspirated precisely at one time</p>	2 µL	2 µL	2 µL
<p>System supplied with UPS (backup power)/Requires floor drain</p>	no/no	no/no	yes/yes
<p>Requires dedicated water system/Water consumption in L per hour</p>	no/0.5 average	no/—	yes/7
<p>Noise generated in decibels</p>	<60	minimal	60
<p>Dedicated pediatric sample cup/Dead volume</p>	no/small biocups	no/—	yes/—
<p>Primary tube sampling/Pierces caps on primary tubes</p>	yes/no	yes/no	yes/no
<p>Sample bar-code reading capability/Autodiscrimination</p>	yes/yes	yes	on sample transport, shortly before sample is aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/no
<p>• Reagent bar-code reading capability</p>	yes	no, uses RFID	yes
<p>Onboard test auto inventory (determines volume in container)</p>	yes	yes	yes
<p>• Measures No. of tests remaining/Short sample detection/Clot detection</p>	yes/yes/yes	yes/yes/no	yes/yes/no
<p>• Automatic detection of adequate reagent for aspiration and analysis</p>	yes	yes	yes
<p>• Hemolysis/Turbidity detection-quantitation</p>	yes/yes	no/no	no/no
<p>Dilution of patient samples onboard</p>	yes	yes	yes
<p>Automatic rerun capability</p>	yes	no	yes
<p>• Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results</p>	yes/yes	yes/no	yes/yes
<p>Autocalibration or autocalibration alert</p>	yes	yes	no
<p>• Calibrants stored onboard/Multipoint calibration supported</p>	yes/yes	no/yes	no/yes
<p>Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse</p>	2 hours/14 days/—/—	8 hours/30 days/—/15 days	daily/7–14 days/—/—
<p>Automatic shutdown/Startup programmable</p>	no/yes	no/no	no/yes
<p>Stat time to completion of all analytes/throughput per hour for:</p>			
<p>• Sodium, potassium, chloride, TC02</p>	<5 minutes/—	3 minutes/200 specimens	2 minutes/450 specimens
<p>• Sodium, potassium, chloride, TC02, glucose, urea, creatinine</p>	7.5 minutes/35 specimens	8 minutes/100 specimens	10 minutes/180 specimens
<p>• Albumin, direct and total bilirubin, AST, ALT, ALP</p>	<11 minutes/23 specimens	9 minutes/—	11 minutes/180 specimens
<p>• Typical time delay from ordering stat test to aspiration of sample</p>	1–2 minutes	<1 minute	—
<p>Frequency of QC required/Onboard SW capability to review QC</p>	8 hours/yes	per shift to daily/yes	per shift to daily/yes
<p>Onboard real-time QC/Support multiple QC lot Nos. per analyte</p>	yes/yes	yes/yes	yes/no
<p>QC results transferred automatically to LIS</p>	yes	yes	yes
<p>Data-management capability/Instrument vendor supplies LIS interface</p>	onboard/no	onboard/yes	onboard/no
<p>• LISs with which system interfaces in active user sites</p>	Antek, Fletcher Flora, Meditech, Orchard, Schuyler House, Sunquest, Technidata	Orchard, Antek, J&S, Fletcher Flora	LabDaQ, Data Innovations, Soft Computer, Misys
<p>Bidirectional interface capability</p>	yes	yes	broadcast download and host query
<p>LIS interface operates simultaneously with running assays</p>	yes	yes	yes
<p>Uses LOINC to transmit orders and results</p>	no	no	no
<p>• How labs get LOINC codes for reagent kits</p>	—	—	—
<p>Lab can control analyzer remotely</p>	no	no	no
<p>Modem servicing available/System can diagnose own malfunctions</p>	yes/yes	no/yes	no/no
<p>On-site time of service engineer/Onboard error codes for troubleshooting</p>	<24 hours/yes	<24 hours/yes	24 hours/yes
<p>• Mean time between failures/To repair failures</p>	—/ <24 hours	1 year/—	—
<p>Onboard maintenance records/Maintenance training demo module</p>	yes/yes	yes/yes	no/no
<p>Training provided with purchase/Advanced operator training</p>	3.5 days at corporate office in California/yes	3 days on site, 3 days at vendor offices/no	3 days on site, 3 days at vendor office/yes
<p>Annual service contract cost (24 hours/7 days)</p>	—	varies	varies
<p>Distinguishing features (supplied by company)</p>	<p>benchtop design; runs more than 52 assays with room for 55 onboard tests; user-friendly, color-coded touchscreen validation station; high throughput (420 tests per hour); clot level and crash protection; auto rerun, autocalibration, autodilution; runs three reagents on a single assay; most reagents in plug-and-play cassettes</p>	<p>simplified user interface accessed through a touchscreen display; RFID-tagged reagents allow for reading and writing capability; all reagent parameters programmed on the wedge, no data entry; easy-to-replace components all located in a slide-out drawer; comprehensive inventories of all system components</p>	<p>small benchtop analyzer for physician office laboratory, as primary system in small lab, or back-up system in large lab; onboard reusable cuvettes provide cost savings on disposables; large reagent menu</p>

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Chemistry analyzers (for low-volume laboratories)

Part 7 of 10 <i>See captodayonline.com/productguides for an interactive version of guide</i>	MedTest DX Dennis Boyle dboyle@medtestdx.com 510 Furnace Dock Road, Cortlandt Manor, NY 10567 866-540-2715 www.medtestdx.com	Mindray Peggy Chan p.chan@mindray.com 8650 154th Avenue NE, Redmond, WA 98052 888-816-8188, ext. 3305 www.mindray.com	Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com
Name of instrument/First year sold in U.S./List price No. of units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Reagents manufactured Operational type/Reagent type	SPOTCHEM EZ/2006/\$12,500 100+/- Japan/Japan/U.S. discrete/single-use strips	BS-200/2009/\$35,800 >100/>10,000 China/China/U.S. batch, random access, discrete, continuous random access/open	Stat Profile pHox Ultra/2011/- -/- U.S./U.S./U.S. discrete/self-contained multi-use cartridges
Sample handling system/Model type	tray/benchtop	carousel/benchtop	sample automatically drawn from syringe, capillary, or open tube/benchtop
Dimensions in inches (H x W x D)/Instrument footprint	6.5 x 13.5 x 8/-	25 x 34 x 28/6.6 square feet	17.2 x 17.3 x 22.3/2.7 square feet
Tests available on instrument in U.S.	albumin, ALT, amylase, ALP, AST, BUN, calcium, CPK, creatinine, fructosamine, GGT, glucose, HDL, IP, lipid panel, LDH, magnesium, total bilirubin, total cholesterol, total protein, triglycerides, uric acid, panel 1 (BUN, glu, cre, cal, alb), panel 2 (ALP, T-BIL, T-ALT, T-protein, AST), more	ALT, AST, ALP, amylase, CK, GGT, LDH, lipase, albumin, BUN, cholesterol, creatinine, glucose, HDL, LDL, yotal protein, triglyceride, total bilirubin, direct bilirubin, uric acid, CRP, HbA1c, CRP(hs), CO2, Apo-A1, Apo-B, sodium, potassium, chloride, calcium, magnesium, phosphate, iron, amphetamine, barbiturate, benzodiazepam, buprenorphine, cannabinoid, cocaine, cotinine, ecstasy, ethyl alcohol, methadone, methaqualone, opiate, oxycodone, phencyclidine, propoxyphene	pH, PCO2, PO2, SO2%, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, ionized Mg, glucose, BUN, creatinine, lactate, bilirubin, deoxyhemoglobin, oxyhemoglobin, methemoglobin, carboxyhemoglobin
Research-use-only assays/Tests in development Analytes for which user-defined methods have been implemented	-/LDL -	- -	- -
Methods supported/Immunoassay methods	optical measurement of reflection intensity of reagent color reaction	photometry, potentiometry, turbidimetric method	potentiometry (ISE), optical, reflectance/-
No. of direct ion selective electrode channels • Must load separate reagent pack for each specimen • Separate reagent pack for each test run	- yes yes	3 no no	12 no no
No. of different measured assays onboard simultaneously • No. of different assays programmed and calibrated at once • No. of user-definable (open) channels/No. active simultaneously	9 card calibration, 21 -	39 39 no limit/39	20 20 0/-
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	- -/no no	- -/yes (2°-12°C) yes	20/200-500 samples (2,600-6,500 tests), depending on lab 45 days/45 days/no -
Reagent container placed directly on system for use Instrument has same capabilities when third-party reagent used	yes no	yes yes	yes -
Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays	up to 15/1/up to 9	60/40/-	-
System is liquid chemistry, dry chemistry, or reconstituted onboard • Uses disposable cuvettes/Maximum No. stored • Uses washable cuvettes/Replacement frequency	dry no/- no/-	liquid yes/80 no/-	ISE no/- no/-
Minimum sample volume aspirated precisely at one time System supplied with UPS (backup power)/Requires floor drain	5 µL no/no	3 µL no	60 µL no (optional)/no
Requires dedicated water system/Water consumption in L per hour Noise generated in decibels	no/- -	no/3.5 ≤75	no/- minimal
Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes	no/- no/no	no yes/no	no/- yes/no
Sample bar-code reading capability/Autodiscrimination • Reagent bar-code reading capability	by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes	yes (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes	yes (optional), by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes
Onboard test auto inventory (determines volume in container) • Measures No. of tests remaining/Short sample detection/Clot detection	yes no no/yes/no	yes yes yes/yes/no	yes yes yes/yes/yes
• Automatic detection of adequate reagent for aspiration and analysis • Hemolysis/Turbidity detection-quantitation	no no/no	yes no/no	yes yes (on CO-oximeter module)/yes (on Co-oximeter module)
Dilution of patient samples onboard Automatic rerun capability • Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	no - no/no	yes yes yes/yes	yes (on CO-oximeter module) no no/no
Autocalibration or autocalibration alert • Calibrants stored onboard/Multipoint calibration supported	no no/no	yes yes/yes	yes yes/yes
Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	-/per box/-/-	24 hours/-/-/-	30-120 minutes/30-120 minutes/-/-
Automatic shutdown/Startup programmable	no/no	no/no	yes/yes
Stat time to completion of all analytes/throughput per hour for: • Sodium, potassium, chloride, TCO2 • Sodium, potassium, chloride, TCO2, glucose, urea, creatinine • Albumin, direct and total bilirubin, AST, ALT, ALP	- 9 minutes/48 samples per hour 9 minutes/48 samples per hour	1 minute/75 specimens 5 minutes/- 5 minutes/-	50 seconds/26-36, depending on use mode 123 seconds/21-24, depending on use mode -
Typical time delay from ordering stat test to aspiration of sample Frequency of QC required/Onboard SW capability to review QC	- daily/no	5 minutes daily/-	<2 seconds 8 hours/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte QC results transferred automatically to LIS	no/no no	yes/yes yes	yes/yes yes
Data-management capability/Instrument vendor supplies LIS interface • LISs with which system interfaces in active user sites	onboard/no -	-onboard/no most LIS vendors	onboard/no most LIS vendors
Bidirectional interface capability LIS interface operates simultaneously with running assays	- yes	yes yes	yes yes
Uses LOINC to transmit orders and results • How labs get LOINC codes for reagent kits	no -	no -	no -
Lab can control analyzer remotely	no	yes	yes
Modem servicing available/System can diagnose own malfunctions	no/no	no/yes	yes/yes
On-site time of service engineer/Onboard error codes for troubleshooting	depot service/yes	yes	<8 business hours/yes
• Mean time between failures/To repair failures Onboard maintenance records/Maintenance training demo module	-/- no/no	12 months/<1 year yes/yes	- yes (includes audit trail of who replaced parts)/yes
Training provided with purchase/Advanced operator training Annual service contract cost (24 h/7 d)	1 day on site/no -	yes/yes varies	yes/yes varies
Distinguishing features (supplied by company)	small analyzer for stat labs, small physician office laboratories, ERs, and imaging centers; analyzer and reagent test strips are CLIA-waived; dry chemistry strips, effective stability, and shelf life; single test strips and panel strips available; customizable testing	carryover prevention program, stable temperature control for reagent and reaction chambers; automatic cuvette and R1 blank checking to ensure accurate result	20-test critical care profile, including ionized Mg, BUN, and creatinine; color touchscreen; integrated CO-oximeter; open software architecture; onboard data management; automated onboard quality control; sealed waste system; auto-monitoring of QC and reagent packs; tankless gas calibration; automated maintenance

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Chemistry analyzers (for low-volume laboratories)

Part 8 of 10 <i>See captodayonline.com/productguides for an interactive version of guide</i>	Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com	Nova Biomedical Corp. info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813 www.novabiomedical.com	Randox Laboratories Graeme McNeill graeme.mcneill@randox.com 515 Industrial Blvd., Kearneysville, WV 25430 304-728-2890 www.randox.com
Name of instrument/First year sold in U.S./List price	Stat Profile pH0x series/1998/—	Nova 16/1995/—	Rx Daytona/2005/—
No. of units in clinical use in U.S./Outside U.S.	—/—	—	>1,000 units worldwide
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	U.S./U.S./U.S.	Japan/Japan/U.K.
Operational type/Reagent type	discrete/self-contained multi-use cartridges-packages-slides	batch, random access/self-contained multiuse cartridges	random access/self-contained multi-use cartridges-packages-slides
Sample handling system/Model type	sample automatically drawn from syringe, capillary, or open tube/benchtop	40-position tray, stat sampling directly from sample container/benchtop	ring/benchtop
Dimensions in inches (H × W × D)/Instrument footprint	15 × 15 × 18/1.9 square feet	20.5 × 19.2 × 20.7/2.75 square feet	19.7 × 30.3 × 24.4/5.1 square feet
Tests available on instrument in U.S.	pH, PCO ₂ , PO ₂ , SO ₂ %, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, glucose, lactate	sodium, potassium, chloride, total CO ₂ , glucose, BUN, creatinine, Hct	acetic acid, acid phosphatase, albumin, aldolase, ALK PHOS, alpha 1 acid glycoprotein, alpha 1 antitrypsin, ALT, ammonia, amphetamines, amylase, amylase pancreatic, APO A-1, APO AII, APO B, APO CII, APO CIII, APO E, ASO, AST, B2 microglobulin, more acetic acid, Apo E, apo CIII, apo AII, alpha-1-antitrypsin, alpha-1-acid glycoprotein, bile acids, butyryl cholinesterase, enzymatic chloride, glutamate, more/—
Research-use-only assays/Tests in development	—	—	—
Analytes for which user-defined methods have been implemented	—	—	—
Methods supported/Immunoassay methods	potentiometry (ISE), optical, reflectance/—	potentiometry/—	photometry, potentiometry (ISE), latex-enhanced immunoturbidimetry/—
No. of direct-ion selective electrode channels	5	8	3
• Must load separate reagent pack for each specimen	no	no	no
• Separate reagent pack for each test run	no	no	no
No. of different measured assays onboard simultaneously	11	8	43
• No. of different assays programmed and calibrated at once	11	8	60
• No. of user-definable (open) channels/No. active simultaneously	0/—	0/—	10/10
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set	11/varies by analyzer and laboratory use pattern	8/(at 8,000 tests/month): 2,700	43/50–11,250
• Shortest/Median onboard reagent stability/Refrigerated onboard	45 days/45 days/no	21 days/21 days/no	8 hours/28 days/yes (8°–15°C)
• Multiple reagent configurations supported	—	—	yes
Reagent container placed directly on system for use	yes	no, requires prehandling (remove clip from sealed bag and mix)	yes
Instrument has same capabilities when third-party reagent used	—	—	yes
Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays	—	60 per tray/40 per tray/280 per tray	664/40/76,115
System is liquid chemistry, dry chemistry, or reconstituted onboard	ISE	—	liquid
• Uses disposable cuvettes/Maximum No. stored	no/—	no/—	no/45
• Uses washable cuvettes/Replacement frequency	no/—	—	yes/minimum 5 years
Minimum sample volume aspirated precisely at one time	45 µL	50 µL	2 µL
System supplied with UPS (backup power)/Requires floor drain	no (optional)/no	no/no	no/no
Requires dedicated water system/Water consumption in L per hour	no/—	no/—	yes/7.5
Noise generated in decibels	minimal	minimal	60
Dedicated pediatric sample cup/Dead volume	no/—	—	yes/50 µL
Primary tube sampling/Pierces caps on primary tubes	yes/no	yes/no	yes/no
Sample bar-code reading capability/Autodiscrimination	yes, by handheld scanner as tubes are loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes	handheld scanner as tubes loaded onto instrument (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes	on sample transport, shortly before sample is aspirated (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/yes
• Reagent bar-code reading capability	yes	alternate method	yes
Onboard test auto inventory (determines volume in container)	yes	yes	yes
• Measures No. of tests remaining/Short sample detection/Clot detection	yes/yes/yes	no/yes/yes	yes/yes/no
• Automatic detection of adequate reagent for aspiration and analysis	yes	yes	yes
• Hemolysis/Turbidity detection-quantitation	no/no	no/no	yes/yes
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability	no	yes	yes
• Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results	no/no	no/no	yes/yes
Autocalibration or autocalibration alert	yes	yes	yes
• Calibrants stored onboard/Multipoint calibration supported	yes/yes	yes/—	yes/yes
Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse	30–120 minutes/30–120 minutes/—/—	2 hours/2 hours/—/—	daily/28 days/7 days/28 days
Automatic shutdown/Startup programmable	yes/yes	—	yes/yes
Stat time to completion of all analytes/throughput per hour for:			
• Sodium, potassium, chloride, TCO₂	50 seconds/44 specimens	52 seconds/69 specimens	13 minutes, 50 seconds/—
• Sodium, potassium, chloride, TCO₂, glucose, urea, creatinine	—	85 seconds/45 specimens	14 minutes, 50 seconds/—
• Albumin, direct and total bilirubin, AST, ALT, ALP	—	—	14 minutes, 30 seconds/—
Typical time delay from ordering stat test to aspiration of sample	<2 seconds	9 seconds	30 seconds
Frequency of QC required/Onboard SW capability to review QC	8 hours (CLIA)/yes	CLIA minimum/yes	shortest: daily; longest: customer discretion/yes
Onboard real-time QC/Support multiple QC lot Nos. per analyte	yes/yes	no/yes	yes/yes
QC results transferred automatically to LIS	yes	yes	yes
Data-management capability/Instrument vendor supplies LIS interface	no/no	onboard and optional add-on/no	onboard/no
• LISs with which system interfaces in active user sites	virtually all	most LIS vendors including Cerner, Misys, McKesson, Soft, others	—
Bidirectional interface capability	yes (broadcast download and host query)	yes	yes (host query)
LIS interface operates simultaneously with running assays	yes	no	yes
Uses LOINC to transmit orders and results	no	no	no
• How labs get LOINC codes for reagent kits	—	—	—
Lab can control analyzer remotely	yes	yes	no
Modem servicing available/System can diagnose own malfunctions	yes/yes	no/yes	yes/yes
On-site time of service engineer/Onboard error codes for troubleshooting	<8 business hours/yes	<8 business hours/yes	within 24 hours/yes
• Mean time between failures/To repair failures	—	—	2 per 3 years/within 8 working hours
Onboard maintenance records/Maintenance training demo module	yes/yes	no/no	no/no
Training provided with purchase/Advanced operator training	yes/yes	yes/yes	3 days on site/yes
Annual service contract cost (24 hours/7 days)	—	—	varies on level
Distinguishing features (supplied by company)	onboard quality control; liquid calibration eliminates gas tanks; remote control; remote review; space-saving design	whole blood analyzer for creatinine and TCO ₂ ; can analyze whole blood, serum, plasma, urine, CSF, and dialysate	benchtop analyzer consolidates testing in a compact platform; dedicated multi-speed paddle mixers allow optimum mixing for each assay; direct ISE module prevents pseudo-hyponatremia
<i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

Chemistry analyzers (for low-volume laboratories)

Part 9 of 10	Roche Diagnostics Corp. Adam Sterle adam.sterle@roche.com 9115 Hague Road Indianapolis, IN 46256 317-521-3099 www.mylabonline.com	Roche Diagnostics Corp. Adam Sterle adam.sterle@roche.com 9115 Hague Road Indianapolis, IN 46256 317-521-3099 www.mylabonline.com	SDI Biomed Robert Silverberg silverberg.r@sdibiomed.com 23679 Calabasas Road, #1000 Calabasas, CA, 91302 818-222-1734 www.sdibiomed.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold in U.S./List price No. of units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Reagents manufactured Operational type/Reagent type	cobas c311/2009/\$125,000 >130/>1,300 Japan/Japan/Germany continuous random access/self-contained multi-use cassettes	COBAS INTEGRA 400 Plus/1999/\$145,000 550/>4,600 Switzerland/Switzerland/U.S. and Germany continuous random access/self-contained multi-use cassettes	SDI CA 480 Clinical Chemistry System/2004/\$65,000 >50/>600 Europe/Europe/U.S. random access/self-contained single-use cartridges-packages-slides
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	sample rotor/floor-standing 50 × 52 × 34/8.5 square feet	rack/benchtop 28.5 × 53 × 26/9.6 square feet	wheel, with 4 independent segments/benchtop 40.5 × 25.4 × 17.7/7.2 square feet
Tests available on instrument in U.S.	>90 tests for anemia, diabetes, cardiac markers, TDM, DAT, general chemistries, ISE, D-dimer, DAT oral fluids	>100 tests for anemia, diabetes, cardiac markers, TDM, DAT, general chemistries, ISE, thyroid function, and D-dimer	albumin, alkaline phosphatase, ALT, amylase, AST, CO ₂ , direct bilirubin, total bilirubin, calcium, cholesterol, CK, creatinine, Gamma-GT, glucose-HK, D-HDL, iron, phosphorus, LDH-L, magnesium, total protein, triglycerides, urea nitrogen, uric acid, more
Research-use-only assays/Tests in development Analytes for which user-defined methods have been implemented	LSD, microalbumin, lidocaine, gentamicin —	— —	—/drugs of abuse none
Methods supported/Immunoassay methods	photometry, potentiometry	fluorescence polarimetry, absorbance photometry, turbidimetry, ion selective potentiometry	photometry, potentiometry/selected methodologies
No. of direct-ion selective electrode channels • Must load separate reagent pack for each specimen	3 indirect no	4 indirect no	3 no
• Separate reagent pack for each test run No. of different measured assays onboard simultaneously • No. of different assays programmed and 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 third-party reagent used Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays	no 45 up to 90 10/10 42 cassettes plus 3 ISE/75-800 tests each, depending on reagent 14 days/84 days/yes (5°–15°C) yes yes yes 173/108/45	no 36 up to 999 10/10 32 cassettes plus 4 ISE/75-800 tests each, depending on reagent 2 weeks/8–12 weeks/yes (12°C) yes yes yes 176/90/40	no 33 33 0/— 30/150 per container 14 days/30 days/yes (14°C) yes yes yes 165/40/33
System is liquid chemistry, dry chemistry, or reconstituted onboard • Uses disposable cuvettes/Maximum No. stored • Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time System supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	liquid no/66 yes/monthly 1 µL yes/yes yes/12 <65 yes/50 µL yes/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	liquid yes/1,000 no/— 2 µL yes/no no/2 maximum <61 yes/50 µL yes/no yes (2 of 5 interleaved, Codabar, codes 39 and 128)/yes	liquid no yes/analyzer uses permanent quartz cuvettes 3 µL yes/no no/1 — no/— yes/no yes/yes
• Reagent bar-code reading capability Onboard test auto inventory (determines volume in container) • Measures No. of tests remaining/Short sample detection/Clot detection • Automatic detection of adequate reagent for aspiration and analysis • Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard Automatic rerun capability • Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert • Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/Drugs of abuse Automatic shutdown/Startup programmable	yes yes yes/yes/yes yes yes/yes yes yes yes/yes yes no/yes 24 hours/lot/lot/lot yes/yes	yes yes yes/yes/yes yes yes/yes yes yes yes/yes yes no/yes 5 hours/lot/lot plus 20–26 weeks/lot plus 6 weeks yes/yes	yes yes yes/yes/no yes no/no yes yes yes/no yes yes/yes 30 minutes/once per week/once per week/once per week no/no
Stat time to completion of all analytes/throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct and total bilirubin, AST, ALT, ALP • Typical time delay from ordering stat test to aspiration of sample Frequency of 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	5 minutes/150 specimens 8 minutes/38 specimens 11 minutes/22 specimens <1 minute lab specific/yes yes/yes yes	5 minutes/— 8 minutes/— 11 minutes/— <1 minute lab specific/yes yes/yes yes	1.5 minutes/60 specimens 6 minutes, 48 seconds/60 specimens 7 minutes, 12 seconds/50 specimens 3 minutes 8 hours/yes yes/yes yes
Data-management capability/Instrument vendor supplies LIS interface • LISs with which system interfaces in active user sites	onboard/no all major LIS providers	onboard/no all major LIS vendors	onboard/— SchuyLab, LabDaq, Fletcher Flora, Medcom
Bidirectional interface capability LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results • How labs get LOINC codes for reagent kits	yes (broadcast download and host query) yes yes Web site (MyLab Online)	yes (broadcast download and host query) yes yes Web site (MyLab Online)	yes yes no —
Lab can control analyzer remotely	no	no	no
Modem servicing available/System can diagnose own malfunctions	yes/yes	yes/yes	yes/yes
On-site time of service engineer/Onboard error codes for troubleshooting • Mean time between failures/To repair failures Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced operator training Annual service contract cost (24 hours/7days)	<8 hours/yes 190 days/3 hours yes (includes audit trail of who replaced parts)/no 2 days on site; 5 days at vendor offices/yes varies	<8 hours/yes 130 days/<3 hours yes (includes audit trail of who replaced parts)/yes 5 days at vendor offices/yes varies	yes, guaranteed within 24 hours/yes 10,000 hours/2 hours yes/no 3–5 days on site/yes \$7,500
Distinguishing features (supplied by company)	convenience and stability of cobas c pack reagents, standardized operator interface and reagents with other cobas chemistry platforms, Hitachi reliability	unique reagent cassette eliminates reagent preparation; menu consolidates testing, including direct LDL, whole blood, HbA1c, and lithium	permanent cuvettes, onboard jet wash/dry system, six minutes to first result, notebook-like operator interface, small footprint

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Chemistry analyzers (for low-volume laboratories)

Part 10 of 10	Siemens Healthcare Diagnostics Matthew Fitzgerald matthew.t.fitzgerald@siemens.com 1717 Deerfield Road Deerfield, IL 60015 800-948-3233 www.usa.siemens.com/diagnostics	Vital Diagnostics Dianna Poissant USsales@vitaldiagnostics.com 27 Wellington Road Lincoln, RI 02865 800-345-2822 www.vitaldiagnostics.com	Vital Diagnostics Dianna Poissant USsales@vitaldiagnostics.com 27 Wellington Road Lincoln, RI 02865 800-345-2822 www.vitaldiagnostics.com
See captodayonline.com/productguides for an interactive version of guide			
Name of instrument/First year sold in U.S./List price No. of units in clinical use in U.S./Outside U.S. Country where designed/Manufactured/Reagents manufactured Operational type/Reagent type	Dimension EXL 200/2011/— >300/— U.S./U.S./U.S. batch, random access, continuous random access/self-contained multi-use cartridges	Envoy 500 Chemistry Analyzer/2005/— 270/— Italy/Italy/Australia random access/self-contained multi-use cartridges-packages-slides rotor/benchtop	Eon 100 Automated Chemistry Analyzer/2011/— 21/15 Italy/Italy/Australia random access, continuous random access/self-contained multi-use cartridges-packages-slides ring/benchtop
Sample handling system/Model type Dimensions in inches (H × W × D)/Instrument footprint	segmented sample wheel 61 × 56 × 41/16 square feet	rotor/benchtop 27 × 40 × 23/6 square feet	ring/benchtop 30 × 29 × 25.5/10 square feet
Tests available on instrument in U.S.	>90	general chemistry, albumin, bilirubin, direct, HbA1c, bilirubin, total, calcium, creatinine, glucose, iron, total, magnesium, phosphorus, protein, total, urea nitrogen (BUN), uric acid, enzyme, alanine aminotransferase (ALT), alkaline phosphatase, more	general chemistry, albumin, bilirubin (direct), bilirubin (total), calcium, carbon dioxide, creatinine, glucose, iron (total), magnesium, phosphorus, protein (total), urea nitrogen (BUN), uric acid, direct LDL, triglycerides, direct HDL, cholesterol, alanine aminotransferase (ALT), alkaline phosphatase (ALP), amylase (AMY), aspartate transaminase (AST), creatine phosphokinase (CPK), more
Research-use-only assays/Tests in development	—/LOCI B12, LOCI folate, LOCI vitamin D, cortisol	—	—/CRP wide range, hsCRP, hemoglobin A1c, microalbumin, UIBC
Analytes for which user-defined methods have been implemented	—	CRP wide range, hsCRP, digoxin, ferritin, fructosamine, lipase, phenobarbital, UIBC, GlyoMark, cystatin C, valproic acid, carbamazepine, IgA, IgG, IgM, ethanol	—
Methods supported/Immunoassay methods	photometry, potentiometry, LOCI, ACMIA, EMIT, PETINIA, turbidimetric	photometry, potentiometry, turbidimetric	photometry, potentiometry
No. of direct-ion selective electrode channels • Must load separate reagent pack for each specimen	3 no	4 no	3 no
• Separate reagent pack for each test run No. of different measured assays onboard simultaneously • No. of different assays programmed and 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	no 47 47 10/47 47/15–240 24 hours/30 days/yes (2°–8°C)	no 40 40 500/40 40/150 80 hours/21 days/yes (12°–15°C)	no 28 28 — 28/100 168 hours/21 days/yes (12°–14°C below room temperature)
• Multiple reagent configurations supported Reagent container placed directly on system for use Instrument has same capabilities when third-party reagent used Walkaway capacity in minutes/Based on No. of specimens/Based on No. of tests-assays System is liquid chemistry, dry chemistry, or reconstituted onboard • Uses disposable cuvettes/Maximum No. stored • Uses washable cuvettes/Replacement frequency Minimum sample volume aspirated precisely at one time System supplied with UPS (backup power)/Requires floor drain Requires dedicated water system/Water consumption in L per hour Noise generated in decibels Dedicated pediatric sample cup/Dead volume Primary tube sampling/Pierces caps on primary tubes Sample bar-code reading capability/Autodiscrimination	yes yes yes can be hours/60/<2,000 liquid, reconstitutes onboard yes/12,000 no/— 2 µL yes/no yes/5 <75 yes/30 µL yes/no shortly after tubes are loaded onto instruments (2 of 5 interleaved, Codabar, codes 39 and 128)/—	yes yes no 240/52/>1,000 liquid no yes/never 1 µL yes/no no/2 >60 no/— yes/no sample loaded on the analyzer by internal bar-code scanner (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/no yes yes yes/yes/no	yes yes no 93/9/17 liquid no yes/1 year 1 µL yes/no no/— >60 no/— yes/no yes, after loading samples and immediately before execution of run (2 of 5 interleaved, UPC, Codabar, codes 39 and 128)/no yes yes yes/yes/no
• Reagent bar-code reading capability Onboard test auto inventory (determines volume in container) • Measures No. of tests remaining/Short sample detection/ Clot detection • Automatic detection of adequate reagent for aspiration and analysis • Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard Automatic rerun capability • Sample volume can be reduced to rerun out-of-linear-range high results/Increased to rerun out-of-linear-range low results Autocalibration or autocalibration alert • Calibrants stored onboard/Multipoint calibration supported Typical calibration frequency for ISE/Metabolites/Therapeutic drugs/ Drugs of abuse Automatic shutdown/Startup programmable	yes yes yes/yes/yes yes yes/yes yes yes yes/no yes yes/yes —/90 days/30 days/30 days no/no	yes no/no yes yes yes/yes yes no/yes 4 hours/7–31 days/—/— yes/yes	yes no/no yes yes yes/no yes no/yes 8 hours/7–28 days/—/— yes/yes
Stat time to completion of all analytes/throughput per hour for: • Sodium, potassium, chloride, TC02 • Sodium, potassium, chloride, TC02, glucose, urea, creatinine • Albumin, direct and total bilirubin, AST, ALT, ALP Typical time delay from ordering stat test to aspiration of sample Frequency of 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	— — — — 24 hours/yes yes/yes yes	3 minutes, 45 seconds/37 specimens 6 minutes, 10 seconds/45 specimens 9 minutes, 26 seconds/26 specimens >1 minute 4–24 hours yes/yes yes	35 seconds/90 specimens 5 minutes, 21 seconds/20 specimens 7 minutes/18 specimens <1 minute 4–24 hours/yes yes/no yes
Data-management capability/Instrument vendor supplies LIS interface • LISs with which system interfaces in active user sites Bidirectional interface capability LIS interface operates simultaneously with running assays Uses LOINC to transmit orders and results • How labs get LOINC codes for reagent kits	onboard/optional add-on cost middleware (syngo or Centralink) — yes (broadcast download and host query) yes yes —	no/no Antek, Fletcher Flora, Orchard, Skyler Lab, Data Innovations, Sunquest broadcast download yes no e-mail inquiry	onboard/no Antek's LabDAQ broadcast download and host query yes no e-mail inquiry
Lab can control analyzer remotely	—	no	no
Modem servicing available/System can diagnose own malfunctions On-site time of service engineer/Onboard error codes for troubleshooting • Mean time between failures/To repair failures Onboard maintenance records/Maintenance training demo module Training provided with purchase/Advanced operator training Annual service contract cost (24 hours/7days)	yes/yes 2–8 hours/— — — 3 days at vendor offices/yes —	yes/yes within 24 hours/yes — yes/yes 4 days on site/ 3 days at vendor offices/yes \$8,995 (M-F, 8 AM–8 PM)	yes/yes <24 hours/yes —/<4 hours no/no yes/yes via distributor
Distinguishing features (supplied by company)	integrates general chemistry with homogeneous LOCI and heterogeneous immunoassays onboard; allows a single platform for >95 percent of most requested tests; eliminates sample splitting between general chemistry tests and immunoassays; fully automated onboard ISD assays; QCC PowerPak onboard; reagent management system standard	CO2 performed as an electrolyte; four-parameter onboard dry ISE; 570 tests per hour; reusable glass cuvettes; small footprint	long-use cuvettes eliminate waste; intuitive software; fast, accurate ISEs; small footprint; virtually maintenance free

Note: a dash in lieu of an answer means company did not answer question or question is not applicable