Aiming to ease lab labor, cost, TAT pressures
Anne Ford

The traditional military strategists’ adage, “Know your enemy,” is advice that laboratory equipment manufacturers have been following for a long time. The enemy, being in this case, the laboratory labor shortage trend, which Grant Howes, director of strategic marketing for Beckman Coulter’s cellular analysis business group, describes as a “now familiar, but ever increasing” dynamic that will “only intensify.” While knowing this particular enemy hasn’t been enough to vanquish it entirely, manufacturers continue to introduce instruments designed to ease the labor shortage’s effects on laboratories. Two of the vendors in this month’s instrumentation survey, Beckman Coulter and Sysmex America, share their perspectives on this and other trends in the hematology analyzer marketplace.

Sysmex America, reports Ron Walczak, director of marketing communications and research, has just received FDA clearance for its XE-5000 hematology analyzer, which the company introduced as part of its XE series expected to be sold as the XE-7100 in 2008, which follows on the heels of the Coulter LH 780 hematology series, introduced in late 2006. Among that series’ features: whole blood count linear range of 0–400,000 and platelet linearity of 0–400,000; automatically enumerated NRBCs; the ability to read even low-print-quality bar-code labels; an RDW-SD parameter; and the ability to obtain an exponentially weighted moving average of CBC, five-part differential, and NRBC results.

Among various volumes and quality results are all very important right now.” And in the future? “Continued increased reliability and less hands-on instrument technology” will be key.

Beckman Coulter plans to launch a new hematology analyzer in 2008, which follows on the heels of the Coulter LH 780 hematology series, introduced in late 2006. Among that series’ features: whole blood count linear range of 0–400,000 and platelet linearity of 0–3,000,000; automatically enumerated NRBCs; the ability to read even low-print-quality bar-code labels; an RDW-SD parameter; and the ability to obtain an exponentially weighted moving average of CBC, five-part differential, and NRBC results, as well as reticulocyte parameters.

“When we look at the near-term future for hematology,” Howes says, “workloads and pressures for shorter turnaround times will continue to increase, as will the pressure to lower costs. That’s why Beckman Coulter’s new products are being designed to provide the solutions labs can use to step up to this new level of challenges.”

Finally, Howes’ colleague Alan Burton, director of marketing for Beckman Coulter’s cellular analysis business group, places great importance on the value of integrated platforms. “Many of our customers know the benefits of integrated platforms,” he says, “and will be happy to know that the range of hematology, chemistry, immunassyay, molecular diagnostics, and flow cytometry platforms made by one manufacturer, as well as reagents, data management, and service, is a trend that promises to continue and grow—especially since this integration addresses so many of the productivity and cost control issues labs face.”

CAP TODAY’s survey of hematology analyzers includes systems not only from Beckman Coulter and Sysmex America but also from Abbott Hematology, Siemens Medical Solutions Diagnostics, and Horiba ABX Diagnostics. Vendors supplied the information listed on this and the following pages. Readers interested in a particular analyzer should confirm it has the stated features and capabilities.

Anne Ford is a writer in Chicago.
## Hematology analyzers

### Part 3 of 11

### Abbott Hematology

**Deborah Archer**  
deborah.archer@abbott.com  
4400 Abbott Park Dr.  
Santa Clara, CA 95054  
800-933-5535  
www.abbottdiagnostics.com

### Beckman Coulter Inc.

**Mary Beth Johnson**  
mjbjohnson@beckman.com  
200 S. Kramer Blvd.  
Brea, CA 92822-6000  
714-993-8438  
www.beckmancoulter.com

### Name of instrument

<table>
<thead>
<tr>
<th>First year installed in U.S./outside U.S./No. of units sold in 2006</th>
<th>No. units installed in U.S./outside U.S./Net price</th>
</tr>
</thead>
</table>
| CELL-DYN 3300  
1997/1997—  
n/a/n/a/$165,000 |

### Test menu

- **Charitable**  
- **Laboratory**  
- **Flags**  
- **PDAs cleared but not clinically released**  
- **Tests not available but submitted for clearance**  
- **Tests in development**  
- **For research use only**  
- **Tests unique to analyzer**  

### Differential method(s) used

**MAPSS (Multi-Angle Polarized Scatter Separation)**  
**Coulter’s 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate technologies**

### Linearly:

- **WBC count (10^9/L)/RBC count (10^12/L)**  
- **Hemoglobin (g/dL)/platelet (10^12/L)**  
- **MCV (fL)/Hct (%)**  
- **Hb/platelet**  
- **MCV or Hct**  

### Precision:

- **±2.7%*/±1.0%**  
- **±1.0%*/±0.4%**  
- **±1.0%*/±0.4%**  
- **±1.0%*/±0.4%**

### Accuracy of automated diff. compared with manual diff.

(see NCCLS H-20A), regression equation

### Interfering substances:

- **WBC**  
- **RBC**  
- **MCV or Hct**  
- **Hb**

### Linear correlation:

- **Hb/platelet**  
- **MCV or Hct**  

### Differential method(s) used

- **WBC**  
- **RBC**  
- **MCV**  
- **Hb**  
- **Platelet**  
- **Platelet fragments, in vitro hemolysis, microcytic RBCs, Pit fragments, long decreased giant Pit.**

### Interfering substances: differential

- **Hemolyzed RBCs**  
- **Autoagglutinins**  
- **NRBC**

### Interfering substances: **biochemical**

**pH**  
**Glucose**  
**Hepatic enzymes**

### Interfering substances: **clinical**

- **Hemoglobin**  
- **Hematocrit**  
- **White blood cell count**

### Interfering substances: **physical**

- **Temperature**  
- **Humidity**  
- **Pressure**

### Interfering substances: **other**

- **Interfering substances: differential**  
- **Interfering substances: biochemical**  
- **Interfering substances: clinical**  
- **Interfering substances: physical**  
- **Interfering substances: other**

### Age- and sex-specific reference ranges

- **Max. CBCs per hr/mputer/CBC & diff. per hr**  
- **Recommended average frequency of calibrations**

### Frequency of blood/lactate controls

- **Min. specimen vol. open/closed/sample dead vol. closed**  
- **Tube sampling supported**  
- **Veterinary capability**

### Interfering substances: **biochemical**

- **pH**  
- **Glucose**  
- **Hepatic enzymes**

### Interfering substances: **clinical**

- **Hemoglobin**  
- **Hematocrit**  
- **White blood cell count**

### Interfering substances: **physical**

- **Temperature**  
- **Humidity**  
- **Pressure**

### Interfering substances: **other**

- **Interfering substances: differential**  
- **Interfering substances: biochemical**  
- **Interfering substances: clinical**  
- **Interfering substances: physical**  
- **Interfering substances: other**

### Max. archived patient data for later comparison

- **Patient-specific archiving**  
- **Max. archived data accessible when system online**  
- **Memory capacity—numeric results—No. specimens**  
- **Memory capacity—histogram/graphics—No. specimens**

### Stored in conjunction with CBC data

- **Hb/platelet**  
- **MCV or Hct**

### Microscopic images & CBC data printed as 1 report

- **Acquisition program based on cost-per-reportable result**  
- **Patient-specific archiving with no. specimens**

### Patient-specific archiving

- **Yes**  
- **No**  
- **Proprietary**

### LIS interface formats supported

- **Information transferred on LIS interface**  
- **LOINC codes transmitted with results**  
- **New labs get LOINC codes for reagent kits**

### Software features

- **Enhanced QC, data archiving, data collection from multiple instruments**  
- **Enhanced QC, data archiving, data collection from multiple instruments**  
- **Enhanced QC, data archiving, data collection from multiple instruments**

### Interfacing with vendor's software systems

- **Command Central**  
- **Command Central**  
- **Command Central**

### Time required for maintenance by lab personnel

- **Daily**  
- **Weekly**  
- **Monthly**  
- **Yearly**

### Onboard diagnostic devices limited to software problems

- **N/A**  
- **Yes**  
- **No**  
- **In development**

### Acquisition program based on cost-per-reportable result

- **Yes**  
- **No**  
- **Proprietary**

### Distinguishing features

- **MAPSS cell-by-cell analysis provides enhanced diff.; focused flow**  
- **2-D optical RBC and PI analysis provides better separation between**

### Summary

**Abbott Hematology**  
**Beckman Coulter Inc.**  
**Mary Beth Johnson**  
**MBJJohnson@beckman.com**  
**200 S. Kramer Blvd.**  
**Brea, CA 92822-6000**  
**714-993-8438**  
**www.beckmancoulter.com**

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Tabulation does not represent an endorsement by the College of American Pathologists.
name of instrument
first year installed in u.s./outside u.s. no. of units sold in 2006 no. units installed in u.s./outside u.s. list price

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mary beth johnson mbjohnson@beckman.com
200 s. kraemer blvd.
bra e 92820-8000
714-993-8438 www.beckmancoulter.com

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name of instrument
test menu:
all instruments have:

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test menu:
charitable
test menu:

beckman coulter inc.
Hematology analyzers

**Part 5 of 11**

**Name of instrument**
First year installed in U.S./outside U.S./no. of units sold in 2006 No. units installed in U.S./outside U.S./ret. price

<table>
<thead>
<tr>
<th>Beckman Coulter Inc.</th>
<th>Beckman Coulter Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mary Beth Johnson</td>
<td>Mary Beth Johnson</td>
</tr>
<tr>
<td><a href="mailto:mbjohnson@beckman.com">mbjohnson@beckman.com</a></td>
<td><a href="mailto:mbjohnson@beckman.com">mbjohnson@beckman.com</a></td>
</tr>
<tr>
<td>520 S. Kraemer Blvd.</td>
<td>520 S. Kraemer Blvd.</td>
</tr>
<tr>
<td>Brea, CA 92822-8000</td>
<td>Brea, CA 92822-8000</td>
</tr>
<tr>
<td>714-993-8438</td>
<td>714-993-8438</td>
</tr>
<tr>
<td><a href="http://www.beckmancoulter.com">www.beckmancoulter.com</a></td>
<td><a href="http://www.beckmancoulter.com">www.beckmancoulter.com</a></td>
</tr>
<tr>
<td>Coulter LH 500</td>
<td>Coulter LH 500</td>
</tr>
<tr>
<td>2003/2000/100 (U.S. only)</td>
<td>1999 Hmx AL, 1999 Hmx CP/110 (U.S. only)</td>
</tr>
<tr>
<td>&gt;900 = 1,000/914,000</td>
<td>AL: 1,775,190/813,000, CP: 130/200/910,000</td>
</tr>
</tbody>
</table>

**Test menu**

<table>
<thead>
<tr>
<th>Charitable</th>
<th>Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC, RBC, Ht, Hct, MCV, MCH, MCHC, % Ht, % Hct, mean, lymph, eos, baso</td>
<td></td>
</tr>
</tbody>
</table>

**POA-cleaned tests but not clinically released**
Tests not available but submitted for clearance
Tests in development
For research use only
Tests unique to analyzer

<table>
<thead>
<tr>
<th>none</th>
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<tbody>
<tr>
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</tr>
<tr>
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<td>none</td>
</tr>
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</table>

**Differential method(s) used**

Linearity:

<table>
<thead>
<tr>
<th>WBC count (10⁹/L)/Hct count (10⁹/L)</th>
<th>Hemoglobin (g/dL)/platelet (10⁹/L)</th>
<th>MCV (fl) or Hct (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–200/0–8</td>
<td>0–20–2,000</td>
<td>50–150 (MCV)</td>
</tr>
<tr>
<td>2.5±/±2</td>
<td>1.5±/±2</td>
<td></td>
</tr>
</tbody>
</table>

**Accuracy of automated diff. compared with manual diff.**

<table>
<thead>
<tr>
<th>MCV in fl</th>
<th>WBC count per mm³</th>
<th>RBC count per mm³</th>
<th>Hb (g/dL)</th>
<th>Platelet</th>
</tr>
</thead>
<tbody>
<tr>
<td>75 ± 7</td>
<td>75 ± 7</td>
<td>75 ± 7</td>
<td>75 ± 7</td>
<td>75 ± 7</td>
</tr>
</tbody>
</table>

**Interfering substances:**

<table>
<thead>
<tr>
<th>WBC</th>
<th>RBC</th>
<th>Hb</th>
</tr>
</thead>
<tbody>
<tr>
<td>lymph&lt;1.5%</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mean diff.</td>
<td>Mean diff.</td>
<td>Mean diff.</td>
</tr>
<tr>
<td>0.5±/±0.5</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Cell types</td>
<td>Cell types</td>
<td>Cell types</td>
</tr>
<tr>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

**Storage in conjunction with CBC data**

<table>
<thead>
<tr>
<th>MCH (fL)</th>
<th>MCHC (%)</th>
<th>MCV (fL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>125 ± 15</td>
<td>125 ± 15</td>
<td>125 ± 15</td>
</tr>
</tbody>
</table>

**Tube solution supported**

<table>
<thead>
<tr>
<th>yes/Tube dependent</th>
<th>yes/Tube dependent</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.25 ± 75 mm or less</td>
<td>13 ± 75 mm or less</td>
</tr>
</tbody>
</table>

**Microsample capability**

<table>
<thead>
<tr>
<th>yes</th>
<th>no</th>
</tr>
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</table>

<table>
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<tr>
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<table>
<thead>
<tr>
<th>yes</th>
<th>no</th>
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**Permits data checks**

<table>
<thead>
<tr>
<th>yes</th>
<th>no</th>
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**Tags and holds results for followup, confirm. testing, or return**

<table>
<thead>
<tr>
<th>yes</th>
<th>yes</th>
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<table>
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<tr>
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<th>yes</th>
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<th>yes</th>
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</table>

**Scannable format: color with threshold**

<table>
<thead>
<tr>
<th>yes</th>
<th>yes</th>
</tr>
</thead>
</table>

**Choice of desired specimen &/or result info. displayed**

<table>
<thead>
<tr>
<th>yes</th>
<th>yes</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>yes</th>
<th>yes</th>
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</table>

**LIS interface format supported**

<table>
<thead>
<tr>
<th>RS-22/32, proprietary</th>
<th>RS-22/32, proprietary</th>
</tr>
</thead>
<tbody>
<tr>
<td>numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS, patient demographics, orders, LIS to instrument—broadcast</td>
<td>numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS, patient demographics, orders, LIS to instrument—broadcast</td>
</tr>
<tr>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>technical support</td>
<td>technical support</td>
</tr>
<tr>
<td>yes, DL2000, Command Central</td>
<td>yes, DL2000, Command Central</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Enhanced OC, data archiving, data collection from multiple instruments, common database, extensive decision rules, delta checking, patient results &amp; graphics, centralized management of instruments</th>
<th>Enhanced OC, data archiving, data collection from multiple instruments, common database, extensive decision rules, delta checking, patient results &amp; graphics, centralized management of instruments</th>
</tr>
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</table>

**Interface avail. or planned to auto. specimen-handling system**

<table>
<thead>
<tr>
<th>yes</th>
<th>no</th>
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**Bar code symbologies read on tube**

<table>
<thead>
<tr>
<th>yes</th>
<th>no</th>
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**Accommodates bar code placement per NCLLS standard Auto2A**

<table>
<thead>
<tr>
<th>yes</th>
<th>yes</th>
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**Time required for maintenance by lab personnel**

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<th>yes</th>
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**Distinguishing features**

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**Technical support**

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<th>yes</th>
<th>no</th>
</tr>
</thead>
</table>
### Hematology analyzers

#### Part 6 of 11

<table>
<thead>
<tr>
<th>Company</th>
<th>Model</th>
<th>Year Installed</th>
<th>U.S. or Outside U.S.</th>
<th>No. of Units Sold in 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beckman Coulter Inc.</td>
<td>Coulter Ac•T 5diff Family</td>
<td>2001/2002</td>
<td>Outside U.S.</td>
<td>115</td>
</tr>
<tr>
<td>Beaker</td>
<td></td>
<td></td>
<td></td>
<td>50</td>
</tr>
<tr>
<td>Corning</td>
<td></td>
<td></td>
<td></td>
<td>30</td>
</tr>
<tr>
<td>HORIBA ABX Diagnostics Inc.</td>
<td>Penta BGC &amp; Hematology Analyzer</td>
<td>2000/2000/52</td>
<td>Outside U.S.</td>
<td>10,000</td>
</tr>
<tr>
<td>PerkinElmer</td>
<td></td>
<td></td>
<td></td>
<td>10,000</td>
</tr>
<tr>
<td>Siemens Healthcare</td>
<td></td>
<td></td>
<td></td>
<td>20,000</td>
</tr>
</tbody>
</table>

#### Test Menu

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>&lt;1 / L</td>
<td>&lt;25,000 / L</td>
</tr>
<tr>
<td>RBC</td>
<td>&lt;4 / L</td>
<td>&lt;10,000 / L</td>
</tr>
<tr>
<td>Hb</td>
<td>&lt;60 g/L</td>
<td>&lt;200 g/L</td>
</tr>
<tr>
<td>MCH</td>
<td>&lt;28 pg</td>
<td>&lt;35 pg</td>
</tr>
<tr>
<td>MCHC</td>
<td>&lt;28 pg%</td>
<td>&lt;35 pg%</td>
</tr>
<tr>
<td>Hct</td>
<td>&lt;30%</td>
<td>&lt;50%</td>
</tr>
<tr>
<td>Plt</td>
<td>&lt;400,000 / L</td>
<td>&lt;1,000,000 / L</td>
</tr>
<tr>
<td>Plateletcrit</td>
<td>&lt;400 / L</td>
<td>&lt;2000 / L</td>
</tr>
</tbody>
</table>

#### Differential Method

- **AIP technology** combining cytochemistry, focused flow impedance, and light absorbance principles of measurement
- **DIAS technology** combining cytochemistry, focused flow impedance, and light absorbance principles of measurement

#### Linearity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>&lt;1 / L</td>
<td>&lt;25,000 / L</td>
</tr>
<tr>
<td>RBC</td>
<td>&lt;4 / L</td>
<td>&lt;10,000 / L</td>
</tr>
<tr>
<td>Hb</td>
<td>&lt;60 g/L</td>
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</tr>
<tr>
<td>MCH</td>
<td>&lt;28 pg</td>
<td>&lt;35 pg</td>
</tr>
<tr>
<td>MCHC</td>
<td>&lt;28 pg%</td>
<td>&lt;35 pg%</td>
</tr>
<tr>
<td>Hct</td>
<td>&lt;30%</td>
<td>&lt;50%</td>
</tr>
<tr>
<td>Plt</td>
<td>&lt;400,000 / L</td>
<td>&lt;1,000,000 / L</td>
</tr>
</tbody>
</table>

#### Differential Substances

- NRBCs, PI clumps, large Plts, lyse-resistant RBCs
- PI clumps, large Plts, lyse-resistant RBCs
- Elevated WBC, Eosinophils
- Extreme lipemia/leukocytosis
- HDL, LDL, VLDL
- LDL/HDL ratio
- HDL mass
- LDL mass
- Apo A-I
- Apo A-II
- Apo B

#### Age- and Sex-Specific Reference Ranges

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>&lt;1 / L</td>
<td>&lt;25,000 / L</td>
</tr>
<tr>
<td>RBC</td>
<td>&lt;4 / L</td>
<td>&lt;10,000 / L</td>
</tr>
<tr>
<td>Hb</td>
<td>&lt;60 g/L</td>
<td>&lt;200 g/L</td>
</tr>
<tr>
<td>MCH</td>
<td>&lt;28 pg</td>
<td>&lt;35 pg</td>
</tr>
<tr>
<td>MCHC</td>
<td>&lt;28 pg%</td>
<td>&lt;35 pg%</td>
</tr>
<tr>
<td>Hct</td>
<td>&lt;30%</td>
<td>&lt;50%</td>
</tr>
<tr>
<td>Plt</td>
<td>&lt;400,000 / L</td>
<td>&lt;1,000,000 / L</td>
</tr>
</tbody>
</table>

#### Archives

- Patient-specific archiving
- Max. archived data accessible when system online
- Memory capacity—numeric results—No. specimens
- Memory capacity—histogram images & CBC data
- Stored in conjunction with CBC data
- Histogram images & CBC data printed as 1 report
- Saved results can be recalled and transmitted
- Saved data can be sorted for reprocessing or report transmission
- Performs delta checks
- Shows trends over time
- User-friendly display
- Choice of desired specimen type

#### LIS Interface

- Format supported
- Information transferred on LIS interface
- LOINC codes transmitted with results
- How labs get LOINC codes for magent kits
- Optional data mgmt. or collation system
- Software features
- Interface avail. or planned to auto. specimen-handling system
- Bar-code symbologies read on tube

#### Time Required for Maintenance

- Time required for maintenance by lab personnel
- Onboard maintenance records
- Time from communication of problem to engineer on site
- Onboard diagnostics limited to software updates
- Mfr. can perform diagnostics vs. modem

#### Acquisition Program

- Acquisition program based on cost-per-reportable result

---

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

**Note:** Transmitted with results.
<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>Pentra XL 80</th>
<th>Pentra DX 120</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. units installed in U.S./outside U.S./list price</td>
<td>114/310/$70,310</td>
<td>19/400/$190,000</td>
</tr>
<tr>
<td>Test menu:</td>
<td>Charitable</td>
<td>standard menu (left) plus: automatic dilution of overrange results</td>
</tr>
<tr>
<td>All instruments have:</td>
<td>Laboratory</td>
<td>WBC, RBC, Hb, MCH, MCHC, WBC, PLT, % MAC, mean, eos, baso, lymph, lymph%, neut, neut%, mono, mono%, retic, retic%, eos, eos%, baso, baso%, lymph%, lymph%, ige, ige%</td>
</tr>
<tr>
<td>+ Flaps</td>
<td>operator selectable flagging</td>
<td>LIC%, LIC%, lyse resistant RBCs, MRV, MFI%, % MRV, NRBC, true NRBC, true MRV, retic, retic%</td>
</tr>
<tr>
<td>FDA-cleared tests but not clinically released</td>
<td>none</td>
<td>double-diff. matrix pending 510 (k)</td>
</tr>
<tr>
<td>Tests not available but submitted for clearance</td>
<td>none</td>
<td>double-diff. matrix pending 510 (k)</td>
</tr>
<tr>
<td>Tests in development</td>
<td>none</td>
<td>—</td>
</tr>
<tr>
<td>For research use only</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Tests unique to analyzer</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

**Differential Differential methods used**

**Linearity:**
- WBC count (10^3/L)/RBC count (10^6/L)
- Hemoglobin (g/dL)/PLT (10^9/L)
- MCV (FL) or Hct (%)

**Precision:**
- WBC count/PLT count
- open, closed/WBC, RBC, Hb, Hct, PLT, MPV

**Accuracy of automated diff. compared with manual diff.**

**Interfering substances:**
- WBC
- RBC
- MCV or Hct
- PLT
- Hb

**Interfering substances: differential**
- NRBCs, low-resist RBCs, extreme hypereosinophilia
- NRBCs, low-resist RBCs, extreme hypereosinophilia

**Age- and sex-specific reference ranges**
- yes
- yes

**Max. CBCs per hr/Max. CBCs & diffs. per hr per CLIA standards/none**
- 60/60
- 120/120

**Recommended average frequency of calibr.**
- 6 months
- 6 months

**Modes calibrated/parameters calibrated**
- yes
- yes

**Frequency of blood/latex controls**
- per CLIA standards/none
- per CLIA standards/none

**Min. specimen vol. open/closed/sample dead vol. closed**
- 35 µL for CBC/35 µL for CBC + diff./5.5 µL
- 30 µL for CBC/35 µL for CBC + diff./5.5 µL

**Tubes sampled supported**
- yes (auto loader 13 > 75; open tube 16 sizes + micro)
- yes (auto loader 13 > 75; closed tube 16 sizes + micro)

**Veterinary capability**
- yes
- yes

**Microsample capability**
- yes, open mode
- yes

**Prepares microscopic slides automatically or flags problems for slide prep**
- yes
- yes

**If auto. slides maker available, no. installed/list price**
- —
- —

**Archives patient data for later comparison**
- yes
- yes

**Patient-specific archiving**
- yes, with MultiLink Data Manager
- yes (MultiLink)

**Max. archived data accessible when system online**
- MultiLink Data Manager; 10,000 instrument only
- unlimited Data Manager; 10,000 instrument only

**Memory capacity—numeric results—No. specimens**
- yes
- yes

**Memory capacity—histo/cytograms—No. specimens**
- yes
- yes

**Comparison of desired specimen to result info. displayed**
- yes
- yes

**LIS interface formats supported**
- proprietary, ASTM 1394 & 1238, HL7, IEEE MIB
- proprietary, ASTM 1394 & 1238, HL7, IEEE MIB

**Information transferred on LIS interface**
- PROPRIETARY, ASTM 1394 & 1238, HL7, IEEE MIB
- PROPRIETARY, ASTM 1394 & 1238, HL7, IEEE MIB

**LOINC codes transmitted with results**
- n/a
- n/a

**How labs get LOINC codes for reagent kits**
- yes (MultiLink)
- enhanced QC, data archiving, data collation from multiple instruments

**Enhanced LOINC code from reagent kits**
- yes (MultiLink)
- enhanced QC, data archiving, data collation from multiple instruments

**Distinguishing features**
- compact 5-part differential instrument with autoloader and autodilution capability, autoloader feature, autodilution
- high-throughput cell counter with integrated reticulocyte methodology and slide-based reader; fluorescent MBG counting, auto rerun and reflex testing, autodilution
**Hematology analyzers**

**Part 8 of 11**

Siemens Medical Solutions Diagnostics

<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>Siemens Medical Solutions Diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td>First year installed in U.S./outside U.S.</td>
<td>1999/1999/1999</td>
</tr>
<tr>
<td>No. units installed in U.S./outside U.S./Net price</td>
<td>&gt;795,100/169,000/$189,000</td>
</tr>
</tbody>
</table>

**Test menus:**

<table>
<thead>
<tr>
<th>Menu</th>
<th>Charitable</th>
<th>Laboratory</th>
<th>Flags</th>
</tr>
</thead>
<tbody>
<tr>
<td>complete RBC lysis</td>
<td>standard menu (left) plus: CHCM, MPX, RDW, HDW, LUC %/&amp;, retic %/&amp;, CHCM, CHCM, MCV, CF: WBC, RBC, PMN, MM, neut, lymph, mononuclear cell, globular cell, &amp; lymph</td>
<td>none</td>
<td>none</td>
</tr>
</tbody>
</table>

**FDA-cleared tests but not clinically released:**

| Tests not available but submitted for clearance | none |

**For research use only:**

| Tests unique to analyzer | none |

**Differential method(s) used:**

**Linearity:**

<table>
<thead>
<tr>
<th>Method</th>
<th>WBC count (10^9/L)</th>
<th>RBC count (10^12/L)</th>
<th>Hemoglobin (g/dL)</th>
<th>platelet (10^9/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RH manual</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>RH automated</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
</tbody>
</table>

**Time from communication of problem to engineer on site:**

| Time required for maintenance by lab personnel | 6 months |
| Time from communication of problem to engineer on site | 6 months |

**Accessories and supplies:**

<table>
<thead>
<tr>
<th>Material</th>
<th>Name</th>
<th>User/vendor</th>
<th>Yes</th>
<th>No</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>slides</td>
<td>Euroslide</td>
<td>user/vendor</td>
<td>yes</td>
<td>no</td>
<td>$100,000</td>
</tr>
</tbody>
</table>

**LIS interface formats supported:**

**Information transferred on LIS interface:**

<table>
<thead>
<tr>
<th>Information transferred</th>
<th>LIS interface formats supported</th>
</tr>
</thead>
<tbody>
<tr>
<td>site demographics and orders (when bar code is read, host is queried for</td>
<td>yes (CentraLink)</td>
</tr>
<tr>
<td>Parameters for holding samples are defined by standards</td>
<td>yes (CentraLink)</td>
</tr>
<tr>
<td>Some results can be transmitted to LIS while others held</td>
<td>yes (CentraLink)</td>
</tr>
<tr>
<td>Scattergram display: cell-specific color</td>
<td>yes (CentraLink)</td>
</tr>
<tr>
<td>Histogram display: color with threshold</td>
<td>yes (CentraLink)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test menu</th>
<th>CHCM, HDW, Ch, CHCM, MCV, MPC, MPF, CSF: WBC, RBC, MM, neut, lymph, mononuclear cell, &amp; lymph</th>
</tr>
</thead>
<tbody>
<tr>
<td>Values</td>
<td>MCH, MCHC, Plt, % neut, lymph</td>
</tr>
<tr>
<td>Minimum</td>
<td>none</td>
</tr>
</tbody>
</table>

**Distinguishing features:**

| unique laser technology provides cellular Hb for RBCs and retics; 2-D PB analysis that eliminates interference from RBC fragments and inclusion of large Pits; dual WBC counts with a linearity of up to 400,000; CF assay | unique laser technology provides direct cellular Hb for RBCs and retics; 2-D PB analysis that eliminates interference from RBC fragments and inclusion of large Pits; dual WBC counts with a linearity of up to 400,000; CF assay |

**Tarrytown, NY 10591**

800-255-6070 www.siemens.com/diagnostics

**Advia 120 Hematology System**

2004/2004/2004... | >2000/1000/$225,000
### Hematology analyzers

#### Part of 11

<table>
<thead>
<tr>
<th>Sysmex America Inc.</th>
<th>Sysmex America Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audrey Woodbeck</td>
<td>Audrey Woodbeck 1</td>
</tr>
<tr>
<td>1 Nelson C. White Pkwy.</td>
<td>Mundelein, IL 60060</td>
</tr>
<tr>
<td>800-379-7639</td>
<td>800-379-7639</td>
</tr>
<tr>
<td><a href="http://www.sysmex.com/usa">www.sysmex.com/usa</a></td>
<td><a href="http://www.sysmex.com/usa">www.sysmex.com/usa</a></td>
</tr>
</tbody>
</table>

#### Name of instrument

First year installed in U.S./outside U.S./no. of units sold in 2006

<table>
<thead>
<tr>
<th>Sysmex XE-2100</th>
<th>2000/1200</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006/1200/12</td>
<td>$230,000</td>
</tr>
</tbody>
</table>

#### Test menu:

- **Test menu:**
  - Standard menu (left) plus: NRBC %, retic %, RDW-SD, RDW-CV, MCV, MCH, MCHC, Hct, Plt count, Hct, WBC count, MCV, MCH, MCHC, Hct, WBC, RBC, Hb, Hct, Plt, microgranulocyte, lymphocytes, eosinophils, basophils

- **Standard menu (right):**
  - Pitt clumps, RBC agglutination, turbidity, WBC ABN scattergram, RBC ABN distribution, RBC lyse resistance, blasts, left shift, atyp. lymph., RBC lympholysis, ret. RBC agglutination

- **FDA-cleared tests but not clinically released:**
  - None

- **Tests not available but submitted for clearance:**
  - None

- **For research use only:**
  - P-LCR, PCT, PWD

- **Tests unique to analyzer:**
  - HPMA, HIC, RET, HIF, IF

#### Differential method(s) used

- **Linearity:**
  - WBC count (per 10^8/L): 0–4,400 (8–250–5,000)
  - Hemooglobin (g/dL): 0.75 (5–1.5)
  - MCV (fL) or Hct (%): 0.81 (%)/4.0
  - Hemoglobin (g/dL): 0.75 (5–1.5)
  - MCV (fL) or Hct (%): 0.81 (%)/4.0
  - MCH (fL): 0.81 (5–1.5)
  - MCHC (%): 0.81 (5–1.5)
  - MCV or Hct: 0.81 (5–1.5)

- **Fluorescent flow cytometry, RF/OC detecting method:**
  - Cold agglut., Plt aggreg., lymphocytes, hypo-lyse-resistant RBCs

- **Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation:**
  - neutrophils: 0.95, y=0.92x+0.46; lymphocytes: 0.96, y=0.92x+2.83; monocytes: 0.97, y=0.77x+1.80; eosinophils: 0.92, y=0.07x+0.29; basophils: 0.82, y=0.1x+0.01; MCV: 0.99, y=1.23x+0.11; Hct: 0.93x+0.0022

#### Interfering substances:

- **WBC:** cold agglutination, lymphocytes, RBC red cell fragility, spherocytosis
- **RBC:** cold agglutination, severe microcytosis, hypochromic RBCs
- **Plt:** cold agglutination, severe microcytosis, hypochromic RBCs

### Age- and sex-specific reference ranges

- Max. CBCs per hr:
  - Max. CBCs & diff.s: 150/150
  - Max. platelet & diff.s: 0–250/0–5,000

- Recommended average frequency of calibr.
  - Open, closed, capillary/WBC, RBC, Hb, Hct, Plt

- Tube sampling supported:
  - Yes

- Veterinary capability:
  - Yes

- Microsample capability:
  - Yes

- Issues with microscopic slides automatically or flags problems for slide prep:
  - Yes with Alpha or HST upgrade

- If auto. sidestream available, No. installed/list price:
  - >1,000

- Archives patient data for later comparison:
  - Yes

- Patient-specific archiving:
  - Yes

- Max. archived accessible when system online:
  - Yes

- Memory capacity—numeric results:
  - Yes

- Memory capacity—histogram—No. specimens:
  - Yes

- Stored in conjunction with CBC data:
  - Yes

- Hi-8 hypocytogram images & CBC data printed as 1 report:
  - Yes

- Results can be recalculated and retested:
  - Yes

- Results can be sorted for reprocessing or report transmission:
  - Yes

- Performs cell checks:
  - Yes

- Taps and results for followup, confirm. testing, or runout:
  - Yes

- Parameters for flags for holding samples are defined by:
  - Yes

- Some results can be transmitted to LIS while others held:
  - Yes

- Scanning display: color by threshold:
  - Yes

- Choice of desired specimen &/or result info. displayed:
  - Yes

- LIS interface formats supported:
  - RS-232/C/TCP IP

- Informaton

#### LUS interface

- RS-232/C/TCP IP
  - Numeric & flag results, histograms & scatterplots, patient demographics, orders, contacts, vendor, proprietary, enhanced QC, data archiving, data retrieval from multiple instruments, multiple sites

- Roche, Labsys, A&T, Thermo

- Codabar, codes 39 & 128, interl. 2 of 5, ITF, WW7, EAN 8 & 13

#### Time required for maintenance by lab personnel

- Onboard maintenance:
  - Daily: <3 min.
  - <24 hours
  - Yes/no
  - Yes, also via Internet

#### Acquisition program based on cost-per-result report

- Thousands of 150 CBCs per hour; random access; discrete testing; O/C, remote diagnostics, body fluid analysis; planelinearity to 5 million, hemocrit non-linear to 75%; hematopoietic progenitor cell testing; immature granulocyte enumeration; immature platelet fraction; reticulocyte hemoglobin equivalent, standardized reagents, controls and operations with other Sysmex X-Series analyzers.

- 150 CBCs/hr; platelet linearity—5 million, hemocrit extended to 75%; standardized technology, reagents, controls and operations

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Tabulation does not represent an endorsement by the College of American Pathologists.
**Hematology analyzers**

### Part 10 of 11

**Sysmex America Inc.**

1 Nelson C. White Pkwy.

Mundelein, IL 60060

800-579-7639

www.sysmex.com/usa

<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>First year installed in U.S./outside U.S./No. of units sold in 2006</th>
<th>No. units installed in U.S./outside U.S./list price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sysmex XE-Alpha N/NST-N</td>
<td>2000/—/150</td>
<td>$1,000,000/—/$2,000,000</td>
</tr>
</tbody>
</table>

**Test menu:**

- **Charitable**
  - Standard menu (left) plus: RDW-SE, RDW-CV, Hgb, RBC, HCT, NRBC, MPV, REC, RPE, WPL, reagents, controls and operations with other X-Series analyzers.
- **Laboratory**
  - None
- **Flips**
  - User defined, all inclusive
- **FDI-cleared tests but not clinically released**
  - None
- **Tests not available but submitted for clearance**
  - None
- **Tests in development**
  - None
- **For research use only**
  - None
- **Tests unique to analyzer**
  - None

**Differential method(s) used:**

- **Linearities:**
  - Fluorescent flow cytometry, IF/IC detecting method
  - Standard menu (left) plus: retic %/plt, IH, HFR, MPV, RDW-SE, RDW-CV

**Accuracy of automated diff. compared with manual diff.**

- (per NCCLS H-20A), regression equation

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Method</th>
<th>Equation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>A</td>
<td>y = 0.77x + 1.88</td>
</tr>
<tr>
<td>RBC</td>
<td>A</td>
<td>y = 11.37x + 1.89</td>
</tr>
<tr>
<td>WBC</td>
<td>A</td>
<td>y = 0.94x + 0.04</td>
</tr>
<tr>
<td>Platelet</td>
<td>A</td>
<td>y = 0.76x + 0.24</td>
</tr>
<tr>
<td>MCV or Hct</td>
<td>A</td>
<td>y = 0.79x + 0.01</td>
</tr>
<tr>
<td>MCH or RBC</td>
<td>A</td>
<td>y = 0.92x + 5.46</td>
</tr>
<tr>
<td>Neut</td>
<td>A</td>
<td>y = 0.95x + 5.46</td>
</tr>
<tr>
<td>Lymph</td>
<td>A</td>
<td>y = 0.88x + 2.46</td>
</tr>
<tr>
<td>Mono</td>
<td>A</td>
<td>y = 0.83x + 0.09</td>
</tr>
<tr>
<td>Eos</td>
<td>A</td>
<td>y = 0.95x + 0.77</td>
</tr>
<tr>
<td>Baso</td>
<td>A</td>
<td>y = 0.83x + 0.09</td>
</tr>
</tbody>
</table>

**Interfering substances:**

- Cold agglut., PIT aggreg., nucle., RBCs, cryoglob., lymph-resistant RBCs
- Cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts in vitro hemolysis
- Cold agglut., PIT aggreg., lymph-resistant RBCs
- Lymph-resistant RBCs

**Interfering substances: differential**

- Age- and sex-specific reference ranges
- Max. CBCs per hr/max. CBCs & diffs, per hr
- Recommended average frequency of calibr.
- Frequency of blood/latex controls
- Min. specimen vol. open/closed/sample dead vol. closed
- Tube sampling supported
- Veterinary capability
- Microsample capability
- Microscopic slides automatically or flags problems for slide prep
- If auto. sidemarker available, No. installed/list price

**Archives patient data for later comparison**

- Yes

**Patient-specific archiving**

- Yes

**Max. archived data accessible when system online**

- Yes

**Memory capacity—numeric results-No. specimens**

- 10,000 samples

**Memory capacity—histogram/data—specimens**

- 10,000 samples

**Modes calibrated/parameters calibrated**

- Yes

**HLA/lymphocytes in blood plasma, severe leukocytosis**

- Yes

**Microscopic slides automatically or flags problems for slide prep**

- Yes

**If auto. sidemarker available, No. installed/list price**

- >1,000/$250,000

**Interface formats supported**

- RS-232C/TCP IP

**Information transferred on LIS interface**

- Yes

**LOINC codes transmitted with results**

- Yes

**New labs get LOINC codes for reagent kits**

- Yes

**Optional data mgmt. or collation system**

- Yes

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

- Yes

**ENHANCED QC, data archiving, data collation from multiple instruments, multiple sites**

- Yes

**Interface avail. or planned to auto. specimen-handling system**

- Roche, Labosys, Ibis, A&T

**Bar-code symbologies read on tube**

- Codabar, codes 39 & 128, interl. 2 of 5, ITF, WW, EAN 8 & 13

**Acceptable bar-code placement per NCCLS standard Auto2A**

- Yes

**Time required for maintenance by lab personnel**

- Daily: <3 min

**Onboard maintenance records**

- Yes

**Time from communication of problem to engineer on site**

- <24 hours

**Onboard diagnostics/limited to software problems**

- No

**Mfr. can perform diagnostics via modems**

- Yes, also via Internet

**Acquisition program based on cost-per-reportable result**

- Yes

**Distinguishing features**

- High throughput, flexible, scalable configurations available; platelet linear—5 million; new parameters for platelet monitoring—HP & retic Hgb measurement & RET He, hematopoietic progenitor cell analysis, lavender top, management, standardized technology, reagents, controls and operations

- High throughput, remote diagnostics; online QC, random access; fluorescent optical platelets; discrete testing; reagent monitoring; customized chartable report formats; XT-V unit for use in toxicology & research and veterinary reference labs, body fluids new FDA cleared, standardized technology, reagents, controls and operations with other X-Series analyzers

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

Part 11 of 11

Sysmex America Inc.
Margaret Traita
1 Nelson C. White Pkwy.
Mundelein, IL 60060
800-379-7639
www.sysmex.com/usa

Name of instrument
First year installed in U.S./outside U.S./No. of units sold in 2006
No. units installed in U.S./outside U.S./list price

| Sysmex XT-1800i | 2002/—/150 | 760/14,000/$125,000 |

Test menu
All instruments have: WBC, RBC, M, Ht, MCV, MCH, MCHC, % lymph, eos, baso, mono, lymphocyte, eos, baso, neut.

| +Charitable | standard menu (left) plus: MPV, RDW-50, RDW-CV |
| Laboratory | none |
| Flags | Pit clumps, PT, ABN distribution, WBC ABN scattergram, blast imm. gran., left shift, stips, lymph, AMY, lymph blasts, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity, NRBC |

FDA-cleared tests but not clinically released
Tests not available but submitted for clearance
Tests in development
For research use only
Tests unique to analyzer

| body fluids | none |
| immature gran. % & # | none |

Accuracy of automated diff. compared with manual diff.

Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation

| neut% r=0.95, y=0.916x+3.38; lymph% r=0.96, y=0.81a x+1.67; mono% r=0.90, y=1.137x+1.89; eos% r=0.94, y=0.97x+0.04; baso% r=0.76, y=0.48a x+0.24 |

Interfering substances: WBC

| cold agglut., PT aggl., cryoglobulin, lyse-resistant RBCs, NRBCs |

Interfering substances: RBC

| cold agglut., severe microcytosis, frag. RBCs, leukocytosis |

Interfering substances: MCV or Hct

| Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100 fL) |

Interfering substances: Platelet

| pseudothrombocytopenia, PT aggl., incr. microcytosis, megaloblasts |

Interfering substances: differential

| lymphopenia, ABN proteins, leukocytosis |

Age- and sex-specific reference ranges

| Max. CBCs per hr/max. CBCs & diffs, per hr |

Recommended average frequency of calibs.

| 60/80 |

--/— |

Tests unique to analyzer

Distinguishing features

| remote diagnostic; online QC; random access; discrete testing; reagent monitoring; charitable report formats; XT-V for use in toxicology, research and veterinary reference labs; unique specimen-gating SW to FDA Part II compliant; body fluids now FDA cleared; standardized technology, reagents, controls and operations with other X-Series analyzers |

Distinguishing features

| standardized technology, reagents, controls and operations to other X-Series analyzers; small sample volume requirements for CBC + 5 part diff. |

Contact vendor

| 800-379-7639 |

Mundelein, IL 60060

1 Nelson C. White Pkwy.

Margaret Triola

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Access program based on cost-per-reportable result

| yes |

Available grants

| yes |

Acquisition program based on cost-per-reportable result

| yes |

Available grants

| yes |

Access program based on cost-per-reportable result

| yes |

Available grants

| yes |

Access program based on cost-per-reportable result

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