Anne Ford

When is a negative actually a plus? When it’s a negative predictive value, or NPV, that makes it possible for emergency medicine departments to exclude particular diagnoses. To that end, bioMérieux recently introduced the Vi-das D-Dimer Exclusion assay—a first-of-its-kind FDA-cleared D-dimer assay for the exclusion of deep vein thrombosis and pulmonary embolism in outpatients presenting to the emergency department,” says marketing manager Vence Turn-minello. “The Vidas D-Dimer Exclusion offers a 99.9 percent NPV.” For something negative, that sounds awfully positive.

The Vidas D-Dimer Exclusion is just one of many new assays for the immunoassay analyzers profiled in this month’s instrumentation survey. With at least 30 assays recently or soon to be launched—to say nothing of multiple new analyzers and a number of software upgrades—laboratories are presented with an abundance of riches.

Take the Binding Site. “We’ve greatly expanded our menu offering on the DX [analyzer] over the past year,” marketing manager Gary Tremain says. “We’ve added an automated anti-CGP and a Ciq bidirectional immunoassay complex assay, expanded our cancer disease panel with TgT IgG, and launched a whole new line of infectious disease markers,” such as those for mumps, Lyme disease, H. pylori, and syphilis. The Binding Site’s customer service team has also noted a tremendous increase in orders for updated software for the DXS analyzer. The software, Tremain says, “correlates many customer-requested features,” such as an improved continuous sample load feature, a new deep-well incubation feature, and greater ease of use.

Beckman Coulter’s list of forthcoming assays is similarly long. “We’re going to launch anywhere from seven to 10 new assays by the end of the year, including intact PT,” says Jim Rigo, global marketing manager for immunoassays. “That includes new tests for anemia, skeletal, cardiac, and more.” The new assay kits will include an assay for EPO and soluble transferrin receptor. Earlier this year, Beckman Coulter introduced a fast HTSH, an intrinsic factor, and an enhanced free T4 test, along with an enhanced test for folate and RBC folate. The company will also launch its new chemistry-Immunoassay system, the UniCel DxC 600, later this year.

Tosoh has the second-generation AIA-360 under development with the primary charge resulting in expanded test menu capabilities. H-patits B markers are in the final stages of optimization in the ST format and will be released as soon as they clear the regulatory process. With all Tosoh analyses, these assays will be available on Tosoh’s AIA platforms.

Nichols Institute Diagnostics recently added al-dosterone, Ht-CCG, IGF-I and IGFBP-3 with age and gender-specific reference ranges, and Tg with recovery to the menu of its Nichols Advantage Specialty System immunoassay analyzer.

And this summer, DiaSorin is planning to introduce three assays on its Liaison chemilumi-nescent system: EBV IgM, VCA IgG, and EBNA IgG. “These assays will complement our existing menu of 25-OH vitamin D and intact PT,” says product manager Mari Kelly. “The DiaSorin EBV assays will be the first automated EBV chemiluminescence assays on the U.S. market. The time to first result is only 35 minutes.

Rounding out the bunch are Hycor, which plans to continue to expand the product menu of its Hy-TeC 288 instrument to include infectious disease assays, and Randox, which, says U.S. business manager Stuart Manery, has “a wide range of assays currently in development, including expansion of routine parameters as well as more esoteric parameters like a maternal screening array, ovarioblastic array, and further applications for screening, diagnosis, and monitoring of various tumors.”

In addition to the scores of new assays, vendors are flaunting new instruments, such as Olympus America’s AU3000 automated immunoassay system. “We will begin placing the AU3000 at customer sites in Europe later this year, and we anticipate release in the States in early 2006,” says Bruce Germaey, director of marketing. “In the first year of launch, we’ll have a 20-test menu including thyroid, fertility, cardiac, and tumor markers. In 2007 we plan to add additional tumor markers, anemia, and infectious disease assays.”

The new instrument can also be used as a stand-alone analyzer or as part of a workcell with Olympus AU chemistry systems.

Visitors to the annual meeting of the American Association for Clinical Chemistry should keep an eye out for new assays and an expanded recording release of updated software for the Dxs analyzer. The software, Tremain says, “incorporates many customer-requested features,” such as an improved continuous sample load feature, a new deep-well incubation feature, and greater ease of use.

All that not enough for you? Awareness Technology has a chemiluminescent microwell reader in research and development; this year’s AACC attendees will be able to see a prototype. “With nine to 12 months, we also hope to have an eight-channel microplate reader released to market,” says sales manager Chris Schneider. Trinity Biotech marketing manager Marlene Jinks says studies now show that the company’s Nexgen Four instrument, which has dual independent robotic pipetting arms, “saves up to 45 minutes over traditional one-arm sequential microplate processing instruments for full-load runs.” And Diamex’s Parsec System, introduced at the 2004 AACC meeting, is on schedule for delivery in the second quarter of this year. The system, says marketing manager Linda Schwartz, is designed with modularity and flexibility: “Modularity provides the ability to simultaneously run different technologies such as EIA, chemiluminescence, IFA, and histopathology,” while “flexibility offers the ability to build the Parsec system to [the customer’s] specific needs.”

CAP TODAY’s survey of immunoassay analyzers includes products from the manufacturers named above and from Bio-Rad, Dade Behring, Grifols USA, Ortho-Clinical Diagnostics, and Roche Diagnostics. Vendors supplied the information listed in the tables. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities.

Anne Ford is a writer in Chicago.
Automated immunoassay analyzers

Part 1 of 22

Name of instrument/First year sold/Where designed

Country where manufactured/Where reagents manufactured

No. of units in clinical use in U.S./Available U.S. operational sites

Operational type/Model type/Sample handling system

Dimensions in inches (H x W x D)/Instrument footprint in square feet

Tests available on instrument in U.S.

Tests cleared but not clinically released

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

Tests not available on other manufacturers’ analyzers

Fully automated microplate system

No. of each analyte performed in separate disposable unit

No. of wells in microplate

Methods supported/Separation methods

No. of different measured analytes obtained simultaneously

No. of different assays programmed, calibrated at once

No. of user-definable (open) channels

No. of different analytes for which system accommodates reagents

Containers available at once/Tests per container set

Shortest/Median reagent stability/Refrigerated onboard

Multiple reagent configurations supported

Reagent container placed directly on system for use

Reagents bar coded/Information in bar code

Same capabilities when 3rd-party reagents used/Inexpensive to replace

Walkway capacity in minutes/Specimens/Tests-assay

System is open (house-brew methods can be used)/Liquid or dry system

Uses disposable cuvettes/Mix. No. stored

Uses washable cuvettes/Replacement frequency

Minimum specimen vol. required

Minimum sample vol. aspirated precisely at once/Min. dead vol.

Supplied with UPS (backup power)/ Requires fluid drain

Requires dedicated water system/Water consumption

Noise generated

Has dedicated pediatric sample cup/Dead vol.

Primary lab tubing/Tube sizes/Pieces cap on primary tubes

Sample bar code-reading capability/Automation/Identification

Bar-code placement per NCLCS standard AutoAnalyzer

Onboard test auto inventory (determines vol. in container)

Measures No. of tests remaining/Short sample detection

Auto detection of adequate reagent or specimen

Cot-detection/Reflex testing capability

Hemolysis detection-Quantification/Turbidity detection-Quantification

Obstruction of patient specimen/unacceptable reagent concentration

Sample vol. can be increased to run sub-linear range high results/

Increased to run out of linear range low results

Time between initial result & reanalysis of sample for rerun

Autoverification or autoalert confirmation

No. of calibrators required for each analyte

Calibrators can be stored onboard/livng, calibration frequency

Multipoint calibr. supported/Multipoint calibr. stored for same assay

How often Qc required

Onboard real-time QC/Support multiple QC lot Nos. per analyte

Automatic shutdown/Shutdown is programmable/Shutdown time

Start time to completion of 8-Hour test

Time delay from ordering stat test to aspir. of sample

Thoroughput per hr for these analytes on each specimen, in Nos. of specimens/Nos. of tests (cycle time)

Can auto transfer QC results to LIS/Onboard capability to review QC

Data management capability/instrument vendor supplies LIS interface interfaces up and running in active use

LIS interface operates simultaneously w/ running assays

Uses LONCIS to transmit order and results

How label get LONCIS codes for reagent kits

Biobidirectional interface capability

Results transmitted to LIS as soon as test time complete

Interface available (or will be) to auto specimen handling system

Modern servicing/Can diagnose own malfunction/Correct malfunctioning component

Contact (via phone [number] malfunctioning part)/w operator

On-site response time of service engineer

Mean time between failures/3 repair failures

Outbound error codes to facilitate troubleshooting

Avg. time to complete maintenance by lab personnel

Onboard maintenance records/Maintenance training demo module

List price/Targeted bed size or daily volume

Annual service contract cost (24 hours/7 days)

Training provided/w purchased/Advanced operator training

Distinguishing features (supplied by vendor)

Standards not represent an endorsement by the College of American Pathologists

Survey edition/Reynaud, MD

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Automated immunoassay analyzers

Part 2 of 2

Name of instrument/First-year sold/Where designed
Country where manufactured/Where reagents manufactured
Operational mode/Model type/Supplied handling system
Dimensions in inches (H x W x D)/Instrument footprint in square feet

Tests available on instrument in U.S.
Tests cleared but not clinically released
Tests not available in U.S. but submitted for clearance
Tests not available in U.S. but available in other countries

Research-use-only assays

User-defined methods implemented for what analytes

Fully automated microparticle system

Methods supported/Supporter methods
No. of different assays measured onboard simultaneously
No. of different assays programmed, calibrated at once
No. of user-definable (up) channels
No. of different analytes for which system acclimates reagent containers onboard at once/Tests per container set
Shortest/Median onboard reagent stabilization/Refrigerated onboard
Multiple reagent configurations supported
Reagent container placed directly on system for use
Reagents bar coded/information in barcode

System is open (open-source) configurations may be used/Liquid or dry system
Uses disposable cuvets/Max. No. stored
Uses washable cuvets/Replacement frequency

Minimum specimen vol. required

Sample storage/Removal schedule/Tests submitted per day

Auto detection of reagent expiration or specimen

Clot detection/Refrig testing capability

Calibration/Reagent stability testing

System is dependent/Reagents backed up by reagent kit

No. of calibrators required for each analyte

Calibrators can be stored onboard/Amb. calibration frequency

Multiplicities, supported/Compatible calibrators, stored for same assay

On-demand test

Start time to completion of NIG test

Data transfer/Does method test to asp. of sample

Throughput per hr for these analytes on each specimen, in No. of specimens/No. of tests (cycle time)

Can auto transfer QC results to LIS/Onboard/Needed to review QC

Data management capability/Instrument vendor supplies LIS interface

Interfaces up and running in active user sites with LIS Interface operant simultaneously w/ running assays

Uses LINC to transmit orders and results

Now have LINC codes for reagent kits

Bidirectional interface capability

Results transmitted to LIS as soon as test time complete

Auto interface available (or will be) for auto specimen handling system

Modern servicing/Can diagnose own malfunction and/or determine

Can order (via modem) manufacturing part(s) w/o operator

On-site response time of service engineer

Mean time between failures/To repair failures

Onboard error codes to facilitate troubleshooting

Avg. time to complete maintenance by lab personnel

Onboard maintenance records/Workmanship training demo module

List price/Tariff rate or daily volume

Annual service contract cost (24 hours/7 days)

Training provided w/ purchase/Advanced operator training

Distinguishing features (supplied by vendor)

Integration of IQC and IQC without compromising del TAT, results, or throughput, because of patented dual-light technology, which removes sample up to 10 ppm; large reagent capacity of 98 assays, with sample load up to 300, 38% efficiency provided via multiple patented technologies

ability to perform general biochemistry

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Tabulation errors

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### Automated immunoassay analyzers

#### Bayer HealthCare Diagnostic Division

- **Name of Instrument/First year sold/Where designed**
  - ADENA Contour/1990/US
  - ADENA Contour CP/immunoassay system/Available September 2009/US

- **Country where manufactured/Where manufactured/No. of units in clinical use in U.S./Outside U.S.**
  - FDA approved

- **Operational type/Model type/Sample handling system**
  - Tabulation

- **Dimensions in inches (H x W x D)/Instrument footprint in square foot**
  - 51.5 x 72.5 x 112.6 sq ft

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

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Method</th>
<th>Analyst</th>
<th>Analyte</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td>Chemical/immunoassay/magnetic particle</td>
<td>no/yes/5/100</td>
<td>yes/no/no</td>
</tr>
</tbody>
</table>

#### Tests cleared but not clinically released

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Method</th>
<th>Analyst</th>
<th>Analyte</th>
</tr>
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<tbody>
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<td>Specimen</td>
<td>Chemical/immunoassay/magnetic particle</td>
<td>no/yes/5/100</td>
<td>yes/no/no</td>
</tr>
</tbody>
</table>

#### Tests not available in U.S. but submitted for clearance

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Method</th>
<th>Analyst</th>
<th>Analyte</th>
</tr>
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<tbody>
<tr>
<td>Specimen</td>
<td>Chemical/immunoassay/magnetic particle</td>
<td>no/yes/5/100</td>
<td>yes/no/no</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Method</th>
<th>Analyst</th>
<th>Analyte</th>
</tr>
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<tbody>
<tr>
<td>Specimen</td>
<td>Chemical/immunoassay/magnetic particle</td>
<td>no/yes/5/100</td>
<td>yes/no/no</td>
</tr>
</tbody>
</table>

#### Research-use-only assays

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Method</th>
<th>Analyst</th>
<th>Analyte</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td>Chemical/immunoassay/magnetic particle</td>
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<td>yes/no/no</td>
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</tbody>
</table>

#### Tests in development

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Method</th>
<th>Analyst</th>
<th>Analyte</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td>Chemical/immunoassay/magnetic particle</td>
<td>no/yes/5/100</td>
<td>yes/no/no</td>
</tr>
</tbody>
</table>

#### Tests not available on other manufacturers’ analyzers

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Method</th>
<th>Analyst</th>
<th>Analyte</th>
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<tbody>
<tr>
<td>Specimen</td>
<td>Chemical/immunoassay/magnetic particle</td>
<td>no/yes/5/100</td>
<td>yes/no/no</td>
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</tbody>
</table>

### Fully automated microsystem

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Method</th>
<th>Analyst</th>
<th>Analyte</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td>Chemical/immunoassay/magnetic particle</td>
<td>no/yes/5/100</td>
<td>yes/no/no</td>
</tr>
</tbody>
</table>

### Methods supported/Selection methods

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Method</th>
<th>Analyst</th>
<th>Analyte</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td>Chemical/immunoassay/magnetic particle</td>
<td>no/yes/5/100</td>
<td>yes/no/no</td>
</tr>
</tbody>
</table>

### List price/Targeted bed size or daily volume

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Method</th>
<th>Analyst</th>
<th>Analyte</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen</td>
<td>Chemical/immunoassay/magnetic particle</td>
<td>no/yes/5/100</td>
<td>yes/no/no</td>
</tr>
</tbody>
</table>

**Table data does not represent an endorsement by the College of American Pathologists.**
Automated immunoassay analyzers

Part 4 of 22

Tableau de bord

Name of instrument/First year sold/Where designed
Country where manufactured/Where reagents manufactured
No. of units in clinical use in U.S./Outside U.S. (Operational type/Model type/Sample handling system
Dimensions in inches (w x h x D)/Instrument footprint in square feet
Tests available on instrument in U.S.
Tests cleared but not clinically released
Tests not available in U.S. but submitted for clearance
Tests not available in U.S. but available in other countries
Research-use-only assays
Tests in development
User-defined methods implemented for what analytes
Tests not available on other manufacturers’ analyzers
Fully automated microparticle system
No. of each analyzer performed in separate disposable unit
No. of wells in microparticle system
Methods supported/Seperation methods
No. of different measured assays onboard simultaneously
No. of assays programmed, calibrated at once
No. of user-definable (span) channels
No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set
Shortest/Medians on board reagent stability/Refrigerated onboard
Multiple reagent configurations supported
Reagent container placed directly on system for use
Reagents barcode information in bar code
Same capabilities when 3rd-party reagents used/Suitability to carryover
Walkway capacity in minutes/Specimen/Tests assays
System in open (benchtop methods can be used) or closed or dry system
Uses disposable cuvets/Max. No. stored
Uses washable cuvets/Replacement frequency
Minimum specimen vol. required
Minimum sample vol. aspirated proximately at once/Med. vol.
Supplied with UPS (backup power)/Requires frequent drain
Requires dedicated water system/Water consumption
Noise generated
Not dedicated pediatric sample cup/Dual vol.
Primary sample tubes/Tube sizes/Pipet cups on primary tubes
Sample barcode reading capability/Autocoding/Carbonation
Bar-code placement under NCSL standard AutoCal
Onboard test auto inventory (determines vol. in container)
Measure No. of tests remaining/Start sample detection
Auto detection of adequate reagent or specimen
Clot detection/rejection testing capability
Hemolysis detection-quantification/Turbidity detection-quantification
Dilution of patient samples onboard/Automatic dilution run levels
Sample vol. can be increased to rerun out-of-liner range high results
Increased to rerun out-of-line range low results
Time between initial result & reinspection of sample for rerun
Auto cancellation or auto-cancellation alert
No. of calibrators run/day, aimed for each analyzer
Calibrators can be stored onboard/Avg. calibration frequency
Multipoint calls, supported/Multiple calls, stored for same assay
How often QC required
Onboard real-time QC/Support multiple QC lots, per analyzer
Automatic shutdown/Startup is programmable/Start-up time
Stat time to completion of A032 test
Time delay from ordering start to asp. of sample
Throughput per day for these analytes on
each species, in No. of specimens/No. of tests (cycle time)
Can auto transfer QC results to LIS/Onboard capability to review QC
Data management capability/Instrument vendor supplies LIS interface
Interfacing systems and running in active user sites
LIS interface operates simultaneously w/running assays
Uses LONIC to transmit orders and results
How labs get LONIC codes for rerun kits
Bidirectional interface capability
Results transmitted to LIS as soon as test time complete
Interface available (or will be) to auto specimen handling system
Modern servicing/Can diagnose own malfunctions/Definite malfunctioning component
Can order (via modem) malfunctioning parts/w/o operator
On-site response time of service engineer
Mean time between failures/To repair failures
Onboard error codes to facilitate troubleshooting
Avg. time to complete maintenance by lab personnel
Onboard maintenance records/Maintenance training demo module
List price/Tariffed border or daily volume
Annual sales contracted cost (24-hours/7 days)
Training provided w/ purchase/Advanced operator training
Distinguishing features (supplied by vendor)
ability to network to up to four Access 2s using a single LIS interface with remote disposability.
Fully automated user-defined retrofit tooling, onboard computer sensitive
help, interface tube capability, continuous random access buffer analyzers, data-100 art sample handling system, software suite: TSB, FPA, HGB, HCT, WBC, RBC

Tabulation not produced by an endorsement from the College of American Pathologists

June 2005

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Automated immunoassay analyzers

### Name of Instrument/First year of release/Where designed

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Year</th>
<th>Manufacturer</th>
<th>Location</th>
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<tbody>
<tr>
<td>Beckman</td>
<td>2004</td>
<td>Beckman Coulter Inc.</td>
<td>California</td>
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<tr>
<td>UH-100</td>
<td>2005</td>
<td>Beckman Coulter Inc.</td>
<td>France</td>
</tr>
</tbody>
</table>

### Country where manufactured/Where reagents manufactured

<table>
<thead>
<tr>
<th>Country</th>
<th>Reagents Manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Operational type/Model type/Sample Handling system

- **Operational type**: Microplate
- **Model type**: Synchron
- **Sample Handling system**: Yes

### Instrument footprint in square feet

- **Synchron LX 715/2000/U.S.**: 65 ft²
- **UH-100/U.S.**: 50 ft²

### Tests Available on Instrument in U.S.

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Method</th>
<th>Reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC, TS, T4, TSH, proINS, FTA, FIS, JGOC, DME-A, proINS, LIV, proINS</td>
<td>Lateral flow assay</td>
<td>Yes</td>
</tr>
<tr>
<td>Proinsulin, estradiol, FSH, free, intrinsic factor antibody, AK, HGV, proINS, corticotropin</td>
<td>Lateral flow assay</td>
<td>Yes</td>
</tr>
<tr>
<td>Antigenemia, calibrators, reagents, DPO-open nucleotide detect, total IgG, dimer, IgG</td>
<td>Lateral flow assay</td>
<td>Yes</td>
</tr>
<tr>
<td>CEA, T4, T3, TSH, proINS, TMA, FIS, JGOC, DME-A, proINS, LIV, proINS</td>
<td>Lateral flow assay</td>
<td>Yes</td>
</tr>
<tr>
<td>Proinsulin, estradiol, FSH, free, intrinsic factor antibody, AK, HGV, proINS, corticotropin</td>
<td>Lateral flow assay</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Tests Cleared but not clinically released

- **CTA, T4, T3, TSH, proINS, FTA, FIS, JGOC, DME-A, proINS, LIV, proINS**
- **Proinsulin, estradiol, FSH, free, intrinsic factor antibody, AK, HGV, proINS, corticotropin**

### Tests Not Available in U.S. but submitted for clearance

- **CTA, T4, T3, TSH, proINS, FTA, FIS, JGOC, DME-A, proINS, LIV, proINS**
- **Proinsulin, estradiol, FSH, free, intrinsic factor antibody, AK, HGV, proINS, corticotropin**

### Tests Not Available in U.S. but available in other countries

- **CTA, T4, T3, TSH, proINS, FTA, FIS, JGOC, DME-A, proINS, LIV, proINS**
- **Proinsulin, estradiol, FSH, free, intrinsic factor antibody, AK, HGV, proINS, corticotropin**

### Research-use only assays

- **CEA, T4, T3, TSH, proINS, FTA, FIS, JGOC, DME-A, proINS, LIV, proINS**
- **Proinsulin, estradiol, FSH, free, intrinsic factor antibody, AK, HGV, proINS, corticotropin**

### Fields of instrument

- **Automation**: Yes
- **Microplate**: Yes
- **Specimen**: Yes
- **Container**: Yes
- **Warranty**: Yes

### Methods supported/Seperation methods

- **Methods**: Lateral flow assay
- **Separation methods**: Yes

### Fully automated microplate system

- **No. of analyzes**: 5
- **No. of wells in microplate**: 8

### List price/Targeted bed size or daily volume

- **List price**: $25,500
- **Targeted bed size or daily volume**: 200

### Distinctive features (supplied by vendor)

- **Lateral flow assay**: 8
- **specimen**: Yes

### Technical support available

- **Customer support**: Yes
- **Technical support**: Yes

### Additional information

- **Technical support**: Yes
- **Customer support**: Yes

---

### Table of instruments

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Year</th>
<th>Manufacturer</th>
<th>Location</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>UH-100/U.S.</td>
<td>2005</td>
<td>Beckman Coulter Inc.</td>
<td>France</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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### Summary

- The Synchron LX 715/2000/U.S. is a fully automated immunoassay analyzer designed for use in laboratories where high throughput and efficiency are required.
- The UH-100 is a similar instrument designed for use in France.
- Both instruments are capable of performing a wide range of tests, including those related to hormone levels and inflammatory markers.
- They are equipped with features such as lateral flow assay and lateral flow detection, allowing for rapid and accurate results.

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### Contact Information

- Beckman Coulter Inc.
  - 2011 S. Kramer Blvd.
  - 94038
  - 714-865-0229
  - www.beckmancoulter.com

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### Additional Resources

- For more information, please visit [Beckman Coulter’s website](http://www.beckmancoulter.com).
- Contact: [Customer Support](mailto:customer.support@beckman.com)
Automated immunoassay analyzers

**Part 62 of 22**

**See accompanying article on page 13**

**Name of instrument/First year sold/Where designed**

DxI Automated System/2000/雎纽纽，E.K.

**Country where manufactured/Where reagents manufactured**

U.S., E.K.

**Operational type/Model type/Selected handpiece system**

–selsalata

**Dimensions in inches (H x W x D) instrument footprint in square feet**

32 x 42 x 30 sq ft

**List price/Targeted size or daily volume**

$46,000 (dependent on modular/200)+ beds
3 days on site, 2 days at vendor offices

**Distinguishing features (supplied by vendor)**

1. Fully open, true four-plate system, modular design of reader, washer, incubators, bar-code reader and automatic drawer results ready easy upgrades and express shipping of replacement modules reducing downtime; software can be trained for learned error recovery

**Additional automated/Manual system capabilities**

Research-use-only assays

Tests in development

–J

**Available on other manufacturers’ analyzers**

–J

**Tests available on all manufacturers’ analyzers**

–J

**Research-use-only assays**

–J

**Tests in development**

–J

**Available on other manufacturers’ analyzers**

–J

**Fully automated microplate**

–J

**No. of each analyte performed in separate disposable unit/No. of wells in microplate**

–J

**Methods supported/Separation methods**

–J

**No. of different measured assays onboard simultaneously/No. of different assays programmed, calibrated at once**

–J

**No. of user-definable (open) channels**

–J

**No. of different analytes for which system accommodates reagent contains onboard at once/Tests per container set**

–J

**Short/Long/Medium onboard reagent stability/Refrigerated temperature/ Multiple reagent configurations supported**

–J

**Reagent container placed directly on system for use/Reagents bar coded/information in bar code**

–J

**Same capabilities when 3rd-party reagents used/Susceptibility to carryover**

–J

**Walkaway capacity in minutes/Specimens/Tests assays**

–J

**System is open (home-brew methods can be used)/Liquid or dry system**

–J

**Uses disposable cuvette/No. stored**

–J

**Uses washable cuvette/Replacement frequency**

–J

**Minimum sample vol. required**

–J

**Sample vol. aspirated precisely at once/Min. vol. dead vol.**

–J

**Supplied with UPS (backup power)/Requires flush drain**

–J

**Requires dedicated water system/Water consumption**

–J

**Noise**

–J

**Non dedicated pediatric: sample cup/Dead vol.**

–J

**Primary tube sampling/Tube sizes/Percaps cans on primary tubes**

–J

**Sample bar-code reading capability/Autodilution/Autosampling**

–J

**Bar-code placement per NCCLS standard AutoSA**

–J

**Onboard test auto inventory (determined vol. in container)**

–J

**Measure no. of tests remaining/Short sample detection**

–J

**Auto detection of adequate reagent or specimen**

–J

**Clot detection/Reflux testing capability**

–J

**Hemolysis detection-quantitation/Turbidity detection-quantitation**

–J

**Shut-off of patient samples onboard/Automatic re-run capability**

–J

**Sample vol. can be increased to run out-of-range high results/ Increased to run out-of-range low results**

–J

**Time between initial result & remanifestation of sample for rerun**

–J

**Auto reanalysis or isobaric detection start**

–J

**No of calibrators required for each analyzer**

–J

**Calibrators can be stored onboard/Calibrating frequency**

–J

**Multiple calibrators, supported/Multiple calibrators, stored for same sample**

–J

**How often QC required**

–J

**Onboard real-time QC/Support multiple QC lot Nos. per analyzer**

–J

**Automatic shutdown/Start-up is programmable/Start-up time**

–J

**Stat time to completion of 8-HCG test**

–J

**Time delay from ordering start to use at sample**

–J

**Throughput per for 4 samples analyses on each specimen, In no. of specimens/No. of tests (cycle time**

–J

**Can auto transfer QC results to LIS/Onboard capability to review QC**

–J

**Data management capability/instrument vendor supplies LIS interface**

–J

**Interfacing software and running in active user sites with**

–J

**LIS interface operates simultaneously w/ running assays**

–J

**Uses LINEQ to transmit orders and results**

–J

**How/why get LINEQ codes for reagent kits**

–J

**Bidirectional interface capability**

–J

**Transmission realized to LIS as soon as test time complete**

–J

**Interface capability (or will be) to auto specimen handling system**

–J

**Modern services/Can diagnose own malfunction/Define malfunctioning component**

–J

**Can order (via modem) malfunctioning parts w/o operator**

–J

**On-site response time of service engineer**

–J

**Mean time between Failures/To repair failures**

–J

**Onboard error codes to facilitate troubleshooting**

–J

**Avg. time to complete maintenance by lab personnel**

–J

**Onboard maintenance records/Maintenance training demo module**

–J

**List price/Targeted bed size or daily volume**

$46,000 (dependent on modular/200)+ beds
3 days on site, 2 days at vendor offices

**Distinguishing features (supplied by vendor)**

Fully open, true four-plate system, modular design of reader, washer, incubators, bar-code reader and automatic drawer results ready easy upgrades and express shipping of replacement modules reducing downtime; software can be trained for learned error recovery

**Training provided w/ purchase/Advanced operator training**

$2,200–3,700 (includes travel)

**As needed on site, 3 days at vendor offices/offers**

**Distinguishing features (supplied by vendor)**

Fully open, true four-plate system, modular design of reader, washer, incubators, bar-code reader and automatic drawer results ready easy upgrades and express shipping of replacement modules reducing downtime; software can be trained for learned error recovery

**Unique dual-function combination solid phase & plating device (DD): assay

unique dual-function combination solid phase & plating device (DD): assay

**Value in customers: U.S. 

Italy/France

$2,200–6,800

$19–32 x 21 in. 

$15–10 x 17 in. 

$4–9 sq ft
Tabulation of instruments

<table>
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<th>Survey of Instruments</th>
<th>Automated immunoassay analyzers</th>
</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>See accompanying article on page 18</td>
<td>Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Dr. Hercules, CA 94547 510-724-7000 <a href="http://www.bio-rad.com">www.bio-rad.com</a></td>
</tr>
<tr>
<td><strong>Name of instrument/First year sold/Where designed</strong></td>
<td>Bio-Rad Laboratories Clinical Diagnostics Group 4000 Alfred Nobel Dr. Hercules, CA 94547 510-724-7000 <a href="http://www.bio-rad.com">www.bio-rad.com</a></td>
</tr>
<tr>
<td>Country where manufactured/Where reagents manufactured</td>
<td>Country where manufactured/Where reagents manufactured</td>
</tr>
<tr>
<td>No. of units in clinical use in U.S./Outside U.S.</td>
<td>No. of units in clinical use in U.S./Outside U.S.</td>
</tr>
<tr>
<td>Operational model/Type/Sample handling system</td>
<td>Operational model/Type/Sample handling system</td>
</tr>
<tr>
<td>Dimensions in inches (H x W x D)/Instrument footprint in square foot</td>
<td>Dimensions in inches (H x W x D)/Instrument footprint in square foot</td>
</tr>
<tr>
<td><strong>Tests available on instrument in U.S.</strong></td>
<td>Contact: Bio-Rad representative</td>
</tr>
<tr>
<td><strong>Tests cleared but not clinically released</strong></td>
<td>Contact: Bio-Rad representative</td>
</tr>
<tr>
<td><strong>Tests not available in U.S. but submitted for clearance</strong></td>
<td>—</td>
</tr>
<tr>
<td><strong>Tests not available in U.S. but available in other countries</strong></td>
<td>Biodata, brucine, HT, TSH, PPD, T4, TSH, 170BP</td>
</tr>
<tr>
<td><strong>Research-use-only assays</strong></td>
<td>—</td>
</tr>
<tr>
<td><strong>Tests in development</strong></td>
<td>—</td>
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<tr>
<td><strong>Tests defined as methods implemented for what analyses</strong></td>
<td>—</td>
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<tr>
<td><strong>Tests not available on manufacturers’ analyzers</strong></td>
<td>—</td>
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<tr>
<td><strong>Fully automated microplate system</strong></td>
<td>Yes</td>
</tr>
<tr>
<td>No. of each analyte performed in separate disposable unit</td>
<td>Yes</td>
</tr>
<tr>
<td>No. of wells in microplate</td>
<td>480</td>
</tr>
<tr>
<td><strong>Methods supported/separation methods</strong></td>
<td>Nor/ml/second/diluent/ml</td>
</tr>
<tr>
<td>No. of different assays onboard simultaneously</td>
<td>Nor/ml/second/diluent/ml</td>
</tr>
<tr>
<td>No. of different assays programmed, calibrated at once</td>
<td>Nor/ml/second/diluent/ml</td>
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<tr>
<td>No. of different analyses for which system accommodates reagent containers onboard at user/Tasks per container set</td>
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<td>Nor/ml/second/diluent/ml</td>
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<td>Reagent container placed directly on system for use</td>
<td>Nor/ml/second/diluent/ml</td>
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<td>Nor/ml/second/diluent/ml</td>
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<td>Same capabilities when 3rd-party reagents used/Usability to carryover Wkbasa no software version 4.0 &amp; updated firmware, depends on amount of usability</td>
<td>Nor/ml/second/diluent/ml</td>
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<td>Requires dedicated water system/Water consumption</td>
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<td>No. of calibrators required for each analyte</td>
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<td>Stat time to completion of 0-100 test</td>
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<td>Throughput per hr for these analytes on</td>
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<td><strong>each specimen, in No. specimens/No. tests (cycle time</strong></td>
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<td>Data management capability/instrument vendor supplies LIS interface</td>
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<td>Interfaces up and running in active user sites</td>
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<td>LIS interface operates simultaneously w/ running assays</td>
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<td>Uses LONIC to transmit orders and results</td>
<td>Uses LONIC to transmit orders and results</td>
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<tr>
<td>How labs get LONIC codes for renum kits</td>
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<td><strong>Biodiagnostic interface capability</strong></td>
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<td>Results transmitted to LIS as soon as test time complete</td>
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<tr>
<td>Interface available or will be to auto specimen handling system</td>
<td>Interface available or will be to auto specimen handling system</td>
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<tr>
<td>**Medications/Gen diagnosis own malfunctions/Determine **</td>
<td>**Medications/Gen diagnosis own malfunctions/Determine **</td>
</tr>
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<td>—multifunctioning component</td>
<td>—multifunctioning component</td>
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<tr>
<td>Can order (via modem) multifunctioning part(s) w/ operator</td>
<td>Can order (via modem) multifunctioning part(s) w/ operator</td>
</tr>
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<td>On-site response time of service engineer</td>
<td>On-site response time of service engineer</td>
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<td>Mean time between failures/To repair failures</td>
<td>Mean time between failures/To repair failures</td>
</tr>
<tr>
<td>Onboard error codes to facilitate troubleshooting</td>
<td>Onboard error codes to facilitate troubleshooting</td>
</tr>
<tr>
<td>Avg. time to complete maintenance by lab personnel</td>
<td>Avg. time to complete maintenance by lab personnel</td>
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<tr>
<td>Onboard maintenance records/Maintenance training demo module</td>
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<td><strong>Lot price/Targeted bed size or daily volume</strong></td>
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<td>Annual service contract cost (24-hours/7 days)</td>
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<tr>
<td>Training provided w/ purchase/Advanced operator training</td>
<td>Training provided w/ purchase/Advanced operator training</td>
</tr>
<tr>
<td><strong>Distinguishing features (supplied by vendor)</strong></td>
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</tr>
<tr>
<td>Code 4-6 adds powerful, new fluid controls, dilution capabilities, audible alarms, and new wash parameters; able to perform pretreatment of sample (pipettes, transfer, transfer to cooled well); five methods for creating sample dilution, easy-to-operate programming accurate pipetting at 1 µl; connection of 1-10 pipetting stations together through an ethernet hub, graphical user interface; added modules for patient data processing</td>
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</tr>
</tbody>
</table>
Automated immunoassay analyzers

<table>
<thead>
<tr>
<th>Part 8 of 22</th>
<th>Bio-Rad Laboratories Clinical Diagnostics Group</th>
<th>Dade Behring Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>4800 Alfred Nobel Dr.</td>
<td>P.O. Box 4011</td>
<td></td>
</tr>
<tr>
<td>Norcross, GA 30092</td>
<td>Newark, DE 19714-0101</td>
<td></td>
</tr>
<tr>
<td>510-724-7300</td>
<td>800-342-0233</td>
<td></td>
</tr>
<tr>
<td><a href="http://www.bio-rad.com">www.bio-rad.com</a></td>
<td><a href="http://www.dabehering.com">www.dabehering.com</a></td>
<td></td>
</tr>
</tbody>
</table>

**Name of instrument/First year sold/Where designed**

- Envisio® Germany
- GERMANY
- Germany
- 10/2006
-多个国家
- 10.4 x 4 x 30 in (10 x 4 x 10 in)

**Tests available on instrument in U.S.**
- Contact Bio-Rad representative
- Mass CK-MB, tropon I, myoglobin, B-2GGL, D-dimter, NT-proBNP

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

**Tests not available in U.S. but submitted for clearance**
- —
- —

**Tests not available in U.S. but available in other countries**
- HAV, HVB, HIV Ag, HCV Ag, HBE Ag, HBE Ab, HTLV I, anti-HBs, total IgG, total IgM, rubella IgG, EIEV VCA IgG, EIEV VCA IgM, EIEB VCA EIEB, EIEB, cytomegalovirus total Ab, CMV total Ab

**Research-use-only assays**
- Not in U.S.

**Tests in development**
- Infection disease & autoimmune panels
- User-defined methods implemented for what analytes
- Tests not available on other manufacturer’s analyzers

**Folly automated microplate system**
- Yes
- Yes

**Methods supported/Seperation methods**
- No. of different measured assays onboard simultaneously
- No. of different assays programmed, calibrated at once
- No. of different calibrants programmed
- No. of different analytes for which system accommodates reagent
- Containers onboard at one time/Tests per container set
- Shortest/Median onboard reagent stability/Refrigerated onboard
- Multiple reagent configurations supported
- Reagent container placed directly on system for use
- Reagents bar coded/information in bar code
- Same capability when 3rd-party reagents used/Incorporability onboard
- Walkaway capacity in minutes/Specimens/Tests assays

**System is open (home-brew methods can be used) Liquid or dry system**
- Yes
- Yes

**Units disposable cuvettes/Max. No. stored**
- —
- —

**Units washable cuvettes/Replacement frequency**
- —
- —

**Minimum specimen vol. required**
- 0.2 µL
- 1 µL

**Minimum sample vol. aspirated precisely at once/Min. dead vol.**
- 10 µL/100 µL
- 200 µL

**Supplied with UPS (backup power) /Required fluor dye**
- Yes
- —

**Required dedicated water system/Water consumption**
- —
- —

**Noise generated**
- 60 decibels
- <66 decibels

**Has dedicated pediatric sample cup/Dead vol.**
- —
- —

**Primary tube sample/Tube sizes/Pieces can primary tubes**
- Yes/C, 10 mi/100 mi
- Yes

**Sample bar-coding capability/Auto/describe/verify**
- Yes
- Yes

**Bar-code placement per NCLL standard Auto**
- Yes
- Yes

**Onboard test auto inventory (determines vol in container)**
- —
- —

**Measurers No. of tests remaining/Short sample detection**
- —
- —

**Auto detection of adequate reagent or specimen**
- —
- —

**Clot detection/Reflex testing capability**
- —
- —

**Hemolytic detection-quantitation/Turbidity detection-quantitation**
- —
- —

**Dilution of patient samples onboard/Automated sample re-run**
- —
- —

**Sample vol. can be increased to rerun out-of-range high results/ Increased to rerun out-of-range low results**
- No
- —

**Time between initial result & resampling of sample rerun**
- —
- —

**Auto-verification or auto-calibration alert**
- —
- —

**No. of calibrators required for each analyte**
- —
- —

**Calibrators can be stored onboard/day, calibration frequency**
- —
- —

**Multiplex cards supported/Multiplex cards, stored for same assay**
- —
- —

**How often does QC required**
- —
- —

**Onboard-real-time QC/Support multiple QC lot Nos. per analyte**
- Yes (yes through linked QC program)
- —

**Automatic shutdown/startup is programmable/Startup time**
- —
- —

**Start time to completion of 8-HGS test**
- 14 min
- 16 min

**Time delay from ordering stat test to aspir of sample**
- n/a
- n/a

**Throughput/hr for these analytes on**
- each specimen, in No. of specimens, of tests (cycle time)
- —
- —

**Can auto transfer QC results to LIS/Onboard capability to review QC**
- —
- —

**Data management capability/instrument vendor supplies LIS interface**
- —
- —

**Interfaces up and running in active user sites with**
- LIS interface operations simultaneously running assays
- —
- —

**Lots UMC to transmit orders and results**
- —
- —

**How labeLs get LOMC codes for reagent kits**
- n/a
- n/a

**Bidirectional interface capability**
- —
- —

**Results transmitted to LIS as soon as test time complete**
- —
- —

**Interface available for win to win to auto specimen handling system**
- —
- —

**Moderate servicing/Can diagnose own failures/Determine malfunctioning component**
- —
- —

**Can order (via modem) malfunctioning part(s)/w/o operator**
- —
- —

**On-site response time of service engineer**
- 24 hr
- 24 hr

**Mean time between failures/Time repair failures**
- —
- —

**Onboard error codes to facilitate troubleshooting**
- —
- —

**Avg. time to complete maintenance by lab personnel**
- 5 min; weekly; 10 min; monthly; 30 min
- 5 min; weekly; 10 min; monthly; 10 min

**Onboard maintenance records/Maintenance training demo mode**
- —
- —

**List price/Targeted bed size or daily volume**
- $65,600–$5,000
- 100 beds

**Annual service contract cost (24 hours/7 days)**
- $45,000/yr
- 3 days to Redmond, Wash, No

**Training provided with purchase/Advanced operator training**
- —
- —

**Distinguishing features (supplied by vendor)**
- Fully automated microplate system that meets the highest level of safety (positive identification of samples, reagents, microplates; clot detection, or contaminations; flexibility of transfering loading of samples, reagents, and microplates; and productivity [four plates, 100 samples, four different assays can be processed simultaneously])
- whole blood collection tubes (hemorhage or centrifuged plasma [hemorhage]), onboard centrifugation: ultra-low test packs; color-coded calibrators packaged on Cepacil plastic packs for electrics, self-contained system (no waste bins, water, etc.), closed container sampling, electronic QC; POC-7-A compliant when interfaced to Therion or MAG Data Managers

Subclass data does not represent an endorsement by the College of American Pathologists

CMYK Page 33
## Automated immunoassay analyzers

**Part 9 of 22**

**Name of instrument/First year sold/Where designed**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>First Year Sold</th>
<th>Where Designed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensional Flow Integrated Chemistry System</td>
<td>2001/69</td>
<td>U.S.</td>
</tr>
</tbody>
</table>

**Country where manufactured/Where reagents manufactured**

<table>
<thead>
<tr>
<th>Country</th>
<th>U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensional Flow Integrated Chemistry System</td>
<td>U.S.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Operational type/Model type/Sample handling system</th>
<th>Dimensional Flow Integrated Chemistry System</th>
<th>U.S.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Dimensions in inches by W x H x Depth in square feet</th>
<th>Dimensional Flow Integrated Chemistry System</th>
<th>U.S.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Tests available on instrument in U.S.</th>
<th>Dimensional Flow Integrated Chemistry System</th>
<th>U.S.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Throughput</th>
<th>Dimensional Flow Integrated Chemistry System</th>
<th>U.S.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Evaluation of tests</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

**Tests cleared but not clinically released**

<table>
<thead>
<tr>
<th>Tests not available in U.S.</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

**Tests not available in U.S. but submitted for clearance**

<table>
<thead>
<tr>
<th>Tests not available in U.S. but available in other countries</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

**Tests in development**

<table>
<thead>
<tr>
<th>User-defined methods implemented for what analytes</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

**Tests not available on other manufacturers’ analyzers**

<table>
<thead>
<tr>
<th>System performs homogeneous immunoassays and general assays on single-platform</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

**Fully automated microplate system**

<table>
<thead>
<tr>
<th>No. of analyte performed in separate disposable unit</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of wells in microplate</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

### Methods supported/SEP methods

<table>
<thead>
<tr>
<th>Methods supported/SEP methods</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of different assays onboard simultaneously</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of different assays programmed, calibrated at once</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of user-selectable assay channels</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

### Tests cleared but not clinically released

<table>
<thead>
<tr>
<th>Tests not available in U.S. but submitted for clearance</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Tests not available in U.S. but available in other countries</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

### Tests in development

<table>
<thead>
<tr>
<th>User-defined methods implemented for what analytes</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

**Tests not available on other manufacturers’ analyzers**

<table>
<thead>
<tr>
<th>System performs homogeneous immunoassays and general assays on single-platform</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

**Fully automated microplate system**

<table>
<thead>
<tr>
<th>No. of analyte performed in separate disposable unit</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of wells in microplate</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

### Methods supported/SEP methods

<table>
<thead>
<tr>
<th>Methods supported/SEP methods</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of different assays onboard simultaneously</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of different assays programmed, calibrated at once</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of user-selectable assay channels</th>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

**Benchmark test(s)**

<table>
<thead>
<tr>
<th>Benchmark test(s)</th>
<th>Benchmark test(s)</th>
</tr>
</thead>
</table>

See [Dade Behring](http://www.dadebehring.com) for more information on MP Biomedicals, circle No. 84 on card.
Automated immunoassay analyzers

Name of instrument/First year sold/Where designed
Country where manufactured/Where manufactured/Manufacturer/
Name of site in clinical use in U.S./Outside U.S. Operational type/Model type/Sampling system
Dimensions in inches (W x H x D)/Instrument footprint in square feet

Tests available on instrument in U.S.

Tests cleared but not clinically released
Tests not available in U.S. but submitted for clearance
Tests not available in U.S. but available in other countries

Research-use-only assays
Tests in development

User-defined methods implemented for what analytes

Tests not available on other manufacturers’ analyzers

Fully automated microplate system
No. of each analyte performed in separate disposable unit
No. of wells in microplate

Methods supported/Separation methods
No. of different measured assays onboard simultaneously
No. of different assays programmed, calibrated, at one time
No. of user-definable (open) channels
No. of different analytes for which system accommodates reagent containers onboard at one time/Tests per container set

Shortest/Median onboard reagent stability/refrigerated onboard
Multiple reagent configurations supported
Reagent container placed directly on system for use
Reagents bar coded/information in barcode

Same capabilities when 3rd-party reagents used/Scannability to computer
Walkaway capacity in minutes/Specimens/Tests-assay
System is open (home-brew methods can be used)/Liquid or dry system

Uses disposable containers/Misc. No. stored

Uses washable containers/Replacement frequency

Minimum specimen vol. required
Minimum sample vol. aspirated precisely at once/Min. dead vol.
Supplied with UPS (backup power)/Requires floor drain
Requires dedicated water system/Water consumption

Noise generated

Has dedicated pediatric sample cup/Dead vol.
Primary tube sampling/Tube sizes/Pierces caps on primary tubes
Sample bar-code reading capability/Barcode discrimination
Bar-code placement per NCCLS standard/Auto ID

Onboard test auto inventory (determines vol. in container)
Measures No. of tests remaining/Short sample detection
Auto detection of adequate reagent or specimen
Cost detection/Approx. testing capability

Hemolysis detection-quantitation/Turbidity detection-quantitation
Dilution of patient samples onboard/Minimum reagent volume
Sample vol. can be run in run-of-line fashion/Minimum volume of plate used for run
Time between initial result & reanalysis of sample for run

Autocalibration or autocalibration alert

No. of calibrators required for each analyte
Calibrators can be stored onboard/aging, calibration frequency
Multiple calibr. supported/Multiple calibr. stored for same assay

How often QC required

Onboard real-time QC/Support multiple QC lot Nos., per analyte

Automatic shutdown/Startup is programmable/Startup time

Start time to completion of 8-12 test(s)
Time delay from ordering test to aspir. of sample
Througput per hr for three analytes on each specimen, in Nos. of specimens/Tests of cycle time
Can auto transfer QC results to LIS/Onboard QC/Output to review QC

Data management capability/Instrument vendor supplies LIS interface
Interfaces up and running in active use with
LIS interface operates simultaneously w/ running assays
Uses LYNX to transmit orders and results
How label get LYNX codes for reagent kits

Bidirectional interface capability
Results transmitted to LIS as soon as test time complete
Interface available (or not) to auto specimen handling system

Weekly service/Can diagnose own malfunction/Determine malfunctioning component
Can order (via random) malfunctioning parts w/o operator
On-site response time of service engineer
Mean time between failures/TV repair failures
Onboard error codes to facilitate troubleshooting
Avg. time to complete maintenance by lab personnel

Onboard maintenance records/Maintenance training demo module

List price/Targeted bed size or daily volume
Annual service contract cost (24 hours/7 days)
Training provided by vendor/Advanced operator training

Diagnostic Products Corp.
Jan Kelly info@dpconline.com
5210 Pacific Camino Drive, San Diego, CA 92122-6493
310-840-0281 www.dpconline.com
Diagnostic Products Corp.
Jan Kelly info@dpconline.com
5210 Pacific Camino Drive, San Diego, CA 92122-6493
310-840-0281 www.dpconline.com

. U.S./U.K.
>5,000 worldwide
Cost, random access/stand-alone test
41 x 48 cm (16 x 18.2 in)

ILUIMMITE 2000/ILUIMMITE 1985/U.S.
. U.S./U.K.
>5,000 worldwide
Cost, random access/stand-alone test
41 x 48 cm (16 x 18.2 in)

ILUIMMITE 1990/2000/U.S.
. U.S./U.K.
>5,000 worldwide
Cost, random access/stand-alone test
41 x 48 cm (16 x 18.2 in)

. U.S./U.K.
>5,000 worldwide
Cost, random access/stand-alone test
41 x 48 cm (16 x 18.2 in)

ATP alergy surc, total IgE, LPS, IgG. IgM. IgA. IgD, intact FPR, Pathogen-O, cytokine

ATP alergy surc, total IgE, LPS, IgG. IgM. IgA. IgD. intact FPR. Pathogen-O, cytokine

ATP alergy surc, total IgE. LPS, IgG. IgM. IgA. IgD. intact FPR. Pathogen-O, cytokine

ATP alergy surc, total IgE. LPS, IgG. IgM. IgA. IgD. intact FPR. Pathogen-O, cytokine
Automated immunoassay analyzers

Part 11 of 22

Name of instrument/First year sold/Who designed the device
Country/Manufacturer/Where manufactured
No. of units in clinical use in U.S./Outside U.S.
Operational type/Model/Type/Sample handling system
Dimensions (in inches H x W x D)/Instrument footprint in square feet

<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>First year sold</th>
<th>Who designed the device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic Products Corp.</td>
<td>1979</td>
<td>Joe Seebold</td>
</tr>
<tr>
<td>Diaspace Corp.</td>
<td>2000</td>
<td>Pat McNeal</td>
</tr>
</tbody>
</table>

See accompanying article on page 16

Test availability in U.S.

<table>
<thead>
<tr>
<th>Tests available in U.S.</th>
<th>Tests cleared but not currently released</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast 100</td>
<td>—</td>
</tr>
<tr>
<td>Fast 200</td>
<td>—</td>
</tr>
<tr>
<td>Fast 300</td>
<td>—</td>
</tr>
<tr>
<td>Fast 400</td>
<td>—</td>
</tr>
<tr>
<td>Test 100</td>
<td>—</td>
</tr>
<tr>
<td>Test 200</td>
<td>—</td>
</tr>
<tr>
<td>Test 300</td>
<td>—</td>
</tr>
<tr>
<td>Test 400</td>
<td>—</td>
</tr>
</tbody>
</table>

Tests available in U.S. but not submitted for clearance

<table>
<thead>
<tr>
<th>Tests available in U.S. but not available in other countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>IA-MRA (CA-19-9), FBC, Sb, hCG, PAPP-A, hPL, anti-HIV, anti-HBV, HIV screening, anti HCV, anti-HBs, anti-HAV,</td>
</tr>
</tbody>
</table>

Test availability for other manufacturers’ analyzers

<table>
<thead>
<tr>
<th>Test availability for other manufacturers’ analyzers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pirmarketed immunoassay microplate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of analyses performed in separate disposable unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of wells in microplate</th>
</tr>
</thead>
<tbody>
<tr>
<td>—</td>
</tr>
</tbody>
</table>

Methods supported/Seperation methods

<table>
<thead>
<tr>
<th>Methods supported</th>
<th>Separation methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supersaturated sample</td>
<td>—</td>
</tr>
<tr>
<td>Supersaturated sample on anion exchange column</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of different measured assays onboard simultaneously</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of different analyses programmed, calibrated at once</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of different analyses for which system accommodates reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contained in/on (in/on) container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Shortest/Median onboard reagent stability/_refrigerated onboard</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 hours/80 days/4°C</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Multiple reagent configurations supported</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reagent container placed directly on system for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reagents bar coded/information in bar code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Same capabilities when 3rd-party reagents used/Susceptibility to carryover</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Walkaway capacity in minutes/Tests/assays</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 minutes/5,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>System is open (home-brew methods can be used)/Liquid or dry system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Uses disposable cuvettes/Film, No. stored</th>
</tr>
</thead>
<tbody>
<tr>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Uses washcoat tubes/Replacement frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>50/100</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Minimum sample vol. required</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 µL/50 µL/500 µL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Supplied with UPS (backup power)/Requires flour drain</th>
</tr>
</thead>
<tbody>
<tr>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requires dedicated water system/Water consumption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Noise generated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No dedicated pediatric sample cup/Dead volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary tube sampling/Tube sizes/Filters on primary tubes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 x 80 mm, 12 x 80 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample bar-code reading capability/Auto-identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bar-code placement per ISO/ICLS standard AutoID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Optional/Background subtraction on demand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Optional/Automatic dilution/automatic dilution start</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of calibrators required for each analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Calibrators can be stored onboard/Arg, calibration frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes/1 week/2 weeks (as needed)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Multiple units supported/Multiple calibrations stored for same assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How often QC required</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/month/5/month</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>On-board real-time QC/Support multiple QC lot No. per analyzer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/3/4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Automatic shutdown/Start-up programable/start-up time</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 min/10 sec/1 sec</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test start time to completion of 0-HCG test</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 min</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time delay from ordering start to test to aspirate of sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Throughput per hr for five analyses on each specimen, in No. of specimens/No. of tests (cycle time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>—/100</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Can auto make QC results available to review QC/Device operator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data management capability/instrument vendor supplies LIS interface</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LIS features can synchronize with LIS/running assays</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Uses LCD/renders/transcriptions/and results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How labs get LCD codes for reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Multiple laboratory interfaces capability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results transmitted to LIS as soon as test time complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interface available (or will be) to be auto specimen handling system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Modern servicing/Can diagnose own malfunctions/Determines</th>
</tr>
</thead>
<tbody>
<tr>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>malfunctioning component</th>
</tr>
</thead>
<tbody>
<tr>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Can order (via modem) malfunctioning part(s) w/in operator</th>
</tr>
</thead>
<tbody>
<tr>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>On-line response time of service engineer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 hr/1 day</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mean time between failures/Ti repair failures</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months/2 years</td>
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<tr>
<th>Error code encountered to facilitate troubleshooting</th>
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<tr>
<th>Avg. time to complete maintenance by lab personnel</th>
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<tbody>
<tr>
<td>1 day/5 min/20 min</td>
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<tr>
<th>On-board maintenance records/Maintenance training demo module</th>
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<tr>
<th>List price/Target bed size or daily volume</th>
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<tbody>
<tr>
<td>$32,000</td>
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<tr>
<th>Annual service contract cost (24 hours/7 days)</th>
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<tr>
<td>$10,000</td>
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<th>Training program to purchase/Advanced operator training</th>
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<tr>
<th>Distinctive features (supplied by vendor)</th>
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<tr>
<td>Large automated immunoassay test menu available, 15 minute stat tests, flexible sample handling, user-friendly testing, new specific antigen testing alongside routine immunoassays, flexible connectivity to automation via LIS, rapid auto-test, auto-dilute, rapid diagnostics, RealTime Solutions (RTS) Internet-based service and support system</td>
</tr>
</tbody>
</table>

| only system (reagents & instrument) FDA cleared, moderately complex rating, automation-ready and containers; user-friendly kit for rapid testing; built-in safeguards to prevent alcohol abuse |

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

CMYK Page 38

June 2005
Automated immunoassay analyzers

Part 12 of 22

Name of instrument/First year sold/Where designed
Parnes System/2005/Italy

See accompanying article on page 18

Panasonic Corp.
Linda Schmitz
Indoh, Shibuya-ku
Tokyo, Japan

Dainippon
Dawn Frazier
180 N. Northeastern Ave.
Davenport, IA 52802

June 2005

40 / CAP TODAY

Name of instrument/First year sold/Where designed

Panasonic System/2005/Italy

Parnes System/2005/Italy

Dainippon

Panasonic System/2005/Italy

Italy/U.S.

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Italy/U.S.
Automated immunoassay analyzers

**Part 13 of 22**

**Diagnosis Inc.**
Brian Lauber  brianaubert@diagnosisinc.com
1061 Northwood Ave.
Lilburn, GA 30047
(678) 524-1039-1010 www.diagnosisinc.com

**Grifols USA Inc.**
John Moderson john.moderson@grifols.com
401 NW 18th Terrace
Miami, FL 33172
(305) 273-0377 www.grifolsusa.com

**Name of instrument/First year sold/Where designed**

Germany/Germany/U.S., U.K.

Triumph 1998/Spain

Spain/U.S., Germany

**Country where manufactured/Where reagents manufactured**

**Number of units in clinical use in U.S./Outside U.S.**

256/256

10,000/1,600

**Operational type/Model/Type of sample handling system**

Continuous, randomized access/benchtop/rack

Continuous, randomized access & cant. random access/benchtop/universal carousel

**Dimensions in inches (H x W x D)/Instrument footprint in square feet**

63 x 138 x 46 & 68 x 60 x 12

20.3 x 61.3 x 3.4 & 17.6 x 14.6 ft

Tests available on instrument in U.S.

25 hydrolyzed EL, Enzym/PIT, ENV IgM, ENM IgA, VCA IgG

**Tests cleared but not currently available**

**Tests not available in U.S. but sold for clinical use**

**Research-use-only assays**

**Tests in development**

ANA screen, cryoantiphospholipids, HSP-1 IgG

**User-defined methods implemented for what analytes**

**Tests not available on other manufacturers’ analyzers**

**Fully automated microplate system**

No.

Yes

**No. of each analyte performed in separate disposable unit**

no

yes

**No. of wells in microplate**

2

8

12

38

250

**Methods supported/Separation methods**

EM/SE rapid workflow, onboard analyzer, 4 individually temperature-controlled incubators

**No. of different measured assays onboard simultaneously**

15

8

**No. of different assays programmed, calibrated at one time**

10

**No. of analyzer-available (open) channels**

0

unlimited

2

**No. of different analytes for which system accommodates reagent/containers onboard at one time/Tests per container set**

containers onboard at one time/Tests per container set

Short-term/Median onboard reagent stability/Stored onboard refrigerated

700 days (yes)/(2°C)

2 years (yes)/room temperature

**Multiple reagent configurations supported**

reagent code

**Reagent container placed directly on system for use**

yes

requires operator providing/programming

**Reagents bar coded/Information in bar code**

yes

no

yes

**Some capabilities when 3rd-party reagents used/Susceptibility to carryover**

yes

yes

yes

**Walkaway capacity in minutes/SensitivityThresholds/to be immediately available**

<100/500

10/50

50/100

**System is open (home brew methods can be used)/Liquid or dry system**

yes/liquid

**Does disposable cuvette/Made to order**

yes/no

**Uses washable cuvette/Replacement frequency**

no

yes

no

**Minimum specimen vol. required**

10 mL

25 mL

50 mL

**Minimum sample vol. aspirated precisely at once/Min. dead vol.**

2 µL/0.5 mL

no

**Supply with UPS (backup power)/Requires floor drain**

no/no

**Requires dedicated water system/Water consumption**

no

**Noise generated**

20 dB

**Has dedicated pediatric cup/Dead vol.**

no

15 mL

<75 mL

**Primary label/sample/Tube sizes/Pieces/primary on primary tubes**

no/yes

yes

yes

**Sample bar code reading capability/reduction/confirmation**

yes/yes/no

**Bar code placement per NCLCS standard AutoA**

yes

**Onboard test auto inventory (determine vol. in container)**

yes

**Measures no. of tests remaining/Short sample detection**

no/yes

**Auto detection of adequate reagent or specimen**

no

yes

yes

**Cet detection/Reflex testing capability**

no

yes

yes

**Hemolytic detection-quantification/Turbidity detection-quantification**

no/no

**Dilution of patient samples onboard/Automatic reagent capability**

yes/no

yes

no

**Sample vol. can be increased to rerun out-of-line-range high results/Increased to rerun out-of-line-range low results**

<20

10

**Time between initial result & reanalysis of sample for rerun**

2 min

10 min

**Autoascultation or autoascultation alert**

no

yes

no

**Number of calibrators required for each analyte**

2

1

0

**Calibrators can be stored onboard/Not used**

<28 days

<28 days

yes/no

**Onboard kit used/Support multiple kits, stored for same assay**

yes

no

yes

**How often QC required**

once

once

**Onboard real-time QC on multiple QC lot(s), per analyzer**

no/yes

yes

**Automatic shutdown/Startup is programmable/Startup time**

<10 min

<5 min

<2 min

**Start time to completion of 8-HC > IgG test**

2 min

2 min

2 min

**Time delay from ending stat test to assay of sample**

throughput per hr for these analytes on each specimen, in No. of specimens/hr of test (cycle time)**

20

20

20

15

10

7

5

3

**Can auto transfer QC results to LIS/Onboard capability to review QC**

yes/yes

no

**Data management capability/Instrument supplier vendors LIS interface**

no/yes

no/yes

yes

**LIS interface operation simultaneously w/running assays**

no

yes

**Uses LIS for transmit orders and results**

no

yes

**How labs get LIS codes for reagent kits**

no

yes

**Bi-directional interface capability**

no

yes

**Results transmitted to LIS as soon as test time complete**

yes/no

no

**Interface available (or will be) to auto sample handling system**

no/yes

**Modern service/can diagnose own malfunction/Perform malfunctioning component**

yes

no

yes

**Can order (via normal) malfunctioning part/w/ operator**

no

yes

**On-site response time of service engineer**

<24 hr

<24 hr

<24 hr

**Mean time between failures/TS repair failures**

<10 min

<10 min

10 min

**Onboard error codes to facilitate troubleshooting**

yes

yes

yes

**Avg. time to complete maintenance by lab personnel**

daily 10 min; weekly 20 min; monthly 30 min

daily 5 min; weekly 20 min; monthly 30 min

daily 5 min; weekly 20 min; monthly 15 min

**Onboard maintenance record/Remaining maintenance demo module**

yes/no

yes

yes

**List price/Targeted bed size or daily volume**

$15,000—

$60,000/more/ or higher

**Annual service contract cost (24 hours/7 days)**

$1,000

$15,000

**Training program provided/Free/Advanced operator training**

3 or 6 days/12 or 16 days

3 or 6 days/12 or 16 days

3 or 6 days/12 or 16 days

**Distinguishing features (supplied by vendor)**

benefits analyzer with high throughput; unique menu offering

multihub or continuous throughput through hub analyzer; user-defined menus, complete system open; easy user-defined and set up for operator; 2 probes for high-speed processing; unique cross-well washing; able to use food probes or disposable tips

**Subsidies do not represent an undue influence by the College of American Pathologists**

**June 2005**

**CAP TODAY / 41**

**SURVEY OF INSTRUMENTS**

**CMYK Page 41**
### Automated immunoassay analyzers

| Name of Instrument/First year sold/Where designed | HySys Biomedical Inc.  
callhysysbiomedical.com  
7275 Chapman Ave.  
Garden Grove, CA 92841  
714-853-3800  
www.hysysbiomedical.com |
| HySys 400/1996/Switzerland  
Switzerland/U.S., Scotland |
| HySys 288/1996/U.S., U.K., Netherlands |

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

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
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### Automated immunoassay analyzers

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Specimen Size</th>
<th>Results Format</th>
<th>Automation</th>
<th>Turnaround Time</th>
<th>Operator Experience</th>
<th>Calibration</th>
<th>Reagent Stability</th>
<th>Storage Temperature</th>
<th>Testing Facility</th>
<th>Other Considerations</th>
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<tbody>
<tr>
<td><strong>Equipment</strong></td>
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**Notes:**
- *Equipment:* Includes the primary equipment used for the immunoassay analysis.
- *Results Format:* Specifies how the results are presented.
- *Automation:* Indicates whether the system is automated or manual.
- *Turnaround Time:* Refers to the time taken to complete the testing process.
- *Operator Experience:* Elaborates on the skills required for operating the equipment.
- *Calibration:* Details the frequency and methods of calibration.
- *Reagent Stability:* Provides information on the stability of reagents.
- *Storage Temperature:* Specifies the temperature range for storage.
- *Testing Facility:* Describes the type of facility where the testing is conducted.
- *Other Considerations:* Includes additional factors to consider.

**References:**
- Laboratory manuals and technical guides.
- Manufacturer’s specifications.
- Industry standards and regulations.

**Contact:**
- Manufacturers’ representatives.
- Local distributors.
- Medical supply companies.

**Supplies:**
- Test kits.
- Reagents.
- Calibration materials.

**Training:**
- On-site training.
- Online tutorials.
- Certification programs.

**Support:**
- Technical support services.
- Customer service.
- Technical consultation.

**Documentation:**
- Test results.
- Client data.
- Quality control records.

**Notes:**
- Equipment specifications and performance characteristics.
- Triplicate or multiple runs.
- Positive and negative controls.
- Inter- and intra-assay variability.

**Contact Information:**
- Manufacturers’ websites.
- Trade shows.
- Conferences.

**Additional Resources:**
- Publications.
- Peer-reviewed journals.
- Online forums.

**Conclusion:**
- Comprehensive evaluation of automated immunoassay analyzers.
- Integration of cutting-edge technology.
- Optimization of workflow.

**Future Trends:**
- Integration of artificial intelligence.
- Miniaturization of equipment.
- Increased portability.

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**Disclaimer:**
- The information provided is for educational purposes only.
- Users are advised to consult the manufacturer’s instructions for specific details.
- This summary is not a substitute for professional medical advice.

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**References:**
- [Manufacturer’s manuals and product specifications.](http://example.com)
- [Technical guides and literature.](http://example.com)
- [Standards and regulatory requirements.](http://example.com)
- [Latest research and trends.](http://example.com)
Automated immunoassay analyzers

Part of 22

Name of instrument/First-year sold/Where designed

Ortho-Clinical Diagnostics, a Johnson & Johnson Company

Raus-Potter, 3601 FolchLab Rd., Raritan, NJ 08869

Ortho-Clinical Diagnostics, a Johnson & Johnson Company

Raus-Potter, 3601 FolchLab Rd., Raritan, NJ 08869

See accompanying article on page 18

Vitaus ISO Diagnostic System/1970’s/US.

Vitaus ISO Diagnostic System/2000’s/US.

U.S./UK.

U.S./UK.

<0.250/week

<0.250/week

Dimensions in inches (W X D X H)/Instrument footprint in square feet

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Tests available on instrument in U.S.

3rd-party, TMT, TT, FTA, TTA, TQT, update, total R-ACS, estradiol, progesterone, LH, FSH, prolactin, N-hipnotic, CEA, AFP, CA-125, CA 15-3, ferritin, cortisol, cancer (screen and source), CH, AR, tropon, A, B, GU, Bile, TSH, NAC, IgA, Immuno, FSA, HbA1c, AP1, HbA1c (fast), myoglobin, alpha-fet, IgG (IgM), Hbs, immune

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Tests cleared but not clinically released

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Tests not available in U.S. but submitted for clearance

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

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

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Research-use-only assays

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Tests in development

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

User-defined methods implemented for what analytes

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Tests not available on other manufacturers’ analyzers

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Fully automated microplate system

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

No. of each analyte performed in separate disposable unit

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

No. of wells in microplate

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Methods supported/Seperatation methods

Cholesterol/cholesterol/individual coated microwell

Cholesterol/cholesterol/individual coated microwell

No. of different measured assays onboard simultaneously

20

56 days/56 days/yes

56 days/56 days/yes

No. of different assays programmed, calibrated at once

20 programmed & calibrated at once; up to 25 kits calibrated per assay

20 programmed & calibrated at once; up to 25 kits calibrated per assay

No. of user-definable (open) channels

20

20

No. of different analyses for which system accommodates reagent containers onboard at user/Tests per container set

Short/medium medium

Short/medium medium

Reagent/medium on-board stability/refrigerated onboard

Multiple reagent configurations supported

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Reagent container placed directly on system for use

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Reagents bar code/information in bar code

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Some capabilities when 3rd-party assays used?/Sensitivity to carryover

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Walkaway capacity in minutes/seconds/Tests/assays

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

System is open (be-mix, open or closed system)/Can be used in liquid or dry system

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Uses disposable cuvettes/Max. No. stored

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

No. of minimum volume required

10 µL

10 µL

Minimum sample vol. aspirated precisely at start/most. dead vol.

10–40 µL/mL

10–40 µL/mL

Supplied with UPS (backup power)/Requires floor drain

No

No

Required dedicated water system/Water consumption

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

No

No

Noise generated

60 decibels

60 decibels

No dedicated pediatric sample cup/Dead vol.

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

No

No

Primary tube sampling/Tube size/Primers caps on primary tubes

No

No

Sample bar code reading capability/Autofill/identification

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Yes

Yes

Bar code placement per NCCLS standard/autocall

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Yes

Yes

Embottled test auto inventory (determined by container set in instrument)

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Yes

Yes

Feature to measure one test/attachment to instrument

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Yes

Yes

No. of calibrators required for each analytic

3

6

Calibrators can be stored onboard/arg. calibration frequency

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Weeks, monthly, bi-monthly, bi-weekly

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Weekly, bi-monthly, bi-weekly

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

No

No

How often QC required

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Once per day

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Once per day

Cookie/cookie support multiple QC list, fly, per analytic

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Yes

Yes

Automatic shutdown/Start-up is programmable/Start-up time

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Yes/yes/immediate upon completion of last sampling

Yes/yes/immediate upon completion of last sampling

Stat time to completion of 0-10 sec test

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

No/40 sec

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

Yes

Yes

Limit pressure/trapped size or daily volume

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

10,000 psi/for majority of customer demand

10,000 psi/for majority of customer demand

Annual service contract cost (24-hours/7 days)

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

$14,000/month for majority of customer demand

$14,000/month for majority of customer demand

Training provided w/ purchase/Advanced operator training

...throughput. Various methods are required to accommodate primary & secondary containers without need for adaptors

$14,000/month for majority of customer demand

$14,000/month for majority of customer demand

Distinguishing features (supplied by vendor)

uses proprietary intellectual technology to perform, monitor, document, and verify diagnostic check performance for each sampled test and assay processing to ensure quality of reported results; uses patented Enhanced Chemiluminescence, Microarray technology; provides simple to use, fully automated, test read-out access, test starting for routine and specialty immunoassay/immunoasay testing features enhance operations with adjustable fill, low-noise, processor monitor and keyboard platform with multi-purpose support arm

uses proprietary intellectual technology to perform, monitor, document, and verify diagnostic check performance for each sampled test and assay processing to ensure quality of reported results; uses patented Enhanced Chemiluminescence, Microarray technology; provides simple to use, fully automated, test read-out access, test starting for routine and specialty immunoassay/immunoasay testing features enhance operations with adjustable fill, low-noise, processor monitor and keyboard platform with multi-purpose support arm

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Automated immunoassay analyzers

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Pharmacia Diagnostics AB
Lorraine Denny loranne.denny@pharmacia.com
4180 Commercial Ave.
Partage, MI 48002
800-346-4304 www.pharmacia.com

Pharmacia Diagnostics AB
Lorraine Denny loranne.denny@pharmacia.com
4180 Commercial Ave.
Partage, MI 48002
800-346-4304 www.pharmacia.com

See accompanying article on page 18

Name of instrument/First year sold/Where designed
Country where manufactured/Where reagents manufactured
No. of units in clinical use in U.S./Outside U.S.
Operational type/Model/Number/sample handling system
Dimensions in inches (H x W x D)/Instrument footprint in square foot

InnogenICA 200 system/2004/Japan, Sweden
Japan, Sweden/Sweden
24/300
continuous random access/standing racks
73 x 50 x 30 in; 26 x 20 in wide computer stand—

InnogenICA 100 system/2003/Spain, Sweden
Japan, Sweden/Sweden
27/180
continuous random access/standing racks
83 x 71 x 40 in; 26 x wide computer stand—

Tests available on instrument in U.S.
greater than 550 ImmunoCAP specific IgE tests, ImmunoCAP total Ig and, ImmunoCAP specific IgG tests

Tests cleared but not clinically released
—

Tests not available in U.S. but submitted for clearance
—

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

Research-use-only assays
—

Tests in development
—

User-defined methods implemented for what analyses
—

Tests not available on other manufacturers’ analyzers
Pharmacia Diagnostics AB ImmunoCAP assays

Fully automated microparticle system
—

No. of each analyte performed in separate disposable unit
—

No. of wells in microparticles
—

Methods supported/Separation methods
Fluoroenzyme immunoassay (FEIA)/ImmunoCAP cellulosic polymer matrix
reaction wells
3 methods

No. of different assays programmed, run, performed at once
3 methods

No. of user-definable (open) channels
—

No. of different analytes for which system accommodates reagent containers on board/Tests per container set
100

Shortest/Median onboard reagent stability/Refrigerated onboard storage
—

Multiple reagent configurations supported
—

Reagent container placed directly on system for use
—

Reagents bar coded/information on system
—

System availability when 3rd-party reagents used/Susceptibility to carryover
—

Walkway capacity in minutes/Specimen/Tests-assays
473/min simultaneous/270 tests

System in open (home-branched methods can be used)/ Liquid or dry system
—

Uses disposable cuvettes/Max. No. stored
—

Uses washable cuvettes/Replacement frequency
—

Minimum specimen vol. required
—

Minimum sample vol. aspirated precisely at once/Min. dead vol.
—

Supplied with UPS (backup power)/Required floor drain
—

Requires dedicated water system/Water consumption
—

Noise generated
—

Has dedicated pediatric sample cup/Dead vol.
—

Primary sample tube/Sampling/Prime cups on primary tubes
—

Sample bar-code reading capability/Automation/discrimination
—

Bar-code placement per MICLS standard AutoDA
—

Onboard test auto inventory (determines vol. in container)
—

Measures No. of tests remaining/Shortest sample detection time
—

Auto detection of adequate reagent or specimen
—

Clot detection/Refrig. testing capability
—

Hemolysis detection—quantification/Totality detection—quantification
—

Dilution of patient sample on-board/Automatic re-run capability
—

Sample vol. can be increased to reach out-of-range high results/
—

Increased to reach out-of-range low results
—

Time between initial result & manifestation of sample for run
—

Auto-calculation or auto-calculation alert
—

No. of calibrators required for each analysis
—

Calibrators can be stored onboard/Auto calibration frequency
—

Multiple calibrators supported/Multiple calibrators, stored for same assay
—

How often QC required
—

Onboard real-time QC/Support multiple QC lot Nos. per analyzer
—

Automatic solutions/Startup is programmable/Startup time
—

Stall time to completion of 8-HCT test
—

Time delay from ordering start test to receipt of sample
—

Throughput per hr for these analytes on
same specimen, in No. of specimens/No. of tests (cycle time)
—

Can auto transfer QC results to LIS/Onboard capability to review QC
—

Data management capability/instrument vendor supplies LIS interface
—

Interface interoperates simultaneously w/running assays
—

Uses LINC for electronic orders and results
—

How labs get LINC codes for reagent kits
—

Biodensification interface capability
—

Results transmitted to LIS as soon as test time complete
—

Interface available (or will be) to auto specimen handling system
—

Modern servicing/Can diagnose even malfunctions/Deteriorate
—

malfunctioning component
—

Can order (via modem) malfunctioning part(s) w/operator
—

On-site response time for service engineer
—

Mean time between failures/To repair failures
—

Onboard error codes to facilitate troubleshooting
—

Avg. time to complete maintenance by lab personnel
—

Onboard maintenance records/Maintenance training demo module
—

List price/Targeted best bids or daily volume
—

Annual service contract cost (24 hours/7 days)
$27,000-25,000-45,000 tests per year
$8,400 (business hours only)

Training provided w/parachute/Advanced operator training
3.5 days of vendor orientation

Distinguishing features (supplied by vendor)
allergy diagnostics is our core business; there are not “add-on” tests; this system and reagents are designed to provide the most accurate specific allergy diagnostic results and use well documented ImmunoCAP® technology; supported by a dedicated sales force to drive business development that only helps the companies they offer physicians and outreach revenue for lab

allergy diagnostics is our core business; there are not “add-on” tests; this system and reagents are designed to provide the most accurate specific allergy diagnostic results and use well documented ImmunoCAP® technology; supported by a dedicated sales force to drive business development that only helps the companies they offer physicians and outreach revenue for lab

Table data not represented by an endorsement by the College of American Pathologists

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June 2005
Automated immunoassay analyzers

Pharmacia Diagnostics AB
Lumines Diagnostics
Lumines Diagnostics AB

Randex Laboratories Ltd.
Julie Thomsen
Evidence support@randex.com
Diamond Rd.
Cranfield, County Amers, BT23 4DF
44 (0) 28 3442 2013
www.randex.com

See accompanying article on page 10

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Name of Instrument/First year sold/Where designed
Country where manufactured/Where restaurants manufactured
Operational type/Model type/Sample handling system
Dimensions in inches (W x D x H)/Instrument footprint in square feet

Tests available on instrument in U.S.
Tests cleared but not clinically released
Tests not available in U.S. but submitted for clearance
Tests not available in U.S. but available in other countries
Research-use-only assays
Tests in development

User-defined methods implemented for what analyses
Tests not available on manufacturers’ analyzers

Pharmacia Diagnostics AB ImmunoCAP assays

 methods supported/Separation methods
No. of different assays measured on board simultaneously
No. of different assays programmed, calibrated at once
No. of user-definable (open) channels
No. of different analytes for which system accommodates reagent containers on board/Tests per container set
Shortest/Median on-board reagent stability/depleted onboard
Multiple reagent configurations supported
Reagent container placed directly on system for use
Reagents bar-coded/information in bar code
Same capabilities when 3rd-party reagents used/Susceptibility to carryover
Walkway capacity in minutes/Spectrometer Tests assays
System in open (home)-brew methods can be used/storage/liquid or dry system
Uses disposable cuvets/Max. no. stored
Uses washable cuvets/Replacement frequency
Minimum specimen vol. required
Minimum sample vol. aspirated precisely at onset/Min. dead vol.
Supplied with UPS (backup power)/Requires floor drain
Requires dedicated water system/Water consumption
Noise generated

No. of dedicated pediatric sample cup/Dead vol.
Primary tube sampling/Tube sizes/Perfocaps on primary tubes
Sample bar-code reading capability/Auto-discrimination
Bar-code placement per NCLD0 standard Auto
Onboard test autorometer (determines vol. in container)
Measures No. of tests remaining/Start sample detection
Auto detection of adequate reagent or specimen
Ct detection/Reflux testing capability
Hemolysis detection-quantitation-Turbidity detection-quantitation
Dilution of patient samples onboard/Auto-redundant reagent supply
Sample vol. can be increased to run on out-of-range high results/
Increased to rerun out-of-range low results
Time between initial result & reappearance of sample for rerun
Autocalibration or auto-calibration alert
No. of calibrators required for each analyte
Calibrators can be stored onboard/Ang. calibration frequency
Microtiter tray supported/Multiplex cards. stored for same assay
How often QC required
Onboard real-time QC/Support multiple QC lot Nos, per analyzer
Automatic shutdown/Start up program/Programmable/Start time

Sate time to completion of 9-0 test
Time delay from ordering test to aspir. of specimen
Throughput per for for these analytes on each specimen, in No. of specimens/No. of tests (cycle time)
Can auto transmit QC results to LIS/Onboard capability to review QC
Data management capability/Instrument vendor supplies LIS interface
Interfaces up and running in active user sites with

LIS interface operates simultaneously w/running assays
Uses LONCD to transmit orders and results
How labs get LONCD codes for reagent kits
Diagnostics interface capability
Results transmitted to LIS as soon as test time complete
Interface available (or will be) to auto specimen handling system
Modern service/Can diagnose own microchip/Determine malfunctioning component
Can order (via modem) malfunctioning part(s) w/operator
On-site response time of service engineer
Mean time between failures/Troubleshooting repairs
On-board error codes to facilitate troubleshooting
Array: Time to complete maintenance by lab personnel
On-board maintenance records/Maintenance training demo module

List price/Targeted bed size or daily volume
Annual service contract cost (24 hours/7 days)
Training provided w/purchase/Advanced customer training

Disturbing features (supplied by vendor)

allergy diagnostic is our core business; these are not "add-on" tests; this
analyte and magnets are designed to provide the most accurate specific
microarray and specific disease groups; tests not reported may be
biologic analyzers simultaneously detect multiple parameters in a single
patient sample; arrays contain multiple test panels applicable to clinical
research applications and specific disease groups; tests not reported may be

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

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Automated immunoassay analyzers

<table>
<thead>
<tr>
<th>Name of Instrument/First year sold/Where designed</th>
<th>Country where manufactured/Where reagents manufactured</th>
<th>No. of uses in clinical use in U.S./Outside U.S.</th>
<th>Operational type/Model type/Sample handling system</th>
<th>Dimensions in inches (H x W x D)/Instrument footprint in square feet</th>
</tr>
</thead>
</table>
| Tests available on instrument in U.S. | TKBF, FTA, T3, T3, T3, T-uptake, Lip, FNK, progest, estradiol, progest,  

| Tests cleared but not clinically released | TG | CA 12-5, anti-HBs, HBeAg, HBcAg confirm |
| Tests not available in U.S. but available in other countries | TKBF, T3, T3, T-uptake, Lip, FNK, progest, estradiol, progest,  

| Research-use-only assays | none |
| Tests in development | none |
| User-defined methods implemented for what analyses | TKBF, T3, T-uptake, Lip, FNK, progest, estradiol, progest,  

| Fully automated microplate system | no |
| No. of each analyte performed in separate disposable unit | n/a |
| No. of wells in microplate | n/a |

Methods supported/Seperation methods | No. of different measured assays onboard simultaneously | 15 |
| No. of different assays programmed, calibrated at once | 60 |
| No. of user-definable (open) channels | 6 |
| No. of different analytes for which system accommodates reagent | 15/100-200 |
| Additional reagents bar code/information in barcode | 6100-200 |
| Same capabilities when 3rd-party reagents used | yes |
| Walkway capacity in minutes/Specimens/Tests-assays | yes |
| System in open (home-brew methods can be used)/Liquid or dry system | yes |
| Uses disposable cuvettes/Max. No. stored | — |
| Uses washable cuvettes/Replacement frequency | no |
| Minimum specimen vol. required | 10 µl |
| Minimum sample vol. aspirated precisely at on-site/Min. vol. | 10 µl |
| Supplied with UPS (backup power)/Requires floor drain | yes |
| Requires dedicated water system/Water Temperature | yes |
| Noise generated | yes |
| Has dedicated pediatric sample cup/Dead vol. | yes |
| Primary tube sampling/Tube sizes/Percents on primary tubes | 3 cm x 10 mm x 10 mm |
| Sample bar-code reading capability/Auto-dilution | yes |
| Bar-code placement per NCCLS standard AutoCL | yes |
| Onboard test auto inventory (determined vol. in container) | yes |
| Measures No. of tests remaining/Short sample detection | yes |
| Auto detection of adequate reagent or specimen | yes |
| Cist detection/Reflux testing capability | yes |
| Hemolysis detection/Quantitation/Turbidity detection-quantitation | yes |
| Dilution of patient samples onboard/Auto-removal of reagents | yes |
| Sample vol. can be increased to run out-of-range high results/High volume samples | yes |
| Increased to run out-of-range low results | yes |
| Time between initial result & reanalysis of sample for rerun | yes |
| Autocalibration or autocalibration alert | yes |
| No. of calibrators required for each analyte | yes |
| Calibrators can be stored onboard/Avg. calibration frequency | yes |
| Multipoint scales supported/Multiple calibrates stored for same assay | yes |
| How often QC required | yes |
| Onboard real-time QC/Support multiple QC lot Nos. per analyzer | yes |
| Automatic shutdown/Startup in programmable/Startup time | yes |

Stat to time to completion of 0-NOx test | 9 min (NOx limit) |
| Time delay from ordering stat test to aspir. of sample | 66 sec |
| Throughput per hr for three analytes on each spec. | 30/60 (60 sec) |
| Can auto transfer QC results to LIS/Onboard capability to review QC | yes |
| Data management capability/instrument vendor supplies LIS interface | yes/yes |
| LIS interface operates simultaneously w/ running assays | yes |
| Uses LONIC to transmit orders and results | yes |
| How long does it take to get LONIC codes for reagent kits | yes |
| Bidirectional interface capability | yes |
| Results transmitted to LIS as soon as test time complete | yes |
| Interface available (or will be) to auto specimen handling system | yes |
| Modern servicing/Can diagnose own malfunctions/Definitive | yes |
| -multifunctioning component | yes |
| Can order (via modem) multifunctioning part(s) w/ operator | no |
| On-site response time of service engineer | <4 hr |
| Mean time between failures/Repair failures | yes |
| Error codes to facilitate troubleshooting | yes |
| Avg. time to complete maintenance by lab personnel | daily: 8 hr; monthly: 5 hr |
| Onboard maintenance records/Maintenance training demo module | yes |
| Let clip price/Targeted bed size or daily volume | n/a |
| Annual service contract cost (24-hours/7 days) | n/a |
| Training provided w/ purchase/Advanced operator training | n/a |
| Distincting features (supplied by vendor) | n/a |

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Automated immunoassay analyzers

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Roch Diagnostics
Lisa Davis, Lisa.davis@roche.com
3119 Hagan Rd.
Indianapolis, IN 46280
800-429-5074
www.roche.com/laboratories/en

TOSOH BioScience Inc.
Susan Koterak, susan.koterak@tosohbio.com
347 Oyster Point Blvd.
South San Francisco, CA 94080
800-346-6744
www.tosohbio.com

Name of instrument/First year sold/Where designed

Country where manufactured/Where reagents manufactured

No. of units in clinical use in U.S./Objective U.S.

Operational type/Model type/Sample handling system

Dimensions in inches (H x W x D)/Instrument footprint in square feet

Tests available on instrument in U.S.

Tests cleared but not clinically released

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

Research-use only assays

User-defined methods implemented for what analytes

Tests not available on other manufacturers’ analyzers

Fully automated microplate system

No. of each sample performed in separate disposable unit

No. of wells in microplate

Methods supported/Separation methods

No. of different measured assays onboard simultaneously

No. of different assays programmed, calibrated at once

No. of user-defined (open) channels

No. of analytes for which system accommodates reagents

containers onboard at Tests per container set

Shortest/Median onboard reagent stability/Refrigerated onboard storage

Maximum reagent configurations supported

Reagent container placed directly on system for use

Reagents bar coded/information in bar code

Same capabilities when 3rd-party reagents used/Usability to carryover

Walkaway capacity in minutes/Specimens/Tests-autoassays

System is open/homogeneous methods can be used/Liquid or dry system

Uses disposable cuvettes/Max. No. stored

Uses washable cuvettes/Replacement frequency

Minimum specimen vol. required

Minimum specimen vol. aspirated precisely at once/Min. dead vol.

Supplied with UPS/Backup power/Requires floor drain

Requires dedicated system or water/Requires floor drain

Noise generated

Has dedicated pediatric sample cup/Dual vol.

Primary tube sampling/Tube sizes/Pieces caps on primary tubes

Sample bar-code reading capability/Bar-code discrimination

Bar-code placement per NCCLS standard AutoDA

Onboard test auto inventory (inventory vol. in container)

Yes

Measures No. of tests remaining/Short sample detection

Auto detection of adequate reagent or specimen

Cet detection/Refriger testing capability

Hemolysis detection-quantitation/Thrombulotest detection-quantitation

Dilution of patient samples onboard/Automatic reten capability

Sample vol. can be increased to reach out-of-range high results

Increased to reach out-of-range low results

Time between initial result & reanalysis of samples for rerun

Auto-calibration or auto-calibration alert

No

No. of calibrators required for each analyte

Calibrators can be stored onboard/lvq, calibration frequency

Multiplicat caps/Support/capable, multiple caps, stored on same sample

How often QC required

Onboard real-time QC/Support multiple QC Int Nos per analyte

Automatic shutdown/Start-up is programmable/Start-up time

Start to completion of B-HCST test

Time delay from ending last test to aspir. of sample

Throughput per hr for these analyzers

on each specimen, in Nos. of specimens/No. of tests (cycle time)

Can auto transfer QC results to LIS/Onboard capability to review QC

Data management capability/instrument supplier LIS interface

Interfacing up and running in action user sites with

LIS interface

ONLINE separators w/ running assays

Uses LONIC to transmit orders and results

How lab get LONIC codes for relevant kits

Bidirectional interface capability

Results transmitted to LIS as soon as test time complete

Interface available (or will be) to auto specimen handling system

Modern servicing/Can diagnose own malfunctions/Determine malfunctions component

Can order (via modem) malfunctioning part/s w/ operator

On-site response time of service engineer

Mean time between failures/Te repair failures

On-board error codes to facilitate troubleshooting

Avg. time to complete maintenance by lab personnel

Onboard maintenance records/Maintenance training demo module

List price/Targeted bed size or daily volume

Annual service contract cost (24 hours/7 days)

Training provided w/purchased/Advanced operator training

Distinguishing features (supplier provided)

expandable liquid ready-to-use reagents that are compatible with other Eliros systems, compatible with Pre-Analytical Systems, LIS technology prevalent, broad menu measuring range and market, best low bound sensitivity, tropiC, anti, value and dilute

utilized test cups; primary label sampling, no reagent preparation, dual 'clot detector; room temp, stability for the first day, automated sample dilution and pretreatment of the second day (no separation); second generation tropon I, appropriate for stat and routine use

750/500/500/200/200 tests per month

$1,000

3 days at vendor's expense

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### Automated immunoassay analyzers

<table>
<thead>
<tr>
<th>Name of Instrument/First year sold/Where designed</th>
<th>Country where manufactured/Where reagents manufactured</th>
<th>No. of units in clinical use in U.S./Outside U.S.</th>
<th>Operational type/Model type/Sample handling system</th>
<th>Dimensions in inches (h x w x d)/Instrument footprint in square feet</th>
</tr>
</thead>
</table>

| Tabulation listinguishing 'raining' ivg at site quanteralibration ~ample pemolysis jar ocode –ses –ses voests of dazeflex time labs between delay in sample get open via Jvia shutdown ~tartup in contract days K via to reagent system manufacturers'违背 | increased in onboard system Water consumption | Noise generated | Has dedicated pediatric/sample cup/Dead vol. | Primary tube sampling/Tube sizes/Pierce cups on primary tubes Sample bar-code reading capability/Auto-discrimination Bar-code placement per NCLL standard AutoDA | Onboard test auto inventory (determines vol. in container) Measures. No. of tests remaining/Start sample detection Auto-detection of adequate reagent or specimen Clot detection/Reflux testing capability Hemolysis detection-quantitation/Turbidity detection-quantitation Dilution of patient samples onboard/Automatic rerun capability Sample vol. can be increased to rerun out-of-limits range high results | Increased to rerun out-of-limits range low results Time between initial result & reparation of sample for rerun Auto-calibration or auto-verification alert | No. of calibrators required for each analyte Calibrators can be onboard/Ang, calibration frequency Multipoint calib. supported/Multipoint calib. stored for same assay How often QC required Onboard real-time QC/Support multiple QC lot nos. per analyte Automatic solutions/Startup is programmable/Startup time |
|-----------------------------------------------|------------------------------------------------------|-----------------------------------------------|-------------------------------------------------|-------------------------------------------------|

| Tests available on instrument in U.S. | Tests cleared but not clinically released | Tests not available in U.S. but submitted for clearance | Tests not available in U.S. but submitted for clearance in other countries Test in development User-defined methods implemented for what analytes Tests not available on other manufacturers’ analyzers |
|-----------------------------------------------|------------------------------------------------------|-----------------------------------------------|-------------------------------------------------|-------------------------------------------------|

<table>
<thead>
<tr>
<th>Full automated microplate system</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
<th>Units</th>
<th>Units</th>
</tr>
</thead>
</table>

| Methods supported/Separation methods | Fluorescence, EIA/ELISA | n/a | n/a |

| No. of different assays programmed, calibrated at once | 25 | n/a | n/a |
| No. of user-definable (open) channels | 0 | n/a | n/a |
| No. of different analytes for which system accommodates reagent containers onboard at once/Tests per unit container | n/a | n/a | n/a |
| Shortest/Median onboard reagent stability/Refrigerated onboard | 72h/72h +/-a | n/a | n/a |
| Multiple reagent configurations supported | yes | n/a | n/a |
| Reagent container placed directly on system for use | yes | n/a | n/a |
| Reagents bar coded/Information in bar code | yes | n/a | n/a |
| Same capabilities when 3-party reagents used/Susceptibility to carryover | n/a/neon | n/a | n/a |
| Walkway capability in minutes/Specimen/Tests assays | 10/20 | n/a | n/a |
| System in open (home-brew methods can be used)/Liquid or dry system | n/a/neon | n/a | n/a |
| Uses disposable cuvettes/was tested | n/a | n/a | n/a |
| Uses washable cuvettes/Replacement frequency | n/a | n/a | n/a |
| Minimum specimen vol. required | 50 µl tube, 100 µl cap | 50 µl tube, 100 µl cap | 50 µl tube, 100 µl cap |
| Supplied with UPS (backup power)/Requires floor drain | n/a | n/a | n/a |
| Requires dedicated recyqater/Water consumption | n/a | n/a | n/a |
| Noise generated | n/a | n/a | n/a |
| Has dedicated pediatric/sample cup/Dead vol. | no | n/a | n/a |
| Primary tube sampling/Tube sizes/Pierce cups on primary tubes Sample bar-code reading capability/Auto-discrimination | n/a | n/a | n/a |
| Bar-code placement per NCLL standard AutoDA | n/a | n/a | n/a |
| Onboard test auto inventory (determines vol. in container) | n/a | n/a | n/a |
| Measures. No. of tests remaining/Start sample detection | n/a | n/a | n/a |
| Auto-detection of adequate reagent or specimen | n/a | n/a | n/a |
| Clot detection/Reflux testing capability | n/a | n/a | n/a |
| Hemolysis detection-quantitation/Turbidity detection-quantitation | n/a | n/a | n/a |
| Dilution of patient samples onboard/Automatic rerun capability | n/a | n/a | n/a |
| Sample vol. can be increased to rerun out-of-limits range high results | n/a | n/a | n/a |
| Increased to rerun out-of-limits range low results | n/a | n/a | n/a |
| Time between initial result & reparation of sample for rerun | 2 | 2 | 2 |
| Auto-calibration or auto-verification alert | n/a | n/a | n/a |
| No. of calibrators required for each analyte | 2 | 2 | 2 |
| Calibrators can be onboard/Ang, calibration frequency | 30-60 days | 30-60 days | 30-60 days |
| Multipoint calib. supported/Multipoint calib. stored for same assay | yes | yes | yes |
| How often QC required | 24 | 24 | 24 |
| Onboard real-time QC/Support multiple QC lot nos. per analyte | yes | yes | yes |
| Automatic solutions/Startup is programmable/Startup time | yes/5 min | yes/5 min | yes/5 min |

**Stain test of completion of 8-HCT test**

- **Time delay from ordering last test to aspiric of sample**
  - **Throughput per for all analytes on each specimens, In No. of spec/ins/No. of tests (cycle time)**
  - **Can auto transfer QC results to LIS/Onboard capability to review QC**
  - **Data management/capability/instrument vendor supplies LIS Interface**
  - **Uses LIS Interface operates simultaneously w/running assays**
  - **Uses LCDW to transmit orders and results**
  - **How labs get LCDW codes for reagent kits**
  - **Biostatic interface capability**
  - **Results transferred to LIS as soon as test time complete**
  - **Interface available (or will be) to auto specimen handling system**
  - **Modern servicing/Can diagnose own malfunction/Determine malfunctioning component**
  - **Can order (via modloeh) malfunctioning part/sw order**
  - **On-line response time of service engineer**
  - **Mean time between failures/To repair failures**
  - **Onboard error codes to facilitate troubleshooting**
  - **Avg. time to complete maintenance by technician**
  - **Onboard maintenance records/Maintenance training demo module**

<table>
<thead>
<tr>
<th>List price/Target bed size or daily volume</th>
<th>Annual service contract cost (hours/24 hours)</th>
<th>Training provided w/ purchase/Advanced operator training</th>
</tr>
</thead>
<tbody>
<tr>
<td>$25,000</td>
<td>$8,000</td>
<td>Training DVD and DVD player, onsite install</td>
</tr>
</tbody>
</table>

**Distinguishing features (supplied by vendor)**

- **unlimited test cap; primary tube sampling; no refrigeration, room temp, stability for five days; fixed-channel TMB sensitivity; second-generation I.**
- **appropriate for stat and routine use; compact size; face tests per sample; random access**

**two models: standard and LA; unified test cap; primary tube sampling; no refrigeration; dual cap detection; room temp; stability for five days; automated sample dilution and pretreatment; third-generation TMB sensitivity; second-generation I.**

**appropriate for stat and routine use**
Automated immunoassay analyzers

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<th>Country where manufactured/Where reagents manufactured</th>
<th>No. of units in clinical use in U.S./Outside U.S.</th>
<th>Operational type/Model type/Sample handling system</th>
<th>Dimensions in inches (H x W x D)/Instrument footprint in square foot</th>
<th>Tests available on instrument in U.S.</th>
<th>Tests cleared but not clinically released</th>
<th>Tests not available in U.S. but submitted for clearance</th>
<th>Tests not available in U.S. but available in other countries</th>
<th>Research-use-only assays</th>
<th>Tests in development</th>
<th>User-defined methods implemented for what analytes</th>
<th>Tests not available on other manufacturers’ analyzers</th>
</tr>
</thead>
<tbody>
<tr>
<td>PersimaIA/1998/Italy</td>
<td>Trinity Biotech</td>
<td>St. Louis, MO 63114</td>
<td>(240 x 46 x 60)</td>
<td>24 x 20 x 25.6 in (61 x 51 x 65 cm)</td>
<td>open system—anymicroplate assay</td>
<td>open system—anymicroplate assay</td>
<td>open system—anymicroplate assay</td>
<td>open system—anymicroplate assay</td>
<td>open system—anymicroplate assay</td>
<td>open system—anymicroplate assay</td>
<td>open system—anymicroplate assay</td>
<td>open system—anymicroplate assay</td>
</tr>
<tr>
<td>Nexus F16/2006/Italy</td>
<td>Trinity Biotech</td>
<td>Hq/C, Hq, Ireland, Germany</td>
<td>—</td>
<td>24 x 15.2 x 9.5 in (61 x 38.7 x 24 cm)</td>
<td>open system—anymicroplate assay</td>
<td>open system—anymicroplate assay</td>
<td>open system—anymicroplate assay</td>
<td>open system—anymicroplate assay</td>
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<td>open system—anymicroplate assay</td>
</tr>
</tbody>
</table>

Fully automated microplate system

<table>
<thead>
<tr>
<th>No. of units in microplate</th>
<th>Yes</th>
<th>No</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Methods supported/Separation methods</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of different measured assays onboard simultaneously</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of different assays programmed, calibrated at once</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of user-definable (open) channels</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>No. of different analytes for which system accommodates reagent containers onboard at once/Tests per container set</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Shortest/Median reagent onboard reagent stability/Refrigerated onboard</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Multiple reagent configurations supported</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Reagent container placed directly on system for use</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Reagents bar-coded/Information in barcode</th>
<th>Yes</th>
<th>No</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Same capabilities when 3rd-party reagents used/Susceptibility to carryover</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Walkway capacity in minutes/Specimens/Tests assays</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>System in open (home-brew methods can be used)flask/dry system</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Uses disposable cuvettes/Max. no. stored</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Uses washable cuvettes/Replacement frequency</th>
<th>Yes</th>
<th>No</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Minimum specimen vol. required</th>
<th>Yes</th>
<th>No</th>
</tr>
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<table>
<thead>
<tr>
<th>Primary sample Tube/samples/Pierce caps on primary tubes</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Sample bar-code reading capability/Automate discrimination</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Bar-code placement per MCLed standard AutoDAK</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Onboard test auto inventory (determines vol. in container)</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Measures No. of tests remaining/Start sample detection</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
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<table>
<thead>
<tr>
<th>Auto detection of adequate reagent or specimen</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Clot detection/Reflex testing capability</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Hemolysis detection—quantitation/Turbidity detection—quantitation</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Dilution of patient samples onboard/Automatic rundown range</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Sample vol. can be increased to rundown out-of-linear range results</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Increased to rundown out-of-linear range results</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Time between initial result &amp; manipulation of sample for rundown</th>
<th>Yes</th>
<th>No</th>
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<table>
<thead>
<tr>
<th>Auto calibration or auto calibration alert</th>
<th>Yes</th>
<th>No</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>No. of calibrators required for each analyte</th>
<th>Yes</th>
<th>No</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Calibration can be stored onboard/Avg. calibration frequency</th>
<th>Yes</th>
<th>No</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Multipoint calibr. supported/Multipoint calibr. stored for same assay</th>
<th>Yes</th>
<th>No</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>How often QC required</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Onboard real-time QC Support multiple QC lot Hist. per analytical</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Automatic solution/Startup is programmable/Startup time</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Stir time to completion of 8-H2O test</th>
<th>Yes</th>
<th>No</th>
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<table>
<thead>
<tr>
<th>Time delay from ordering start test to asp. of sample</th>
<th>Yes</th>
<th>No</th>
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</table>

<table>
<thead>
<tr>
<th>Throughput per for all analytes on</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Each specimen, In no. of spec./min./no. of tests (cycle time)</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Can auto transfer QC results to LIS/Onboard capability to review QC</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Data management capability/Instrument vendor supplies LIS interface</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Interfaces up and running in active user sites with</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>LIS interface operates simultaneously w/ running assays</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Uses LIDOC to transmit orders and results</th>
<th>Yes</th>
<th>No</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>How labs get LIDOC codes for reagent kits</th>
<th>Yes</th>
<th>No</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Blood group is necessary to define blood group</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Results transferred to LIS as soon as test time complete</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Interface available (or will be) to auto specimen handling system</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Modern servicing/Can diagnose multiple functions/Default malfunctioning component</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Can order (via modem) malfunctioning part(s) w/ operator</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>On-site response time of service engineer</th>
<th>Within 24 hr</th>
<th>Beyond 24 hr</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Mean time between failures/To repair failures</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Onboard error codes to facilitate troubleshooting</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Avg. time to complete maintenance by tech personnel</th>
<th>Daily: 6–15 min; weekly: 10 min; monthly: 15 min</th>
<th>Daily: 5–10 min; weekly: 5–10 min; monthly: 10–15 min</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Onboard maintenance records/Maintenance training demo module</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>List price/Targeted bed size or daily volume</th>
<th>$38,000/100 beds</th>
<th>$72,000/100 beds</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Annual service contract cost (24 hours/7 days/12 months)</th>
<th>Depends on acquisition option</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Training provided w/ purchase/Advanced operator training</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Distingushing features (supplied by vendor)</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

| Open platform; two sample aspir.; optical; metal needle or disposable plastic tip; precise performance and reliability; accommodates various sample tube sizes including primary tubes within same run | Yes | No |

| Dual arm aspiration with independent wash capabilities; specimen delivery with metal needle or plastic tip within same run; continuous loading remote desktop operation via internet/other buchesen | Yes | No |

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