Smaller, but sophisticated

Anne Ford

To Dan Siegenthaler, Beckman Coulter chemistry marketing manager, just because a laboratory does a low volume of testing doesn’t mean it has low-capability needs. “Advanced technology is important to low-volume labs just like it is to the large core labs and reference laboratories,” he says. “They still need analyzers with a large test menu. Just like larger labs, smaller-volume labs want to consolidate workstations, too.” Taking heed of these requirements are the vendors of chemistry analyzers for low-volume labs whose instruments are profiled in this issue. From new instrumentation and new tests to enhanced technological capabilities, these manufacturers have much to offer the lower-volume market.

Practicing what Siegenthaler preaches, Beckman Coulter recently launched the UniCel DxC 600 clinical system for low- to mid-volume laboratories (profiled in the July issue of CAP TODAY, page 68). With an onboard capacity of 65 reagents, the DxC 600 can perform more than 100 chemistry tests, “which is comparable to that of our larger e-volume chemistry systems,” Siegenthaler adds. And like the company’s higher-volume instruments, the DxC 600 features closed-tube sampling. “While cap-piercing technology is widely available on many different hematology platforms, we’re the only company in the world to offer such a device on our chemistry systems for low- to high-volume hospitals,” he says. Beckman Coulter also plans to make closed-tube sampling available on the UniCel DxC 600i, an integrated chemistry-immunoassay system in development now.

Several other companies are offering or will soon offer new assays for their existing low-volume analyzers—such as Abaxis, which has added the Lipid Plus with an AST/ALT/glucose assay and a chemotherapy evaluation panel to its Piccolo point-of-care analyzer. The Piccolo, says company representative Ron Blasig, “provides complete chem panel results in 13 minutes.” Meanwhile, Thermo Electron plans to make an ISE module for sodium, potassium, and chloride testing available on its Data Pro line of analyzers by September. “The Data Pro is a benchtop analyzer with a throughput of 240 tests per hour,” says company representative Bola Nicholson. “It comes in four different models that make it cost-effective for different laboratory needs.” Potential customers can also look forward to Abbott’s i-Stat cartridge, the Chemt+, which the company plans to introduce by the end of the year. Designed for low- to mid-volume testing, it will offer testing for sodium, potassium, chloride, BUN/creatinine, glucose, calcium, and total carbon dioxide. “The test cartridge will also provide hematocrit and hemoglobin results,” says Joe Baugh, senior product manager.

When it comes to technology improvements, the consensus is clear: The shortage of medical technologists increases smaller-volume laboratories’ reliance on instrument automation and ease-of-use just as much as it does for their higher-volume counterparts. “ Labs just don’t have access to the labor resources they need to operate at an optimal level, so chemistry and other systems are going to have to do many of those functions for them,” Siegenthaler says. Nicholson concurs: “Laboratories are forced to train staff that normally would not have responsibilities for instrumentation. This leaves it up to instrument manufacturers to provide instruments that are not complicated and require minimum maintenance.”

That explains technological enhancements such as those on Roche’s Integra 400 Plus, which, says product manager Todd Atkinson, “incorporates key new features including clot detection, an external data station with flat-screen monitor, and LED FP lamp, and auto-start software update.” The Integra 400 Plus, he adds, features the same multiple measuring technologies and reagent cassette format as its predecessor, the Integra 400. At Abbott, recent improvements in technology include what Baugh calls “a new downloader/recharge docking station system that allows our customers to use a very robust rechargeable battery pack instead of lithium batteries. This product really helps in those busy emergency departments.”

Besides the improved automation, quality control, ease of use, and cost efficiency, what else are customers likely to clamor for in the future? Baugh sums it up: “Wireless! I think in the next few years you will see many vendors’ products with wireless capabilities.” If Baugh is right, the wireless technology that’s made it possible to surf the Internet on a laptop at Star-bucks may soon sweep laboratories as well.

CAP TODAY’s survey of chemistry analyzers for low-volume laboratories includes products from the manufacturers listed above and from Alfa Wassermann, Analox Instruments, Clinical Data, Dade Behring, Hemagen Diagnostics, Nova Biomedical, Ortho-Clinical Diagnostics, and Randox Laboratories. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities.

Anne Ford is a writer in Chicago.
### Chemistry analyzers (for low-volume labs)

**Part 1 of 10**

**Name of instrument/First year sold in U.S.**
- Axion Inc.
- Ron Blankenship: [rblankenship@axion.com](mailto:rblankenship@axion.com)
- 2340 Whipple Rd.
- Union City, CA 94587
- 800-672-2947
- www.axion.com

**List price**
- Percoll®/1995
- $10,000
- $5,000
- U.S./U.S.

**Operational type/Rating type**
- self-contained system with multi-test reag. panel

**Sample handling system/Model type**
- disc loaded directly into instrument/benchtop
- 5.5 x 5 x 11.5/17 sq ft

**Tests available on instrument in U.S.**
- ALP, ALT, AST, GGT, amylase, albumin, total protein, bilirubin total, BUN, creatinine, calcium, cholesterol, glucose, uric acid, sodium, creatine kinase, potassium, TCO₂, chloride, cholesterol, HSL ratio, HDL, LDL, triglycerides-VLDL, phosphorus, direct bilirubins, magnesium

**Tests cleared but not clinically released**
- LDH

**Tests not available in U.S. but available in other countries**
- Research-use only assays/Tests in development

**User-defined methods implemented for what analytes**
- none

**Methods supported/immunoassay methods**
- enzymatic/n/a

**No. of direct ion selective electrode channels**
- n/a

**No. of direct ion selective electrode channels 
 + Must load separate reag. pack for each specimen/No. of diff. assays in pack**
- n/a
  - 4-14 analytes (chemistries) for 11 diff. chem. elec. profiles: resp., self-contained with each disk

**No. of different measured assays onboard simultaneously**
- n/a
  - 26
  - 54
  - 14

**No. of different assays programmed, calibrated at once**
- n/a
  - 4/14

**No. of user-definable (open) channels/No. active simultaneously**
- n/a
  - 4/14

**No. of different analytes for which system accommodates reag. containers onboard at once/Tests per container set**
- n/a
  - 26

**Shortest/median onboard reag. stability/refrigerated onboard**
- n/a
  - 6 months/12 months/n/a

**Multiple reag. configurations supported**
- yes

**Reag. container placed directly on system for use**
- yes

**Instrument has some capabilities when 3rd-party reag. used**
- yes

**Reag. only if part reportable result for standard chemistries**
- n/a

**Therapeutic/diagnostic special analytes**
- yes

**Walkaway capacity in minutes/No. of specimens/No. of tests-assays**
- n/a
  - <15/14

**System is liquid, dry, or reconstituted onboard**
- n/a

**Uses disposable cuvettes/Max. No. stored**
- n/a
  - 100

**Uses washable cuvettes/Replacement frequency**
- n/a
  - n/a/n/a

**Minimum sample volume aspirated precisely at one time**
- n/a

**Supplied with UPS (backup power)/Requires floor drain**
- n/a
  - n/a

**Requires dedicated water system/Water consumption in L per hour**
- n/a
  - n/a

**Noise generated in decibels**
- n/a

**Dedicated pediatric sampling/Specimen pack on primary tubes**
- n/a

**Sample bar-code reading capability/Autodiscrimination**
- n/a

**Reagent bar-code reading capability**
- n/a

**Bar-code placement per DSL standard Auto2A**
- yes

**On-board test auto inventory (particulates volume in container)**
- n/a

**Measures No. of tests remaining/Short sample detection/Total detection**
- n/a
  - n/a

**Automatic detection of adequate reag. for resp. & analysis**
- yes

**Homogeneity/Turbidity detection-quantification**
- n/a

**Dilution of patient samples onboard/Automatic rerun capability**
- n/a

**Sample volume can be reduced to rerun out-of-line-range-high results/ Increased to rerun out-of-line-range-low results**
- n/a

**Autoalteration or autoalteration alert**
- n/a

**Calibrators stored onboard/Multipoint calibration supported**
- n/a

**Typical calibr. frequency for ISE/Metabolics/Ther. drugs/Drops of abuse**
- n/a

**Automatic shutdown/Startup programmable**
- yes

**Start time to completion of all analytes, throughput per hr. for:**
- n/a
  - 15 min, 4 specimens
  - 15 min, 4 specimens
  - 15 min, 4 specimens

**Typical time delay from ordering slot test to aspiration of sample**
- n/a

**How often QC required/On-board SW capability to review QC**
- n/a

**On-board real-time QC/Support multiple QC info Nus. per analyte**
- n/a

**QC results transferred automatically to LIS**
- n/a

**Data mgmt. capability/Instrument vendor supplies LIS interface**
- on-board

**Interfaces up and running in active user sites with**
- 15

**Bidirectional interface capability**
- yes

**Test results transmitted to LIS as soon as chem. time complete**
- yes

**LIS interface operates simultaneously with running assays**
- yes

**Uses LOPC to transmit orders & results**
- no

**How labs get LOINC codes for reagent kits**
- n/a

**Lab can control analyzer remotely**
- n/a

**Interface avail. (or will be) to automated specimen handling system**
- n/a

**Modern service available/Can diagnose own malfunctions/ Determine malfunctioning component**
- n/a

**On-site time of avg. engineer/On-board error codes for troubleshooting**
- n/a
  - 24 hr/yes
  - 3 years/n/a

**Mean time between failures/To repair failures**
- n/a
  - 1 year
  - weekly; none; monthly; none

**Average time to complete maintenance by lab personnel**
- n/a

**On-board maintenance records/Maint. training demo module**
- n/a

**Training provided with purchase/Advanced oper. training avail.**
- n/a

**Annual service contract cost (24 h/7 d)**
- n/a

**1-year warranty, extended warranty—$1,200**

**Distinguishing features**
- compact chemistry system using a few drops of whole blood, serum, or plasma provides turnaround of results at point of care, including hands-on time, in 15 minutes

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Tabulation does not represent an endorsement by the College of American Pathologists.
Chemistry analyzers (for low-volume laboratories)

<table>
<thead>
<tr>
<th>Part 2 of 10</th>
<th>Abbott Laboratories</th>
<th>Alfa Wasserman Diagnostic Technologies LLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of instrument/Post year sold in U.S.</td>
<td>6-STAT 1/2000</td>
<td>ACE (AEC) Aeta Clinical Chemistry System 2004</td>
</tr>
<tr>
<td>List price</td>
<td>$6,000</td>
<td>$1,800+990/ea.</td>
</tr>
<tr>
<td>No. units in clinical use in U.S./Outside U.S.</td>
<td>1,500/500</td>
<td>batch, random access, discrete, cont., random access, stat/clinical</td>
</tr>
<tr>
<td>Country where designed/Manufacturer/Where reagents mfld</td>
<td>U.S./A. Canada</td>
<td>test system with open reag. system; channel</td>
</tr>
<tr>
<td>Operational type/Reagent type</td>
<td>small-container single-use cartridges-packaging-slides</td>
<td>ring with up to 5 segments (15 samples/vog/batch/chop)</td>
</tr>
<tr>
<td>Sample handling system/Model type</td>
<td>none/Hand</td>
<td>ACE 17.5 x 7.5 x 23.5 x 23.5 ft.</td>
</tr>
<tr>
<td>Dimensions in inches (h x w x d/Footprint)</td>
<td>23.4 x 7.6 x 7.24 cm.</td>
<td></td>
</tr>
<tr>
<td>Tests available in instrument in U.S.</td>
<td>sodium, potassium, chloride, lithium, calcium, BUN, glucose, creatinine, lactate, Hct, plt, pCO2, pO2, ActCl, Calculated Hb, TCO2, HCO3, BE, AST, total, uric acid, S-CRP, WBC, D-dimer, platelet count, prothrombin time, etc.</td>
<td>urine, plasma, 17-OHCS, testosterone, estradiol, progesterone, cortisol, etc.</td>
</tr>
<tr>
<td>Tests cleared but not clinically released</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Tests not available in U.S. but available in other countries</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Research use-only assays/Tests in development</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Uterd defined methods implemented for what analytes</td>
<td>none</td>
<td>none</td>
</tr>
</tbody>
</table>

**Methods supported/Immunoassay methods**

| No. of direct ion selective electrode channels | 10 | 60 |
| Must load separate reag. pack for each specimen/No. of diff. assays in pack | 2 | 3 |
| Separate reag. pack for each test run | yes | no |
| No. of different measured assays onboard simultaneously | 15 | 20 |
| No. of different assays programmed, calibrated at once | up to 16 | 15/16 |
| No. of user-definable (open) channels/No. active simultaneously | n/a/16 | 10/100-150 tests per bottle |
| No. of different analyzers for which system accommodates reag. containers onboard at once/Tests per container set | n/a/4 | n/a/16 |
| Shortest/Median onboard reag. stability/fragile/refrigerated onboard | 1-4 days/no | n/a |
| Multiple reag. configurations supported | n/a/na | yes |
| Reag. container placed directly on system for use | n/a | yes |
| Instrument has some capabilities when 3rd-party reag. used | n/a | yes |
| Reag. only cost per reportable result for standard chemistries/Therapeutic drugs/Special analytes | $3.50 | $3.50 |
| Walkaway capacity in minutes/No. of specimens/No. of tests-assays | 2 min/1 up to 16 | 75/75/248 |
| System is liquid, dry, or rehydrated onboard | yes | yes |
| Univ disposable cuvettes/Max. No. stored | n/a | 24/48 |
| Univ washable cuvettes/Replacement frequency | n/a | n/a |
| Minimum sample volume aspirated precisely at one time | 40 µl | 3 µl |
| Supplied with UPS backup power/Required floor drain | n/a/yes | n/a |
| Requires dedicated water/Water consumption in l. per hour | n/a/15 | n/a/50 |
| Noise generated in decibels | n/a | n/a |
| Dedicated pediatric sample cup/Donor volume | no/50 | yes/100 |
| Primary sampling/Pierces caps on primary tubes | yes/no | yes |
| Sample bar-code reading capability/Automatic/desynchronization | yes | yes |
| Bar-code placement per CLSI standard/Auto | yes | yes |
| Onboard test auto inventory (determines volume in container) | yes | yes/no |
| Measures No. of tests remaining/Short sample detection/Clot detection | n/a/yes | yes/no/yes |
| Automatic detection of adequate reag. for: spec. & analysis | yes | yes/no |
| Hemolysis/Turbidity detection-quantification | yes | yes/no |
| Dialysis of patient samples onboard/Automatic reusability | yes | yes/no |
| Sample volume can be reduced to rerun on-insource high results/Increased to rerun out-of-liner range low results | yes | yes |
| Auto-calibration or autocalibration alert | yes | yes/yes |
| Calibrants stored onboard/Multipoint calibration supported | n/a | yes |
| Typical cad or frequency for ISE/Metabolic/Ther. drugs/Drugs of abuse | n/a/yes | yes/yes |

**Stat time for all analytes, throughput per hr. for:**

| Sodium, potassium, chloride, TCO2 | 2 min, n/a | 2 min, n/a |
| Calcium, phosphorus, chloride, TCO2, glucose, urea, creatinine | 2 min, n/a | 2 min, n/a |
| Alium, direct & total bil., AST, ALT, ALP | 2 min, n/a | 2 min, n/a |
| Typical time delay from ordering test to test to aspir. of sample | shortest interval: 24 hr, longest interval: each new/lytes | shortest interval: 24 hr, longest interval: each new/lytes |
| How often QC required/Onboard SW capability to review QC | onboard/yes | onboard/yes |
| Onboard real-time QC/Support multiple QC test sets. per analyte | yes | yes |
| QC results transferred automatically to LIS | yes | yes |

**Data mgmt. capability/Instrument vendor supplies LIS interface**

| Interface setup and running in active user sites with Bidirectional interface capability | optional add-on ($45,000 including LIS interface, SW mfr: | onboard/no |
| Test results transmitted to LIS as soon as chem. Time complete LIS interface operates simultaneously with running assays | yes | yes (broadcast download & host query) |
| Does LONIC to transmit orders & results | yes | yes |
| What labs get LONIC codes for reagent kits | yes | yes/no |

**Lab can control analyzer remotely**

| Interface available, or will be to automated specimen handling system | yes | no |

**Modern servicing available/Can diagnose own malfunctions/ Determine malfunctioning component**

| On-site time of svc. engin./Onboard error codes for troubleshooting | replacement/yes | >2 hrs/yes |
| Mean time between failures/Trc repair failures | not determined/24 hr | 2 per 1-24 hr |
| Average time to complete maintenance by lab personnel | daily; never; weekly; monthly; none | daily; 3 mic; weekly; 30 min; monthly; 30 min |
| Onboard maintenance reports/Maint. training demo module | n/a | 4.5 days at manufacturer’s facility/yes |
| Training provided with/Purchased/Advanced, operator. training avail. | n/a | yes/yes |
| Annual service contract cost (24 mo.) | 450 | n/a |

**Dispoilng features**

| Handheld portable analyzer | easy-to-use, multilab testing; closed-hub sampling; stat interrupt capability; extensive test menu; onboard sample and reagent refrigeration; onboard reagent inventory management | n/a/yes |
## Chemistry analyzers (for low-volume laboratories)

### Part 3 of 10

<table>
<thead>
<tr>
<th>Name of instrument/Post year sold in U.S.</th>
<th>Analyte Instruments U.S.A. Inc.</th>
<th>Beckman Coulter Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>List price</td>
<td>Synchroom CX3 Delta/995</td>
<td>$72,300</td>
</tr>
<tr>
<td>Country where designed/Manufactured/Where reagents refd.</td>
<td>discrete/open reagent system</td>
<td>continuous random access/open reagent system</td>
</tr>
<tr>
<td>Operational type/Reagent type</td>
<td>---</td>
<td>sectors, disposable/flank-storing</td>
</tr>
<tr>
<td>Sample handling system/Method type</td>
<td>---</td>
<td>--</td>
</tr>
<tr>
<td>Dimensions in inches (H x W x D)/Instrument footprint</td>
<td>12 x 12 x 12/1 ft</td>
<td>60 x 27 x 30/5 ft</td>
</tr>
</tbody>
</table>

### Tests available on instrument in U.S.

<table>
<thead>
<tr>
<th>Test available on instrument in U.S.</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>glucose, lactate, cholesterol, urea</td>
<td>sodium, potassium, chloride, CO₂, calcium, creatinine, BUN, glucose, total protein</td>
</tr>
</tbody>
</table>

### Methods supported/Immunoassay methods

<table>
<thead>
<tr>
<th>Method supported/Immunoassay methods</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxygen electrode</td>
<td>--</td>
</tr>
<tr>
<td>photometry, autochemistry/fluorimetry, direct turbidimetric, particle-enhanced turbidimetric, enzyme immunoassay</td>
<td>--</td>
</tr>
</tbody>
</table>

### No. of different reagent electrode channels

- Must load separate reag. pack for each specimen/No. of diff. assays in pack
- Separate reag. pack for each test run
- No. of different measured assays onboard simultaneously
- No. of different assays programmed, calibrated at once
- No. of different reagents dispensable (open channels)/No. active simultaneously
- No. of different analytes for which system accommodates
- Reagent, containers onboard at once/Tests per container set
<table>
<thead>
<tr>
<th>No. of different reagent electrode channels</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>no</td>
<td>--</td>
</tr>
<tr>
<td>no</td>
<td>--</td>
</tr>
<tr>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1/100-300</td>
<td>5/400-2,400 tests per container</td>
</tr>
</tbody>
</table>

### Therapeutic drugs/ Special analytes

<table>
<thead>
<tr>
<th>Therapeutic drugs/ Special analytes</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walkaway capacity in minutes/No. of specimens/No. of tests-assays</td>
<td>400/50/31,827</td>
</tr>
<tr>
<td>System is liquid, dry, or reconstituted onboard</td>
<td>liquid</td>
</tr>
<tr>
<td>Uses disposable covers/Max. No. stored</td>
<td>no/na</td>
</tr>
<tr>
<td>Uses washable covers/Replacement frequency</td>
<td>no/yes</td>
</tr>
<tr>
<td>Minimum sample volume aspirated precisely at one time</td>
<td>2.5 µl</td>
</tr>
<tr>
<td>Supplied w/ UPS (backup power)/Requires floor drain</td>
<td>no</td>
</tr>
<tr>
<td>Requires dedicated water system/Water consumption in l per hour</td>
<td>no</td>
</tr>
<tr>
<td>Noise generated in decibels</td>
<td>70</td>
</tr>
<tr>
<td>Dedicated pediatric sample cup/Volume</td>
<td>no</td>
</tr>
<tr>
<td>Primary sample volume/Pieces caps on primary tubes</td>
<td>no</td>
</tr>
<tr>
<td>Sample bar-code reading capability/Auto-discrimination</td>
<td>--</td>
</tr>
<tr>
<td>Reagent bar-code reading capability</td>
<td>--</td>
</tr>
<tr>
<td>Bar-code placement per CLIA standards AutoDx</td>
<td>yes</td>
</tr>
<tr>
<td>Ondemand test auto inventory (determines volume in container)</td>
<td>no</td>
</tr>
<tr>
<td>Measures No. of tests remaining/Short sample detection/Cat detection</td>
<td>no/yes</td>
</tr>
<tr>
<td>Automatic detection of adequate reagent for aspir. &amp; analysis</td>
<td>yes</td>
</tr>
<tr>
<td>Hemolytic/Turbidimetric detection-quantitation</td>
<td>no/required/no required</td>
</tr>
<tr>
<td>Dilution of patient samples onboard/Automatic reagent refill system</td>
<td>no/required/no required</td>
</tr>
<tr>
<td>Sample volume can be reduced to run out-of-linear-range high results/</td>
<td>Increased to run out-of-linear-range low results</td>
</tr>
<tr>
<td>Auto-calibration/Alert support</td>
<td>no</td>
</tr>
<tr>
<td>Calibrates stored onboard/Multipoint calibration supported</td>
<td>no</td>
</tr>
<tr>
<td>Typical calib. frequency for ISE/Metabolites/Ther. drugs/Dugs of abuse</td>
<td>no</td>
</tr>
<tr>
<td>Automatic shutdown/Start programmable</td>
<td>no</td>
</tr>
</tbody>
</table>

### Stat time to completion of all analytes, Throughput per hr., for:

<table>
<thead>
<tr>
<th>Stat time to completion of all analytes, Throughput per hr., for:</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium, potassium, chloride, TCO₂</td>
<td>52 sec, 75</td>
</tr>
<tr>
<td>Sodium, potassium, chloride, TCO₂, glucose, urea, creatinine</td>
<td>8 min, 75</td>
</tr>
<tr>
<td>Albumin, direct &amp; total bil., ALT, AST, ALP</td>
<td>n/a, n/a</td>
</tr>
<tr>
<td>Total protein</td>
<td>45 sec</td>
</tr>
<tr>
<td>Hemoglobin, WBC, RBC, PCV</td>
<td>24 hrs</td>
</tr>
</tbody>
</table>

### Data mg/dl, capability/instrument vendor supplies LIS interface

<table>
<thead>
<tr>
<th>Data mg/dl, capability/instrument vendor supplies LIS interface</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interfaced up and running in active user sites with</td>
<td>--</td>
</tr>
<tr>
<td>Bidirectional interface capability</td>
<td>no</td>
</tr>
<tr>
<td>Test results transmitted to LIS as soon as chem, time complete</td>
<td>yes</td>
</tr>
<tr>
<td>LIS interface operates simultaneously with running assays</td>
<td>yes</td>
</tr>
<tr>
<td>Uses LIONC to transmit orders &amp; results</td>
<td>yes</td>
</tr>
<tr>
<td>How labs get LIONC codes for reagent kits</td>
<td>n/a</td>
</tr>
</tbody>
</table>

### Lab can control analyzer remotely

<table>
<thead>
<tr>
<th>Lab can control analyzer remotely</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interface avail. (will be) to automated specimen handling system</td>
<td>no</td>
</tr>
</tbody>
</table>

### Modern servicing available/Can diagnose own malfunctions/ Determine malfunctioning component

<table>
<thead>
<tr>
<th>Modern servicing available/Can diagnose own malfunctions/ Determine malfunctioning component</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>On-site time of svc, engineer/Onboard error codes for troubleshooting</td>
<td>no/a/na</td>
</tr>
<tr>
<td>Mean time between failures/Tx repair failures</td>
<td>no/a/na</td>
</tr>
<tr>
<td>Average time to complete maintenance by lab personnel</td>
<td>metro: same day; rural: same or next day/yes</td>
</tr>
<tr>
<td>Onboard maintenance records/Manual. training demo module</td>
<td>no/a/na</td>
</tr>
<tr>
<td>Training provided with purchase/Advanced oper. training avail.</td>
<td>daily: 1 min; weekly: 1 min; monthly: 10 min</td>
</tr>
<tr>
<td>Annual service contract cost (4 hr/d)</td>
<td>$500</td>
</tr>
</tbody>
</table>

### Distinguishing features

<table>
<thead>
<tr>
<th>Distinguishing features</th>
<th>--</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large test menu; small sample size; cost per test; 20-second analysis time</td>
<td>fast stat chemistry analyzer; centrifugal sector; bar-coded calibrations and controls; test-quant; reagent load while running; ready-to-use liquid reagents; ISE systems; pulled xenon light source; available DL2000 Sample Manager</td>
</tr>
</tbody>
</table>

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**CMYK Page 24**

**August 2005**
Chemistry analyzers (for low-volume laboratories)

Part 4 of 10

Beckman Coulter Inc.
200 South Kramer Blvd.
P.O. Box 8000
Brea, CA 92622-8000
800-526-3281 www.beckmancoulter.com

Beckman Coulter Inc.
200 South Kramer Blvd.
P.O. Box 8000
Brea, CA 92622-8000
800-526-3281 www.beckmancoulter.com

Name of instrument/First year sold in U.S. Lab price
No. units in clinical use in U.S./Outside U.S.
Country where designed/Manufactured/Where reagents refined. Operational type/Reagent type
Sample handling system/Model type Dimensions in inches (W x D x H) Instrument footprint

Tabulations

Tests available on instrument in U.S.

- ALP, ALT, amylase, AST, BUN, calc., CO2, chloride, creat., CK-MM, creatinine, cr. fibrinogen, cr. lipids, cr. protein, electrolytes, fructose, glucose, hematocrit, hemoglobin, Hct, iron/TIBC, Iop, LD, LDL, MCH, MCHC, MCV, melastatic, protein, serum, total protein, total sugar, triglyceride, triglyceride-glucose bilirubin, uric acid, uric acid, urin. esoteric chemistries: ammonia, cholesterol, hemoglobin A1c, lactate, micro-albumin, prothrombin, sodium; drugs of abuse testing; Therapeutic drug monitoring; proteins: anti-streptolysin O, IAA, lpl, MPA, thromboplastin factor, transferrin; thyroid: T3, T4, T3-T4, TSH, T4-TSH, TSH, T4-TSH, TSH, T4, T3, T3, TSH

Tests cleared but not clinically released

Tests not available in U.S. but submitted for 510(k) clearance

Tests not available in U.S. but available in other countries

Research-use-only assays/Tests in development

Use-defined methods implemented for what analytes

GBL, cyclic AMP, homocysteine, histamine

GBL, cyclic AMP, homocysteine, histamine

Methods supported/Immunoassay methods

- Phlebotomy, point-of-care/bilirubin turbidimetric, direct turbidimetric, particle enhanced turbidimetric, enzyme immunoassay

No. of direct ion selective electrode channels
- Must load separate mag. for each specimen/No. of assays in pack
- Separate mag. pack, standard pack

No. of different measured assays on board simultaneously

- No. of different assays programmed, calibrated at once

- No. of user-defeatable (upon) channels/No. active simultaneously

- No. of different analytes for which system accommodates

- Reag. containers loaded at once/Tests per container set

- Shortest/Meidan on-board reagent, stability/flushed on-board reagent

- Multiplex, configurations supported

- Reag. container placed directly on system for use

- Instrument has same capabilities when 3rd-party reag. used

- Reag. only cost per reportable result for standard chemistries/

- Therapeutic drugs/Special analytes

- Therapeutic drugs/Special analytes

- Walkway capacity in minutes/no. of specimens/No. of tests-assays

- System is liquid, dry, or reconstituted on-board

- Does disposable cuvettes/Max. No. reconstituted

- Does washout cycles/Replacement frequency

- Minimum sample volume aspirated precisely at one time

- Supplied with UPS (backup power)/Requires floor drain

- Requires dedicated water system/Water consumption in L per hour

- Noise generated in decibels

- Dedicated pediatric sample cup/flushed on-board volume

- Primary tube sampling/Perfuses caps on primary tubes

- Sample bar-code reading capability/Activity/dilution

- Reagent bar-code reading capability

- Reagent bar-code reading capability

- Bar-code placement per CLIA standard AutoA

- Onboard test auto inventories (determined volume in container)

- Measure As No. of tests remaining/Short sample detection/Critical detection

- Automatic detection of adequate reag. for assay. & analysis

- Hemoglobin/Turbidity detection-quantification

- Dilution of patient samples on-board/Automatic renan capability

- Sample volume can be reduced to renan from on-board high result

- Increased to renan off-line-of-range low results

- Autocalibration or autocalibration alert

- Calibrators stored on-board/Multipoint calibration supported

- Typical calibr. frequency for ISE/Metabolics/Ther. drugs of abuse

- Automatic standards (Bar-coded)

- Start time to completion of all analyses, throughput per hr. or

- Sodium, potassium, chloride, TC02

- Sodium, potassium, chloride, TG02, glucose, uric acid

- Albumin, direct & total bil., AST, ALT, ALP

- Typical time delay from starting test to stat. of assay

- How often QC/recommended/On-board QC capability to review QC

- On-board real-time GC/support output of multiple QC limit tests per analysis

- QC results transferred automatically to LIS

- Data merger, capability/Instrument vendor supplies LIS interface

- Interfaces up and running in active user sites with

- Bidirectional interface capability

- Test results transmitted to LIS as soon as chem. time. Complete LIS interface operates simultaneously with running assays

- How labs get LIONC codes for reagent kits

- Lab can control analyzer remotely system existence

- Modern servicing available/Can diagnose own malfunctions/ Determine malfunctioning component

- On-site time of sec. engine/On-board error codes for troubleshooting

- Mean time between failures/Time repair failures

- Average time to complete maintenance by lab personnel

- Onboard maintenance records/Maint. training module

- Training provided with/advanced op/advanced training. avail.

- Annual service contract cost (14 kHz / d)

- Distinguishing features

- Sample index: contributory categories; cit. detection; bar-coded calibrators and controls; host query; reagent load while running; ready-to-use liquid reagents; Polychromatex ring, packed sodium-lithium source; polyethylene corrosion; semipermeable glass cuvettes, available DL2000 Sample Manager

- Sample index: contributory categories; cit. detection; bar-coded calibrators and controls; host query; reagent load while running; ready-to-use liquid reagents; Polychromatex ring, packed sodium-lithium source; polyethylene corrosion; semipermeable glass cuvettes, available DL2000 Sample Manager

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August 2005

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

**Part of 10**

- **Clinical Data Inc.**
  - 2 Thayer Blvd
  - Newport, RI 02840
  - 401-847-3822
  - www.clinical.com

- **Siemens**
  - 940-234-2623
  - www.siemens.com

See accompanying article on page 20

**Name of instrument/First year sold in U.S.**

- **LabPalz**
  - 7/5,000
  - Netherlands/Netherlands/U.S.
  - free-standing

- **User-friendly instrument for small laboratories**
  - 1,400
  - continued random-access/self-contained single-use & multi-use cartridge-modules & open-reagent system
  - 45 x 15 x 31 (without monitor)/10.5 x 12.5

- **Tests available in instrument**
  - **ALT**, alkaline phosphatase, albumin, amylase, aspartate aminotransferase, bilirubin direct & total, calcium, C1, C1, Co2, chloride, cholesterol, creatinine, digoxin, direct & indirec & L, glucose, total iron, magnesium, phosphatase, potassium, total protein, sodium, testosterone, triglycerides, BUN, uric acid, HbA1C

- **Tests cleared but not clinically released**
  - 3

- **Tests not available in U.S.**
  - 3

- **Research-use only assays/Tests in development**
  - none

- **Methods supported/Immunoassay methods**
  - photometry, potentiometry (0E)/immunoturbidimetric

- **Bar code placement per CLSI standard AutoA**
  - yes/no

- **Onboard test auto inventory (determines volume in container)**
  - yes

- **Measures No. of times running/short sample detection/lost detection**
  - yes

- **Automatic detection of adequate read/for analysis & screening**
  - yes

- **Homology/Transversion detection-functional**
  - yes

- **Dilution of patient samples out/instrument & automatic rerun capability**
  - yes

- **Sample volume can be reduced to rerun out-of-range-line-range results/ increased to rerun out-of-range-range low results**
  - yes

- **Automatic calibration/automatic alert**
  - yes

- **Calibration stored onboard/Manual/Computer**
  - yes

- **Typical call frequency for SLCL/Reference/Normal/Abnormal**
  - yes

- **Automatic/semi-automatic/semi-automatic/semi-automatic**
  - yes

- **Start time from completion of all analyses, throughput per hr for:**
  - **Sodium, potassium, chloride, TCO2**
    - 8 min.
  - **Sodium, potassium, chloride, TCO2**
    - 10 min.
  - **Albumin, direct & total bil, AST, ALT, ALP**
    - 10 min.
  - **Other tests in CLSI range**
    - 4 hrs/10 min.

- **Data report, capability/instrument vendor supplies LUS interface**
  - optional add-on/yes

- **Interfaces up running in active user sites with**
  - none

- **Bidirectional interface capability**
  - yes

- **Test results transmitted to LIS as soon as chem. test complete**
  - yes

- **LIS interface operates simultaneously with running assays**
  - yes

- **Uses LHCN to transmit orders & results**
  - no

- **New labs get LHCN codes for reagent kits**
  - no

- **Lab can control analyzer remotely**
  - yes

- **Interface avail. (will be) to automated specimen handling system**
  - none

- **Modern servicing available/Can diagnose own malfunctions**
  - no/yes

- **Determine malfunctioning component**
  - yes

- **On-site test of use, engineer/Onboard error codes for troubleshooting**
  - within 24 hrs

- **Mean time between failures/Repair failures**
  - within 24 hrs

- **Average time to complete maintenance by lab personnel**
  - daily 15 min.; weekly: 20 min; monthly: 60 min

- **Board maintenance records/Main TRAINING module**
  - 5 days at site

- **Training provided with purchase/advanced operator training available**
  - none

- **Annual service contract cost (24 hrs/7 days)**
  - no

- **Distinguishing features**
  - reusable cassettes; dry RE with CO2; 2-30 μl sample size; onboard wash system; ready-to-use liquid reagents

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**CMYK Page 27**

**CAP TODAY / 27**

**SURVEY OF INSTRUMENTS**

**August 2005**
<table>
<thead>
<tr>
<th>Method</th>
<th>Platform</th>
<th>Test(s)</th>
<th>Analytes/Units</th>
<th>Turnaround Time</th>
<th>Test Feasibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Photometry</td>
<td>—</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Potentiometry</td>
<td>(ISE)</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

**Part 6 of 10**

Hemagen Diagnostics Inc.  
Nova Biomedical Corp.  

**Name of instrument/First year sold in U.S.**  
Analyzer Benchtop Chemistry System/1986  
Stat Profile Critical Care Apex/2002  

**List price**  
$9,000  
$25,000-$50,000  

**No. of units in clinical use in U.S./Outside U.S.**  
10  
50,000+  

**Country where designed/Manufactured/Where reagents mailed**  
Colombia, BO 21040  
Waltham, MA 02154-1041  

**Operational type/Reagent type**  
batch/self-contained single use cartridges/packages slides  
sample automatically drawn from syringe, capillary, or open tube/benchtop  

**Sample handling system/Model type**  
retur/bothexit  
17.2 x 13.7 x 22.5 ft  

**Dimensions in inches (H x W x D)/Instrument footprint**  
8.5 x 25 x 1/2.5 sq ft  

**Tests available on instrument in U.S.**  
ALP, GGT, UPT, GPT, BUN, glucose, calcium, cholesterol, creatinine, triglycerides, amylase, uric acid, total bilirubin, total protein, HDL cholesterol  
ph, PCC, PT, SD, %, hematocrit, hemoglobin, sodium, potassium, chloride, ionized calcium, ionized Mg, glucose, BUN, creatinine, lactate, descreatinase, oxyphenibut, methemoglobin, carbonyl/methemoglobin  

**Tests cleared but not clinically released**  
none  
none  

**Tests not available in U.S. but submitted for 510(k) clearance**  
none  
none  

**Tests not available in U.S. but available in other countries**  
none  
none  

**Research-use-only tests/Tests in development**  
none—  
none  

**User-defined methods implemented for what analytes**  
none  
none  

**Methods supported/mm económay methods**  
photometry—  
potentiometry (ISE), optical, reflectance/na  

| * Must load separate reag. pack for each specimen/No. of diff. assays in pack | yes/14  
| — | no/na  
| — | no  
| — | 10  
| — | 10  
| — | 10/14  
| — | 19/200–500 samples (2,600–5,600 tests), depending on lab  
| — | no  
| — | no  
| — | 45/45 days/na  
| — | na/na  
| — | na/na  
| — | 10 µL/80 µl  
| — | 60 µL  
| — | no (optional)/no  
| — | na/no  
| — | 40–60 µg/mg test (cost varies with volume); handheld instr. rearg.  
| — | 12–120 minutes/120 min/h/h/a  
| — | yes/yes  
| — | no  
| — | yes  
| — | yes/yes  
| — | yes/yes  
| — | yes (on co-examinee module)/yes (on co-examinee module)  
| — | yes (on co-examinee module)/no  
| — | na/no  
| — | yes/yes  
| — | yes  
| — | yes/yes  
| — | yes  
| — | yes  
| — | 62 sec, 23–38, depending on use mode  
| — | 134 sec, 23–38, depending on use mode  
| — | <2 sec  
| — | 8–10 min  
| — | yes/yes  

**Data negrt, capability/instrument vendor supplies LIS interface**  
na/yes (included in price)  

**Interfaes up and running in active user sites with**  
in development  
na/na  

**Bidirectional interface capability**  
no  
yes  

**Test results transmitted to LIS as soon as chem. time complete**  
—  
—  

**LIS interface operates simultaneously with running assays**  
—  
—  

**Uses LINC in transmit orders & results**  
—  
—  

**How labs put LINC codes for reagent kits**  
na/na  

**Lab can control analyzer remotely**  
—  
—  

**Interface avail. (or will be) to automated specimen handling system**  
—  
—  

**Modern servicing available/Can diagnose own malfunctions?**  
—  
—  

## Survey of Instruments

**Distinguishing features**  
uses only 90 µl of sample & requires less than 60 seconds of prep work; minimal maintenance required, offered with sodium, potassium, and chloride ISE units  
comprehensive 19-test critical care profile, including ionized Mg, BUN, and creatinine; color touch screen; integrated co-examinee; open software architecture; onboard data management; automated onboard quality control; sealed waste system; automated monitoring of QC and reagent packs; tankless gas calibration; automated maintenance

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

<table>
<thead>
<tr>
<th>Part 7 of 10</th>
<th>Nova Biomedical Corp.</th>
<th>Nova Biomedical Corp.</th>
</tr>
</thead>
<tbody>
<tr>
<td>List price</td>
<td>$12,000-$15,000</td>
<td>$22,000-$25,000</td>
</tr>
<tr>
<td>No. units in clinical use in U.S./Outside U.S.</td>
<td>9,000 U.S.; 4,500 other</td>
<td>9,000 U.S.; 4,500 other</td>
</tr>
<tr>
<td>Country where designed/Manufactured/Where reagents mfd.</td>
<td>U.S.</td>
<td>U.S.</td>
</tr>
<tr>
<td>Operational type/Reagent type</td>
<td>Discrete/Pre-packaged &amp; self-contained multi-use cartridges—packaging-units: sample automatically drawn from syringes, capillary, or open tube/handtop</td>
<td>batch, random access/self-contained multiliner cartridges</td>
</tr>
<tr>
<td>Flow rate</td>
<td>26.0 ml/min</td>
<td>40 positions tray, stir sampling directly from sample container/handtop</td>
</tr>
<tr>
<td>Dimensions in inches (H x W x D)/Instrument footprint</td>
<td>15 x 15 x 81/9 sq ft</td>
<td>28.5 x 19.2 x 20.375 sq ft</td>
</tr>
<tr>
<td>Tests available on instrument in U.S.</td>
<td>Potassium, sodium, chloride, blood urea, glucose, BUN, creatinine, Hct</td>
<td>sodium, potassium, chloride, triad CO2, glucose, BUN, creatinine, Hct</td>
</tr>
<tr>
<td>Tests cleared but not clinically released</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Tests not available in U.S. but submitted for FDA clearance</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Research-use only assays/Tests in development</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>User-defined methods implemented for what analytes</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Methods supported/Immunoassay methods</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of direct ion selective electrode channels</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>• Must load separate reag. pack for each specimen/No. of diff. assays in pack</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>• Separate reag. pack for each test run</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>No. of different measured assays onboard simultaneously</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>No. of different assays programmed, calibrated at once</td>
<td>11</td>
<td>8</td>
</tr>
<tr>
<td>No. of user-definable open channels/No. active simultaneously</td>
<td>0/8</td>
<td>0/8</td>
</tr>
<tr>
<td>No. of different analyzers for which system accommodates reag. containers onboard at once/Tests per container set</td>
<td>1/4</td>
<td>1/4</td>
</tr>
<tr>
<td>Shortest/Median onboard reag. stability/Refrigerated onboard storage</td>
<td>45 days/45 days</td>
<td>21 days/21 days</td>
</tr>
<tr>
<td>Multiple reag. configurations supported</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Reag. container placed directly on system for use</td>
<td>requires operator prehandling, preparation</td>
<td>requires operator prehandling, preparation</td>
</tr>
<tr>
<td>Instrument has any capabilities when 3rd-party reag. used</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Reag. only cost per reportable result for standard chemistries/Therapeutic drugs/Drug class analytes</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Walkaway capacity in minutes/No. of specimens/No. of tests- assays</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>System is liquid, dry, or reconstituted onboard</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Uiv disposable cuvettes/Max. No. stored</td>
<td>no</td>
<td>n/a</td>
</tr>
<tr>
<td>Uiv washable cuvettes/Replacement frequency</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Minimum sample volume aspirated precisely at one time</td>
<td>40 μl</td>
<td>38 μl</td>
</tr>
<tr>
<td>Supplied with UPS (backup power)/Requires floor drain</td>
<td>no (optional)/no</td>
<td>n/a</td>
</tr>
<tr>
<td>Requires dedicated water system/Water consumption in L per hour</td>
<td>minimal</td>
<td>minimal</td>
</tr>
<tr>
<td>Noise generated in decibels</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Indicated pediatric sample cup/demand volume</td>
<td>0.5 mL</td>
<td>0.1 mL</td>
</tr>
<tr>
<td>Primary tube sampling/Freres caps on primary tubes</td>
<td>yes/no</td>
<td>yes/no</td>
</tr>
<tr>
<td>Sample bar-code reading capability/Auto-discrimination</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Reagent bar-code reading capability</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Bar-code placement per CLSI standard AutoDx</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Opaque test card inventory (determines container in use)</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Measure No. of tests remaining/Short sample detection/Out of range detection</td>
<td>yes</td>
<td>n/a</td>
</tr>
<tr>
<td>Automatic detection of adequate reag. for asp. &amp; analysis</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Hemolysis/Turbidity detection-quantification</td>
<td>yes/yes*</td>
<td>no/yes</td>
</tr>
<tr>
<td>Dilution of patient samples onboard/Automatic reen capability</td>
<td>yes/no</td>
<td>yes/no</td>
</tr>
<tr>
<td>Sample volume can be reduced to run without reagent &amp; range high results</td>
<td>no</td>
<td>n/a</td>
</tr>
<tr>
<td>Increased to run out-of-range low results</td>
<td>no</td>
<td>n/a</td>
</tr>
<tr>
<td>Automation or automation support</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Calibration stored onboard/Multipoint calibration supported</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Typical calibr. frequency for ISE/Metabolites/Ther. drugs/Dx of Abuse</td>
<td>30–120 min/30–120 min/n/a</td>
<td>2 to 4 hrs/n/a</td>
</tr>
<tr>
<td>Automatic shutdown/Startup programmable</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Stat time to completion of all analyses, throughput per hr. for:</td>
<td>10 s</td>
<td>10 s</td>
</tr>
<tr>
<td>• Sodium, potassium, chloride, TC02</td>
<td>15 s</td>
<td>15 s</td>
</tr>
<tr>
<td>• Sodim, potassium, chloride, TC02, glucose, urea, creatinine</td>
<td>15 s</td>
<td>15 s</td>
</tr>
<tr>
<td>• Albunin, direct &amp; total bil., AST, ALT, ALP</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Typical time delay from entering stat test to asp. of sample</td>
<td>&lt;2 sec</td>
<td>&lt;2 sec</td>
</tr>
<tr>
<td>How often QC required/Board SW capability to review QC</td>
<td>8 h (CLIA)/yes</td>
<td>8 h (CLIA)/yes</td>
</tr>
<tr>
<td>Onboard real-time QC/Support many multiple QC lot Nos. per analyzer</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>QC results transferred automatically to LIS</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Data interg., capability/Instrument vendor supplies LIS interface</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Interfaces up and running in active user sites with</td>
<td>virtually all</td>
<td>onboard &amp; optional add-on ($12,255, SW ref.: Nova/Nx)</td>
</tr>
<tr>
<td>Bidirectional interface capability</td>
<td>yes (broadcast download &amp; host query)</td>
<td>yes</td>
</tr>
<tr>
<td>Test results transmitted to LIS as soon as chem. time completes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>LIS interface operates simultaneously with running assays</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>For DOx to forward trend results</td>
<td>yes</td>
<td>n/a</td>
</tr>
<tr>
<td>New tests &amp; DOx codes for reagent kits</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Lab can control analyzer remotely</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Interface aval. will be 1st to automated specimen handling system</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Manual sampling available/Can diagnose own malfunctions/ Determine malfunctioning component</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>On-site time of use, service/Engineering/Board error codes for troubleshooting</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Mean time between failures/Ts repair failures</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Average time in complete maintenance by lab personnel</td>
<td>30 min/day; weekly; &lt;5 min; monthly; &lt;15 min</td>
<td>n/a</td>
</tr>
<tr>
<td>Onboard maintenance records/Start/monitor, training demo module</td>
<td>1 day on site/year</td>
<td>n/a</td>
</tr>
<tr>
<td>Training provided with/Purchase/Advanced oper. training avail.</td>
<td>by analyzer configuration &amp; geographic location; discounts for multiple-year contract or 5-year maintenance rental or lease</td>
<td>n/a</td>
</tr>
<tr>
<td>Annual service contract cost (24 h/7 d)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

| Distinguishing features | onboard quality control; liquid calibration eliminates gas tanks; remote control, remote review, space saving design | whole blood analyzer for creatinine & TC02 can analyze whole blood, serum, plasma, urine, C8F, and dialysate |

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* on-cabinet module

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

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**Survey of Instruments**

August 2005

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CMYK Page 30
## Chemistry analyzers (for low-volume laboratories)

### Part 8 of 10

<table>
<thead>
<tr>
<th>Name of instrument/First year in U.S.</th>
<th>Ortho-Clinical Diagnostics</th>
<th>Randez Laboratories</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTS-8</td>
<td>$69,900</td>
<td>$40,000</td>
</tr>
<tr>
<td>DTS-9</td>
<td>$74,900</td>
<td>$39,900</td>
</tr>
<tr>
<td>DTS-10</td>
<td>$79,900</td>
<td>$40,000</td>
</tr>
</tbody>
</table>

### List price

- No. of units in clinical use in U.S.: 100
- No. of units sold worldwide: 1,000
- Country where designed: U.S.
- Where reagents marketed: Worldwide
- Operational type/Reagent type: Widespread
- Sample handling system/Model type: Half
- Dimensions in inches (H x W x D): 32 x 18.7 x 13.7

### Tests available on instrument in U.S.

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procalcitonin</td>
<td>Measures procalcitonin, a marker of infection</td>
</tr>
<tr>
<td>CK-MB</td>
<td>Measures CK-MB, a marker of myocardial damage</td>
</tr>
<tr>
<td>Ferritin</td>
<td>Measures ferritin, a marker of inflammation</td>
</tr>
<tr>
<td>Albumin</td>
<td>Measures albumin, a marker of liver function</td>
</tr>
<tr>
<td>AST</td>
<td>Measures AST, a marker of liver damage</td>
</tr>
<tr>
<td>ALT</td>
<td>Measures ALT, a marker of liver damage</td>
</tr>
<tr>
<td>MCV</td>
<td>Measures MCV, a marker of red cell size</td>
</tr>
<tr>
<td>RDW</td>
<td>Measures RDW, a marker of red cell variation</td>
</tr>
<tr>
<td>CRP</td>
<td>Measures CRP, a marker of inflammation</td>
</tr>
<tr>
<td>LDL</td>
<td>Measures LDL, a marker of cholesterol</td>
</tr>
<tr>
<td>HDL</td>
<td>Measures HDL, a marker of cholesterol</td>
</tr>
<tr>
<td>Triacylglycerols</td>
<td>Measures triacylglycerols, a marker of cholesterol</td>
</tr>
</tbody>
</table>

### Tests cleared but not clinically released

- Test for HIV-1/2, HBV, and HCV
- Test for Chlamydia trachomatis
- Test for Gonorrhea

### Tests not available in U.S. but available in other countries

- Test for Chagas disease
- Test for Lyme disease

### User-defined methods implemented for what analytes

- None

### Methods supported/Immunocassette methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Photometry</td>
<td>Measures photometrically, a marker of light</td>
</tr>
<tr>
<td>Enzymatic</td>
<td>Measures enzymatically, a marker of enzyme activity</td>
</tr>
</tbody>
</table>

### Bar code reading capability

- Yes

### Data entry, capability/Instrument vendor supplies LIS interface

<table>
<thead>
<tr>
<th>Function</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfur</td>
<td>Measures sulfur, a marker of metabolism</td>
</tr>
<tr>
<td>Sodium</td>
<td>Measures sodium, a marker of electrolyte balance</td>
</tr>
<tr>
<td>Potassium</td>
<td>Measures potassium, a marker of electrolyte balance</td>
</tr>
<tr>
<td>Calcium</td>
<td>Measures calcium, a marker of bone health</td>
</tr>
</tbody>
</table>

### Distinguishing features

- Disposable disposables allow for seamless integration with the analyzer |
- Rapid testing allows for quick results |
- Easy-to-use interface for user-friendly operation |

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**Tabulation does not represent an endorsement by the College of American Pathologists**
Chemistry analyzers (for low-volume laboratories)

Roche Diagnostics Corp.
Todt Akhirvonsen Minsk@roche.com

See accompanying article on page 20

Roche Diagnostics Corp.
Todt Akhirvonsen Minsk@roche.com

Name of instrument/First year sold in U.S.
Lab price
Units in clinical use in U.S./Outside U.S.
Country where designed/Manufactured/Where reagents infltd.
Operational type/Typical output
Sample handling system/Model type
Dimensions in inches (W x D x H)/Instrument footprint

Cobas Integra 400 Plus/1999
$175,000
2,600,000
42
Switzerland/Switzerland/U.S. & Germany
Continuous random access/self-contained multi-use cassettes
40 x 33 x 32 (W x D x H) in sq ft

Test results available on instrument in U.S.

## Chemistry analyzers (for low-volume labs)

<table>
<thead>
<tr>
<th>Name of instrument/first year sold in U.S.</th>
<th>Data Pro PLUS/2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>List price</td>
<td>$45,000</td>
</tr>
<tr>
<td>No. units in clinical use in U.S./outside U.S.</td>
<td>4/995</td>
</tr>
<tr>
<td>Country where designed/Manufactured</td>
<td>Argentina/Australia</td>
</tr>
<tr>
<td>Operational type/Reagent type</td>
<td>Batch, random access, discrete, continuous random access/liquid-based</td>
</tr>
<tr>
<td>Sample handling system/Model type</td>
<td>Multi-use cartridges/Package single, open reagent system</td>
</tr>
<tr>
<td>Dimensions in inches (W x H x D)</td>
<td>33.5 x 18.5 x 23.8/1.03 sq ft</td>
</tr>
<tr>
<td>Tests available on instrument in U.S.</td>
<td>Alb, alk, phos, cr, AST, ALT, Ca, chloride, chol, CK, CO2, crea, direct bilirubin, GOT, glucose (MO), HDL, ino, LDH, Mg, phosphorus, total bilirubin, total protein, triglycerides, uric acid</td>
</tr>
<tr>
<td>Tests cleared but not clinically released</td>
<td>—</td>
</tr>
<tr>
<td>Tests not available in U.S. but available in other countries</td>
<td>—</td>
</tr>
<tr>
<td>Research-use only assays/Tests in development</td>
<td>none</td>
</tr>
<tr>
<td>User-defined methods implemented for what analytes</td>
<td>none</td>
</tr>
</tbody>
</table>

### Methods supported/immunoassay methods/ids
- No. of direct ion selective electrode channels
  - Must-load separate req, pack for each specimen/No. of diff. assays in pack
  - Separate req. pack for each test run
- No. of different measured assays embdedd simultaneously
- No. of different assays programmed, calibrated at once
- No. of user-definable (open) channels/No. active simultaneously
- No. of different analytes for which system accommodates
  - resp. containers onboard at once/Tests per container set
  - Shortest/Med longest onboard reag. stability/refrigerated onboard
  - Multiple req. config. supported
- Resp. container placed directly on system for use
- Instrument has same capabilities when third-party req. used
- Resp. req. only cost per reportable result for standard chemistries/Tests
- Therapeutic drug/Special analytes
  - Walkway capacity in minutes/No. of specimens/No. of tests-assays
- System is liquid, dry, or reconstituted onboard
- Uses disposable cuvettes/Max. No. stored
- Uses washable cuvettes/Replacement frequency
- Minimum sample volume aspirated prior to one time
- Supplied with UPS (backup power)/Requires floor drain
- Requires dedicated water system/Water consumption in L per hour
- Noise generated in decibels
- Dedicated pediatric sample cap/Dead volume
- Primary tube sampling/Pediatric caps on primary tubes
- Sample bar-code reading capability/Autodiscrimination
  - Walkway capacity in minutes/No. of specimens/No. of tests-assays
  - System is liquid, dry, or reconstituted onboard
  - Uses disposable cuvettes/Max. No. stored
- Uses washable cuvettes/Replacement frequency
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### Specifications
- Start time to completion of all analytes, throughout per hr. for:
  - Sodium, potassium, chloride, TCO2
  - Sodium, potassium, chloride, TCO2
  - Sodium, potassium, chloride, TCO2
  - Sodium, potassium, chloride, TCO2
  - Sodium, potassium, chloride, TCO2
- Typical time delay from ordering stat test to aspirate of sample
- How often OC required/Onboard SR capability to review OC
- Onboard real-time GC/Support multiple OC with No. per analyze OC results transferred automatically to LIS
- Data report capability/instrument vendor supplies LIS interface
  - Interface updates and running in active user sites with
  - Bidirectional interface capabilities
  - Test results transmitted to LIS as soon as chem. time complete
  - LIS interface updates simultaneously with running assays
  - Uses LORC to transmit orders & results
  - How labs get LORC codes for reagent kits
- Lab control analyzer remotely
- Interface avail. (or will be) to automated specimen handling system
- Modern servicing available/Can diagnose own malfunctions/
- Determine malfunctioning component
  - On-site time of use, engineer/Onboard error codes for troubleshooting
  - Mean time between failures/Repair failures
  - Average time to complete maintenance by lab personnel
  - Onboard maintenance records/Maint. training demo module
  - Training provided with purchase/Advanced user. training avail.
  - Annual service contract cost (in $’s/yr)
- Distinctive features
  - open system; compact benchtop; user friendly Windows software

### Details
- Thermo Electron Corp
- John McCollom
- 330 S outh 10th St.
- Louisville, KY 40202
- 800-586-9115
- www.Thermo.com/clinlab/nhem

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