Hematology analyzers: an overview of what’s new

Brendan Dabbkowski

Putting their money where their market is, companies in CAP TODAY’s hematology analyzers product guide are introducing systems to meet growing test demands and the need for enhanced functionality.

“Automated hematology systems with advanced, clinically relevant parameters that can potentially impact treatment guidelines, care pathways, patient flow, and return on investment are essential,” says Alan Burton, director of marketing, hematology, at Sysmex America. To this end, Sysmex recently added to its product lineup the XT-4000i automated hematology analyzer. The XT-4000i provides 34 parameters, including immature granulocyte and reticulocyte hemoglobin. It has a body fluid-specific mode that provides a reportable RBC count, WBC count, WBC differential, and total count for all common body fluid samples. The system, Burton says, can run 100 samples per hour and uses fluorescent flow cytometry, hydrodynamic focusing, and advanced cell-counting methods to deliver rapid results. The XT-4000i can be used with the company’s Work Area Manager decision support software, he adds, to improve sample and data workflow and decrease turnaround time.

Sysmex recently launched its cell image analysis portfolio (not featured in the product guide), which includes the CellView DM1200 and DM96 systems for mid-size to large hematology laboratories and the Medica EasyCell Assistant for smaller hematology labs.

Abbott Hematology has added to its hematology program two software packages—V3 and V4—for the company’s Cell-Dyn Sapphire hematological analyzer, says Bill Bailey, U.S. marketing manager, hematology. Both software bundles allow Sapphire users to troubleshoot problems and receive updates remotely through Abbott-Link, which, he says, translates to improved reliability and increased uptime for high-volume hematological labs.

Abbott launched in June the Pathfinder sample management system. The product, says Bailey, combines “process management, Cell-Dyn instrument technology, comprehensive middleware, and logical sample management to reduce manual steps and optimize technologist efficiency and productivity.”

Finally, Siemens Healthcare Diagnostics recently introduced additional automated body fluid-specific applications to its Advia 2120i system to complement the company’s cerebrospinal fluid assay. Automating these labor-intensive assays allows laboratories to better balance rising work volumes with decreasing staffing, says Fred Stelling, director of global hematologic marketing. Looking to the future, Siemens is focusing on integrating hematology results and other lab data into a “wider network of intelligent information management,” he says.

CAP TODAY’s guide to hematology analyzers includes products from the aforementioned manufacturers and from Beckman Coulter and Horiba Medical. Companies supplied the information listed. Readers interested in a particular system should confirm it has the stated features and capabilities.

Brendan Dabbkowski is CAP TODAY associate editor.
## Hematology analyzers

### Part 2 of 14

<table>
<thead>
<tr>
<th>Abbott Hematology</th>
<th>Abbott Hematology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rick Goch</td>
<td>Karen Busch</td>
</tr>
<tr>
<td>5440 Patrick Henry Dr.</td>
<td><a href="mailto:karen.busch@abbott.com">karen.busch@abbott.com</a></td>
</tr>
<tr>
<td>Santa Clara, CA 95054</td>
<td><a href="http://www.abbottdiagnostics.com">www.abbottdiagnostics.com</a></td>
</tr>
</tbody>
</table>

### Name of instrument
- **CELL-DYN Ruby**
- **CELL-DYN Emerald**

### Test menu:
- Charitable (standard menu: WBC, RBC, Hb, Hct, MCV, MCHC, PLT, percent, n tert. menu, lymph, eos, baso)
- **Laboratory**
- **Flags**

### FDA-cleared tests not currently released
- **Tests available but submitted for clearance**
- **Tests in development**
- **Tests not available but submitted for clearance**

### Age- and sex-specific reference ranges

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cell-Dyn Ruby</th>
<th>Cell-Dyn Emerald</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCV/Plt</td>
<td>5.3–75.6 fL/1.7 percent</td>
<td>5.3–75.6 fL/1.7 percent</td>
</tr>
<tr>
<td>Hct/Plt</td>
<td>41–61 percent/14.0–9.0 mm</td>
<td>41–61 percent/14.0–9.0 mm</td>
</tr>
</tbody>
</table>

### Microsample capability
- **yes**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cell-Dyn Ruby</th>
<th>Cell-Dyn Emerald</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>5.0–15.0 × 10⁹/µL</td>
<td>5.0–15.0 × 10⁹/µL</td>
</tr>
<tr>
<td>RBC</td>
<td>4.0–5.5 × 10¹²/µL</td>
<td>4.0–5.5 × 10¹²/µL</td>
</tr>
<tr>
<td>Hb</td>
<td>12.0–16.0 g/dL</td>
<td>12.0–16.0 g/dL</td>
</tr>
<tr>
<td>Hct</td>
<td>36.0–47.0 percent</td>
<td>36.0–47.0 percent</td>
</tr>
</tbody>
</table>

### Accuracy of automated differential compared with manual

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cell-Dyn Ruby</th>
<th>Cell-Dyn Emerald</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCV/Plt</td>
<td>1.7 percent</td>
<td>1.7 percent</td>
</tr>
<tr>
<td>Hct/Plt</td>
<td>1.7 percent</td>
<td>1.7 percent</td>
</tr>
</tbody>
</table>

### Differential methods used
- MAPSS (Multi-Angle Polarized Scatter Separation)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Cell-Dyn Ruby</th>
<th>Cell-Dyn Emerald</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC count</td>
<td>0.02–246 × 10⁹/µL</td>
<td>0.02–246 × 10⁹/µL</td>
</tr>
<tr>
<td>RBC count</td>
<td>0.00–53 × 10¹²/µL</td>
<td>0.00–53 × 10¹²/µL</td>
</tr>
<tr>
<td>MCHC</td>
<td>0.8 percent</td>
<td>0.8 percent</td>
</tr>
<tr>
<td>MCV/Plt</td>
<td>58–173 fL</td>
<td>58–173 fL</td>
</tr>
</tbody>
</table>

### Interfering substances:
- **WBC**
- **RBC**
- **MCV or Hct**
- **Platelet**
- **Hemoglobin**

### Interfering substances: differential
- **WBC**
- **RBC**
- **MCV or Hct**
- **Platelet**
- **Hemoglobin**

### LIS interface formats supported
- **LIS1/LUS CLSI**

### LQAC codes transmitted with results
- **no**

### Optional data management or collection system
- **Software features**

### Accommodates bar-code placement per CLSI standard Auto2A
- **yes**

### Time required for maintenance by lab personnel
- **daily: 30 seconds; weekly: 5 minutes; monthly: 10 minutes**

### Acquisition program based on cost-per-reportable result
- **no**

### Distinguishing features (supplied by company)
- **touch-sensitive screen, all optical technology; onboard maintenance videos; lyse-resistant RBC mode; rules-based result annotations**

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Note: *please see the CELL-DYN Ruby operator’s manual for product labeling, including warnings, limitations, and precautions*
**Hematology analyzers**

### Test menu

- **Charitable (standard menu; WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&delt; nucleo, mono, lymph, eos, baso):**
  - **Laboratory**
  - **Flags**
- **FDA-cleared tests but not clinically released**
- **Tests not available but submitted for clearance**
- **FDA-cleared tests but not clinically released**
- **Tests unique to analyzer**
  - **IRE, veterinary capabilities**

### Differential method(s) used

- **WBC count (10³/L):**
- **Hemoglobin (g/dL):**
- **MCV (fL):**
- **Hct (%):**
- **MCH (pg):**
- **MCHC (g/dL):**
- **MPV (fL):**
- **PLT (10⁴/µL):**

### Interfering substances

- **WBC:**
- **RBC:**
- **MCV or Hct:**
- **Platelet:**
- **Hemoglobin:**

### Age- and sex-specific reference ranges

### Maximum CBCs per hour

### Recommended average frequency of calibration

### Interfering substances: differential

### Microsample capability

### Preparation of microscopic slides automatically or flags problems for slide prep

### If automatic slide maker available, No. installed/list price

### Archives patient data for later comparison

### Patient-specific archiving

### Maximum archived data accessible when system online

### Memory capacity—numeric results—No. specimens

### Memory capacity—histo/cytograms—No. specimens

### Stored in conjunction with CBC data

### Histocytogram images and QC data printed as one report

### Saved results can be recalled and retransmitted

### Saved data can be sorted for reprocessing or report transmission

### Performs delta checks

### Logical connectivity

### Tag and holds results for follow-up, confirmatory testing, or rerun

### Parameters for flags for holding samples are defined by

### Some results can be transmitted to LIS while others held

### Scattergram display: cell-specific color

### Histogram display: color with threshold

### Choice of desired specimen and/or result information displayed

### LIS interface formats supported

### Information transferred on LIS interface

### LOINC codes transmitted with results

### How labs get LOINC codes for reagent kits

### Optional data management or collation system

### Software features

### Interface available or planned to automate specimen-handling system

### Accommodates bar-code placement per CLSI standard

### Time required for maintenance by lab personnel

### Onboard maintenance records

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

### Onboard diagnostics/limited to software problems

### Manufacturer can perform diagnostics via modem

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

### Distinguishing features (supplied by company)

### MAPSS (Multi-Angle Polarized Scatter Separation)

### Flow cytometric digital analysis using volume, conductivity, and five angles of light scatter, digital signal processing, advanced algorithm applications, high-definition cellular resolution, DataFusion

### Linearity:

### Precision:

### Accuracy of manual-differential compared to manual differential (per CLSI H-20A), regression equation

### Interfering substances: WBC

### Interfering substances: RBC

### Interfering substances: MCV or Hct

### Interfering substances: Platelet

### Interfering substances: Hemoglobin

### Interfering substances: Differential

### Age and sex-specific reference ranges

### Maximum CBSs per hour

### Recommended average calibration frequency

### Modes calibrated/parameters calibrated

### Frequency of blood/latex controls

### Minimum specimen volume open/closed

### Tube sampling supported

### Veterinary capability

### Microsample capability

### Prepares microscopic slides automatically or flags problems for slide prep

### If automatic slide maker available, No. installed/list price

### Archives patient data for later comparison

### Patient-specific archiving

### Maximum archived data accessible when system online

### Memory capacity—numeric results—No. specimens

### Memory capacity—histo/cytograms—No. specimens

### Stored in conjunction with CBC data

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### Onboard maintenance records

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

### Onboard diagnostics/limited to software problems

### Manufacturer can perform diagnostics via modem

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

### Distinguishing features (supplied by company)
### 26 / CAP TODAY

#### December 2010

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**Hematology analyzers**

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**Part 4 of 14**

**Beckman Coulter**

Jim Cureton  jcureton@beckman.com

250 S. Kraemer Blvd

Brea, CA 92821

714-961-4942  www.beckmancoulter.com

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<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>First year installed in U.S./Outside U.S./No. of units sold in 2009</th>
<th>No. units installed in U.S./Outside U.S./List price</th>
</tr>
</thead>
<tbody>
<tr>
<td>LH 1500 Hematology Automation Series</td>
<td>2002/2003/15</td>
<td>&gt;65/25/varies</td>
</tr>
</tbody>
</table>

---

**Test menu:**

- **Charitable (standard menu):** WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&amp; neut, mono, lymph, eos, baso:
  - Standard menu (left) plus: RDW, MPV, retic %&amp; IRF, HRF, graded RBC morph., NRBC %&amp; TNC &amp; RBC on CSF, synovial, and serous fluids
  - Laboratory
  - Flags
  - User-definable age- gender- and/or location-based reference intervals; action and critical limits; user-definable RBC morphology; user-selectable sensitivity for differential, abnormal population suspect messages
  - FDA-cleared tests but not clinically released
  - Tests not available but submitted for clearance
  - Tests in development
  - Tests not available but submitted for clearance
  - FDA-cleared tests but not clinically released
  - Tests not available but submitted for clearance
  - FDA-cleared tests but not clinically released

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**Tests unique to analyzer IVD:**

- NRBC, body fluids; RUO: MSCV, WBC RPD

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**Tests not available but submitted for clearance**

- NRBC, body fluids, RDW-SD; RUO: MSCV, RSF, MAF, WBC RPD

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**Methodologies used**

- Coulter’s 3-D VCS biophysical flow cytometry with IntelKinetics, AccuGate, and AccuFlex technologies

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**Manufacturers can perform diagnostics via modem**

- Yes yes

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**Onboard diagnostics/limited to software problems**

- Yes/no yes/no

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

- — —

---

**Onboard maintenance records**

- Yes yes

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**Time required for maintenance by lab personnel**

- Daily: automation system = 5 minutes; monthly: automation = 15 minutes, analyzer = 2 minutes

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**Distinguishing features (supplied by company)**

- System automatically loads and unloads cassettes, performs retic and report testing, sorts tubes for off-line tests, stores tubes with availability for retrieval for any test type; multiple configurations available; RUO: WBC research population data

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**Contact information**

- Jim Cureton  jcureton@beckman.com

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**Corporate headquarters**

- Brea, CA 92821

---

**Website**

- www.beckmancoulter.com

---

**Phone number**

- 714-961-4942

---

**Facsimile number**

- 714-961-4942

---

**Address**

- 714-961-4942

---

**Company website**

- www.beckmancoulter.com

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**Technical support**

- jdcureton@beckman.com

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**Note:** A dash in lieu of an answer means company did not answer question or question is not applicable.
### Hematology analyzers

#### Part 5 of 14

Beckman Coulter  
250 So. Kraemer Blvd  
Brea, CA 92821  
714-961-4942  
www.beckmancoulter.com

Beckman Coulter  
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Brea, CA 92821  
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**Name of instrument**  
Coulter LH 750

**First year installed in U.S./outside U.S./No. of units sold in 2009**  
2001/2001/250 (U.S.)

**No. units installed in U.S./outside U.S./List price**  
$2,400/$2,300/$199,000

**Test menu:**  
- **Charitable (standard menu):** WBC, RBC, Hb, Hct, MCV, MCHC, PLT, %& neut, mono, lymph, eos, baso;  
- **Laboratory**  
  - Flags
- **Tests unique to analyzer IVD:** NRBC, body fluids; RUO: MSCV, WBC RPD —
- **Tests not available but submitted for clearance — —**
- **Test in development — —**
- **FDA-cleared tests but not clinically released — —**
- **Tests in development — —**
- **For research use only MSCV, HLR %& RPD, PCT, WBC research population data (RPD) PCT, PDW**
- **Tests unique to analyzer IVD:** NRBC, body fluids; RUO: MSCV, WBC RPD

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**Differential method(s) used**  
- **Coulter's 3-D VCS biophysical flow cytometry with Intellicount, AccuGate, and Accuflex technologies**

**Linearity:**  
- WBC count (10^9/L)
- RBC count (10^12/L)
- Hemoglobin (g/dL), platelet (10^9/L)

**Preciseion:**  
- WBC count/RBC count
- Hemoglobin/platelet
- MCV or Hct

**Accuracy of automated differential compared with manual differential (per CLSI H-50A), regression equation**  
- MCV: very high WBC, very high concentration of very large PLTs, agglutinates; MCV: very high WBC, very high concentration of very large PLTs, agglutinates
- PLT: very high WBC, severe lypemia, heparin, very low PLT, black blood; PLT: very high WBC, severe lypemia, heparin, very low PLT, black blood

**Interfering substances:**  
- **Hemoglobin**
  - very high WBC, severe lypemia, heparin, very low PLT, black blood
- **Platelet**
  - very high WBC, severe lypemia, heparin, very low PLT, black blood

**Age- and sex-specific reference ranges**  
- Max RBCs per hour/Max RBCs and differentials per hour

**Recommended average frequency of calibration**  
- as dictated by your lab procedures, local or national regulations

**Modes calibrated/parameters calibrated**  
- primary/RBC, WBC, Hb, MCV, PLT, MPV

**Frequency of blood/latex controls per CLIA, CAP, JCAHO, state or lab SOP/once per day**  
- not specified/once per day

**Minimum specimen volume open/closed/Sample dead volume closed**  
- 200 µL/300 µL, 550 µL with slidemaker/1.0 mL

**Tube sampling supported**  
- yes (multiple sizes and styles)

**Veterinary capability**  
- no

**Microsample capability**  
- no

**If automatic slide maker available, No. installed/list price**  
- $400(/U.S.)/$110,000

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

**Patient-specific archiving**  
- yes

**Maximum archived accessible when system online**  
- 20,000 samples

**Memory capacity—numeric results—No. specimens**  
- 20,000 samples

**Memory capacity—histo/cytograms—No. specimens**  
- 20,000 samples

**Stored in conjunction with CBC data**  
- yes

**Histo/cytogram images and CBC data printed as one report**  
- yes

**Saved results can be recalled and retransmitted**  
- yes

**Saved data can be sorted for reprocessing or report transmission**  
- yes

**Performs delta checks**  
- yes

**Tags and holds results for followup, confirmatory testing, or rerun**  
- yes

**Parameters for flags for holding samples are defined by**  
- user or vendor

**Scattergram display: cell-specific color**  
- yes

**Histogram display: color with threshold**  
- yes

**Choice of desired specimen and/or result information displayed**  
- yes

**LIS interface formats supported**  
- RS-232, proprietary

**Information transferred on LIS interface**  
- numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast

**LOINC codes transmitted with results**  
- technical support

**How labs get LOINC codes for reagent kits**  
- yes, DL2000, Command Central

**Optional data management or collection system**  
- enhanced QC data archiving, common database, extensive decision rules, delta checking, patient results and graphics, centralized management of all instruments

**Bar-code symbologies read on tube**  
- Codabar, codes 39 and 128, Interleaved 2 of 5, NW7

**Computer uses bar-code placement per CLSI standard Auto2A**  
- Beckman Coulter

**Time required for maintenance by lab personnel**  
- monthly: 2 minutes

**Onboard maintenance records**  
- yes

**Time from communication of problem to engineer on site**  
- as dictated by your lab procedures, local or national regulations

**Onboard diagnostics/limited to software problems**  
- yes/no

**Manufacturer can perform diagnostics via modem**  
- yes

**Extensive decision support, extended linearity for WBC and PLT**  
- yes

**Application program available on cost-per-reportable result**  
- yes

**Distinguishing features (supplied by company)**  
- extended decision support, enhanced linearity for WBC and PLT, low review rate, small footprint, superior reliability, ProService, electronic IQAP

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**Notes:**
- A dash in lieu of an answer means company did not answer question or question is not applicable.
- Hematology analyzers does not represent an endorsement by the College of American Pathologists.
<table>
<thead>
<tr>
<th>Test menu</th>
<th>Coulter Ac+T Sdiff Family</th>
<th>Coulter Ac+T Sdiff AL</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Chartable (standard menu: WBC, RBC, Hct, Hct, MCV, MCH, MCHC, WBC, PLT; %&amp;iff seed, mono, lymph, eos, baso)</td>
<td>standard menu (left) plus: RDW, MPV, elt # (ATL), elt lymph % (ATL%), immature cells # (IMM), immature cells % (IMM%), PCT, PWD, IMM, ATL</td>
<td>standard menu (left) plus: RDW, MPV, elt # (ATL), elt lymph % (ATL%), immature cells # (IMM), immature cells % (IMM%), PCT, PWD, IMM, ATL</td>
</tr>
<tr>
<td>• Laboratory</td>
<td>competitive high/low, definitive and suspect messages</td>
<td>complete operator selectable flagging</td>
</tr>
<tr>
<td>• Flags</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>FDA-cleared tests but not clinically released</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Tests not available but submitted for clearance</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Tests in development</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>For research use only</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Tests unique to analyzer</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

### Differential method(s) used

- Coulter’s 3-D VCS technology
- AcV technology combining cytochemistry, focused flow impedance, and light absorbance principles of measurement

### Test menu:
- Coulter HemX
- 1999 HemX AL
- >1.140/2.200/$139,000

### 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
- ---

### Age- and sex-specific reference ranges

<table>
<thead>
<tr>
<th>Test</th>
<th>Lower Reference Limit (LRL)</th>
<th>Upper Reference Limit (URL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>900</td>
<td>5,000</td>
</tr>
<tr>
<td>RBC</td>
<td>4.5</td>
<td>6.0</td>
</tr>
<tr>
<td>MCV</td>
<td>71</td>
<td>80</td>
</tr>
<tr>
<td>MCH</td>
<td>27</td>
<td>30</td>
</tr>
<tr>
<td>MCHC</td>
<td>32</td>
<td>36</td>
</tr>
<tr>
<td>Hb</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td>Hct</td>
<td>38</td>
<td>45</td>
</tr>
</tbody>
</table>

### Interfering substances:

- RBC: Hemoglobin, platelets, and leukocytes.
- WBC: Interfering substances include very high WBC, severe lipemia, elevated WBC, lipemia, very small RBCs, and WBC fragments may cause no fit.
- Platelets: Interfering substances include very high WBC, severe lipemia, rare lyse-resistant RBCs.
- Hemoglobin: Interfering substances include high triglycerides may affect lysing, lyse-resistant RBCs, NRBCs, PLT clumps, large PLTs, and RBC and WBC fragments.

### hematology analyzers

- Beckman Coulter
- Jim Cureton jcureton@beckman.com
- 250 So. Kramer Blvd
- Brea, CA 92821
- 714-981-4942
- www.beckmancoulter.com
- Kelly Colwell
- jdcureton@beckman.com
- Jim Cureton
- 714-981-4110
- www.beckmancoulter.com
- December 2010

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

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**Distinguishing features (supplied by company)**

- VCS technology; low review rate; no routine daily maintenance; triplicate counting; aperture burn circuit; sweepflow; SmartStart system; autoloader and single-sample models

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

- Quantitative five-part WBC differential; aspirates only 30 μL of sample; requires small space footprint and runs quietly. AL has auto repeat based on decision rules.
### Hematology analyzers

**Part 7 of 14**

**HORIBA Medical**

Jim Knowles

jimknowles@horiba.com

34 Bussen

Irvine, CA 92618

888-903-5001 ext. 4553


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**Name of instrument**

Pentra 60C — Hematology Analyzer

Pentra XL 80

**First year installed in U.S./outside U.S./No. of units sold in 2009**

2000/2000/85

2004/2003/2

**No. units installed in U.S./outside U.S./List price**

>350/>600/$49,476

>200/>900/$73,826

**Test menu:**

- **Charitable (standard menu):** WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&+Hed, mono, lymph, eos, baso.
- **Laboratory**
  - atyp. lymph, atyp. lymph %, LIC, LIC %
- **Flags**
  - Standard menu (left): RDW, MPV
  - Operator selectable flagging

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

- ---

**Tests not available but submitted for clearance**

- ---

**Tests in development**

- ---

**For research use only**

- PCT, PDW, ATL, LIC

**Tests unique to analyzer — automatic dilution protocol**

- ---

**Tests not available but submitted for clearance**

- ---

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

- ---

**Tests in development**

- ---

**For research use only**

- PCT, PDW, ATL, LIC

**Differential method used**

- **HORIBA Medical**

**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>Hemoglobin</td>
<td>9–12 g/dL</td>
<td>16–21 g/dL</td>
</tr>
</tbody>
</table>

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

- yes

**Onboard diagnostics/limited to software problems**

- yes/yes no/yes

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

- 24 hours

**Time required for maintenance by lab personnel**

- weekly: 15 minutes

**Contact information**

**Manufacturer**

HORIBA Medical

Jim Knowles

jimknowles@horiba.com

34 Bussen

Irvine, CA 92618

888-903-5001 ext. 4553


---

**Notes on differences between models**

- Horiba Medical

**Performance characteristics**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standard</th>
<th>MultiLink</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>9–12 g/dL</td>
<td>9–12 g/dL</td>
</tr>
<tr>
<td>Platelet</td>
<td>150–450 × 10^9/L</td>
<td>150–450 × 10^9/L</td>
</tr>
</tbody>
</table>

**Other features**

- Auto rerun feature

**Technical data**

- ---

---

**References**

- Proprietary: ASTM 1394 and 1238, HLT, IEEE MIB

---

**Distinguishing features (supplied by company)**

- Reliable 5-part WBC differential technology — MTBF more than 200 days; small footprint; small sample size of 53 µL

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**Differential method(s) used**

<table>
<thead>
<tr>
<th>Linearity:</th>
<th>WBC count (10^9/L)/RBC count (10^12/L)</th>
<th>Hemoglobin (g/dL)/platelet (10^11/L)</th>
<th>MCV (fL) or Hct (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precision:</td>
<td>WBC count/RBC count</td>
<td>Hemoglobin/platelet</td>
<td>MCV or Hct</td>
</tr>
<tr>
<td>Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interfering substances:</td>
<td>WBC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interfering substances: differential</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Age- and sex-specific reference ranges |
| Maximum CBCs per hour/Maximum CBCs and differentials per hour |
| Recommended average frequency of calibration |
| Months calibrated/parameters calibrated | open, closed/WBC, RBC, Ht, Plt, MPV |
| Frequency of blood/latex controls per CLIA standards/none |
| Minimum specimen volume open/closed/Sample dead volume closed |
| Tube sampling supported/yes |
| Veterinary capability/yes |
| Microsample availability/yes, open mode |
| Prepares microscopic slides automatically or flags problems for slide prep | yes |
| If automatic slidemaker available, No. installed/list price | —/— |

| Archives patient data for later comparison |
| Patient-specific screening |
| Maximum archived data accessible when system online |
| Memory capacity—numeric results—No. specimens |
| Memory capacity—history/cytograms—No. specimens |
| Stored in conjunction with CBC data |
| Stored in conjunction with CBC and MPV data |
| Saved results can be recalled and retransmitted |
| Saved data can be sorted for reprocessing or report transmission |
| Performs delta checks |
| Tags and holds results for followup, confirmatory testing, or rerun |
| Parameters for flags for holding samples are defined by user/yes |
| Some results can be transmitted to LIS while others held |
| Scattergram display: cell-specific color/yes |
| Histogram display: color with threshold/yes |
| Choice of desired specimen and/or result information displayed/yes |

| LIS interface formats supported |
| Information transferred on LIS interface |
| LDINC codes transmitted with results |
| How labs get LDINC codes for reagent kits |
| Optional data management or collection system |
| Software features |
| Interface available or planned to automate specimen-handling system |
| Bar-code symbologies read on tube |
| Accommodates bar-code placement per CLSI standard Auto2A |

| Time required for maintenance by lab personnel |
| Outboard maintenance records |
| Time from communication of problem to engineer on site |
| Outboard diagnostics/limited to software problems |
| Manufacturer can perform diagnostics via modem |
| Acquisition program based on cost-per-reportable result |

**Distinguishing features (supplied by company)**

- High-throughput cell counter with integrated reticulocyte methodology and slidekeeper/stainer; fluorescent MBPC counting, auto rerun and reflex testing, autovalidation
- Unique laser technology provides cellular Hb for RBCC and retic; 2-D PLT analysis that eliminates interference from RBCC fragments and inclusion of large PLTs; dual WBC counts with a linearity of up to 400,000; CSF assay

**Note:** A dash in lieu of an answer means company did not answer question or question is not applicable.
### Hematology analyzers

<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>Test menu</th>
<th>Test results available but not submitted for clearance</th>
<th>Tests in development</th>
<th>For research use only</th>
<th>Tests unique to analyzer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advia 2120 Hematology System</td>
<td>Charitable (standard menu: WBC, RBC, Ht, Hct, MCV, MCH, MCHC, PLT, % neut, mono, lymph, eos, baso)</td>
<td>Laboratory</td>
<td><strong>Flags</strong></td>
<td>CHCM, HOV, CHCM, cellular Hg, MCV, CSF: WBC, RBC, PMN, MN, neut, lymph, mono</td>
<td>CHCM, HOV, CHCM, cellular Hg, MCV, CSF: WBC, RBC, PMN, MN, neut, lymph, mono</td>
</tr>
</tbody>
</table>

### Differential method(s) used

#### Linearity:
- WBC count (10^9/L): 0–400; CSF WBC 0–5,000/0–1.3; CSF RBC 0–1,500
  - 0.02–400: 22.5%/3,500
  - 30–180 (MCV): 30–180 (MCV)

#### Interfering substances:
- WBC: peroxidase cytochem. staining with light scatter and absorption; base-cytochem. striping with 2-angle laser light scatter
- RBC: cold agglutinins, extreme sickle cell
- Platelet: none
- Hemoglobin: none

### Age- and sex-specific reference ranges

- **Maximum CBCs per hour:** 120/120
- **Frequency of blood/latex controls:** once per shift/night required
- **Minimum specimen volume open/closed:** 175 µL/175 µL (<300 tube size dependent)
- **Tube sampling supported:** yes
- **Microscope capability:** yes
- **Parameters for flags for holding samples are defined by:** user or vendor
- **Scattergram display:** cell-specific color
- **Histogram display:** color with threshold
- **Choice of desired specimen and/or result information displayed:** yes

### LIS interface formats supported

- **LIS transmit frequency:** once per shift/night required (tube size dependent)
- **LIS to instrument—broadcast:** once per shift/night required
- **Host query for patient demographics and orders (when bar code is read, host is queried for orders):** yes

### Distinguishing features (supplied by company)

- Unique laser technology provides direct cellular Hg for RBCs and reticulocytes;
- 2-D PLT analysis that eliminates interference from RBC fragments and inclusion of large PLTs; dual WBC counts with a linearity of up to 400,000; CSF assay
- Laser technology provides direct cellular Hg for RBCs and reticulocytes; 2-D PLT analysis eliminates interference from RBC fragments and inclusion of large PLTs; dual WBC counts with a linearity of up to 400,000; CSF assay
<table>
<thead>
<tr>
<th>Feature</th>
<th>Sysmex America</th>
<th>Sysmex America</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of instrument</td>
<td>Sysmex XT-400H</td>
<td>Sysmex poct-100</td>
</tr>
<tr>
<td>No. units installed in U.S./Outside U.S./List price</td>
<td>32/150/$195,700</td>
<td>&gt;800/—/$18,000</td>
</tr>
<tr>
<td>Test menu</td>
<td>standard menu (left): plus: % and R, retic % and R, IB, IBF, RET-Lite, PLT-O, BF</td>
<td>WBC, RBC, HB, Hct, MCV, MCH, MCHC, PLT, %&amp;h neut, lymph, MBD</td>
</tr>
<tr>
<td>• Charitable (standard menu: WBC, RBC, HB, Hct, MCV, MCH, MCHC, PLT, %&amp;h neut, mono, lymph, eos; basin,)</td>
<td>—</td>
<td>RDW-SD, RDW-CV, MPV</td>
</tr>
<tr>
<td>• Flags</td>
<td>PLT clumps, PLT ABN distribution, blast, imm gran, left shift, atyp lymph, ABN lymph/plaits, NRBC, RBC lyse resistance, RBC ABN distribution, RBC aggregation, turbidity</td>
<td></td>
</tr>
<tr>
<td>FDA-cleared tests but not clinically released</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Tests not available but submitted for clearance</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Tests in development</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>For research use only</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Tests unique to analyzer</td>
<td>reticulocyte hemoglobin, immature reticulocyte fraction, reportable immature granulocyte % and %, BF, RBC/WBC/two-part differential</td>
<td></td>
</tr>
<tr>
<td>Differential method(s) used</td>
<td>fluorescent flow cytometry</td>
<td>direct current (DC)</td>
</tr>
<tr>
<td>Linearity</td>
<td>0–440/0–8</td>
<td>1.0–9.0/0.3–7.0</td>
</tr>
<tr>
<td>• WBC count (10^3/L)/RBC count (10^7/L)</td>
<td>0–25.0/0–5.00</td>
<td>0.1–25.0/0–999</td>
</tr>
<tr>
<td>• Hemoglobin (g/dL)/platelet (10^11/L)</td>
<td>0–60 (Hct)</td>
<td>0–60 Hct</td>
</tr>
<tr>
<td>• MCV (% or Hct)</td>
<td>&lt;3.0 percent/&lt;=1.5 percent</td>
<td>&lt;=3.5 percent/&lt;=2.0 percent</td>
</tr>
<tr>
<td>• MCHC (pg/cell)</td>
<td>&lt;=1.5 percent/&lt;=1.0 percent</td>
<td>&lt;=2.0 percent Hct</td>
</tr>
<tr>
<td>• MCH (fl)</td>
<td>Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation</td>
<td></td>
</tr>
<tr>
<td>• Hct (%)</td>
<td>neut % = 0.95, lymph % = 0.90, mono% = 0.80, eos % = 0.94, baso % = 0.76; neut % = 0.85–1.0 x 10^9/L, lymph % = 0.85 x 1.0 x 10^9/L, mono % = 0.85 x 1.0 x 10^9/L, eos % = 0.87 x 1.0 x 10^9/L, baso % = 0.24 x 1.0 x 10^9/L</td>
<td></td>
</tr>
<tr>
<td>• Interfering substances: WBC</td>
<td>cold agglutinin, severe microcytosis, fragmented RBC, leukocytosis</td>
<td></td>
</tr>
<tr>
<td>• cold agglutinin, severe microcytosis, fragmented RBC, leukocytosis</td>
<td>cold agglutinin, severe microcytosis, fragmented RBCs</td>
<td></td>
</tr>
<tr>
<td>• RBC</td>
<td>cold agglutinin, severe microcytosis, fragmented RBCs</td>
<td></td>
</tr>
<tr>
<td>• MCV or Hct</td>
<td>cold agglutinin, severe microcytosis, fragmented RBCs, RBC aggregation, leukocytosis</td>
<td></td>
</tr>
<tr>
<td>• Platelet</td>
<td>PLT aggregation, pseudotuberculosis, giant platelets, microcytosis, cryoglobulin</td>
<td></td>
</tr>
<tr>
<td>• Hemoglobin</td>
<td>leukocyte (lymphocytes)(&gt;100,000)/µL, lipemia, abnormal protein</td>
<td></td>
</tr>
<tr>
<td>Interfering substances: differential RBC</td>
<td>lyse-resistant RBC</td>
<td></td>
</tr>
<tr>
<td>• Age- and sex-specific reference ranges</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Maximum CBCs per hour/Maximum CBCs and differential per hour</td>
<td>100/100</td>
<td>30/30</td>
</tr>
<tr>
<td>Recommended average frequency of calibration</td>
<td>once by year by FSR</td>
<td>per regulatory agency requirements</td>
</tr>
<tr>
<td>• Modes calibration parameters calibrated</td>
<td>open-closed/WBC, PLT, RBC, HGB, Hct</td>
<td></td>
</tr>
<tr>
<td>Frequency of blood/platelet controls</td>
<td>by per regulatory requirements/none</td>
<td></td>
</tr>
<tr>
<td>Minimum specimen volume open/closed/Sample day volume closed</td>
<td>85 µL/150 µL/1 µL</td>
<td></td>
</tr>
<tr>
<td>Tube sampling supported</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>yes diameter = 12–15 mm; length = &lt;75 mm</td>
<td>yes, diameter: 13–15 mm; height: &lt;=75 mm microtubes</td>
<td></td>
</tr>
<tr>
<td>Veterinary capability</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Microsample capability</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Preparers microscopic slides automatically or flags problems for slide preparation</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>If automatic slider available, No. installed/list price</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Archives patient data for later comparison</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Patient-specific archiving</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Maximum archived data accessible when system online</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>yes 100,000 samples</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Memory capacity—numeric results—no. specimens</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>10,000 samples</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Memory capacity—histo/cytograms—no. specimens</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>10,000 samples</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>• Stored in conjunction with CBC data</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>• Histocytograms images and CBC data printed as one report</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>• Saved results can be recalled and retransmitted</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>• Saved data can be sorted for reprocessing or report transmission</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>• Performs delta checks</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>• Tags and holds results for followup, confirmatory testing, or rerun</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>• Parameters for flags for holding samples are defined by</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>• Some results can be transmitted to LIS while others held</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>• Scattergram display: cell-specific color</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>• Histogram display: color with threshold</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>• Choice of desired specimen and/or result information displayed</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>LIS interface formats supported</td>
<td>ASTM 1394 and 123B</td>
<td>RS-223C</td>
</tr>
<tr>
<td>Information transferred on LIS interface</td>
<td>numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders</td>
<td></td>
</tr>
<tr>
<td>LOINC codes transmitted with results</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>How labs get LOINC codes for reagent kits</td>
<td>contact vendor</td>
<td>contact vendor</td>
</tr>
<tr>
<td>• Optional data management or collection system</td>
<td>yes, Sysmex WAM (work area manager)</td>
<td>yes, Antek</td>
</tr>
<tr>
<td>• Software features</td>
<td>enhanced GC, data archiving, data collection from multiple instruments, wide area network capabilities</td>
<td></td>
</tr>
<tr>
<td>Interface available or planned to automate specimen-handling system</td>
<td>Codabar, codes 39 and 128, ASTM, Interleaved 2 of 5, ITF, NW7</td>
<td></td>
</tr>
<tr>
<td>Bar-code symbologies read on tube</td>
<td>codes 39 and 128, ASTM, ITF, NW7, JAN-8 and 13</td>
<td></td>
</tr>
<tr>
<td>Accommodates bar-code placement per CLSI standard Auto2A</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Time required for maintenance by lab personnel</td>
<td>daily &lt;=3 minutes</td>
<td>daily &lt;=2 minutes; weekly: &lt;=2 minutes; monthly: &lt;=2 minutes</td>
</tr>
<tr>
<td>Onboard maintenance records</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Time from communication of problem to engineer on site</td>
<td>&lt;=24 hours</td>
<td>&lt;=24 hours; depot service</td>
</tr>
<tr>
<td>Manufacturer can perform diagnostics via modern</td>
<td>no/no</td>
<td>no/no</td>
</tr>
<tr>
<td>Acquisition program based on cost-per-reportable result</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Distinguishing features (supplied by company)</td>
<td>unique testing parameters: fluorescent optical platelets, IS &amp; % RET-He, body fluids (Csf, serum, synovial), WBC/RBC/two-part differential, standardized technology, reagents, controls, and operations with other Sysmex X series analyzers; simplified operations with extended linearity, high-throughput, remote monitoring capabilities</td>
<td></td>
</tr>
<tr>
<td>hydrodynamic focusing, automatic floating diacriminators, ISBT-compliant, data masking software for blood donor centers</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>
### Hematology analyzers

#### Sysmex America

<table>
<thead>
<tr>
<th>Tabulation does not represent an endorsement by the College of American Pathologists.</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2010</td>
</tr>
</tbody>
</table>

#### Name of instrument
- **First year installed in U.S./Outside U.S./No. of units sold in 2009**
  - Syteme XE-5000
    - 2008/2009/125
    - >400/1,300/$250,122

#### Test menu:
- **Charitable (standard menu): WBC, RBC, Hb, Hct, MCV, MCH, MCHC, ST, PLT, %&dagger; neut, lymph, MLD**
  - **Laboratory**
    - **Flags**
      - RDW-SD, RDW-CV, MPV, histogram error flags; WBC, RBC, PLT

#### FDA-cleared tests but not clinically released
- **Tests not available but submitted for clearance**
  - reticulocyte hemoglobin, immature platelet fraction, hematopoietic progenitor cell, immature reticulocyte fraction, reportable immature granulocyte %&dagger;, RBC/ WBC/T%two-part differential

#### Differential method(s) used
- **Linearly**
  - **WBC count (10/L)**: 1.0–99/90.3–7.0
  - **Hemoglobin (g/dL)/platelet (10^12/L)**: 0.5–25 / 0–100
  - **MCV (fl)/Hct (%)**: 10–60 / Hct

#### Accuracy of automated differential compared with manual differential (per CLSI H-20A, regression equation)
- **WBC**
  - cold agglutinin, PLT aggregation, erythrophagocytosis, NRBC, cyroglobulins
- **RBC**
  - cold agglutinin, severe microcytosis, fragmented RBCs, leukocytosis
  - (>100,000/L)
  - Hct: cold agglutinin, leukoscytosis (>100,000/L), abnormal red cell fragility, spherocytosis
  - Pseudotumor, PLT aggregation, increased microcytosis, megalocytic PLTs
  - Leukemia (>100,000/L), lipemia, abnormal protein

#### Age- and sex-specific reference ranges
- **Maximal CBCs per hour/Maximal CBCs and differentials per hour**
  - **Recommended average frequency of calibration**
    - per regulatory agency requirements
  - **Modes calibrated/parameters calibrated**
    - primary, whole blood mode/PLT, RBC, HGB, Hct, PLT

#### Tube sampling supported
- **Preparation**
  - yes
  - no

#### Microsample capability
- **Prepares microsopic slides automatically or flags problems for slide prep**
  - no

#### IF automatic slide maker available, No. installed/list price
- >1,200/price depends on configuration

#### LIS interface formats supported
- **RS-232C**
  - ASTM 1393, TCP/IP, ASTM E1381
  - numeric and flag results, histograms and scatterplots, host query for patient demographics and orders
  - contact vendor
  - yes
  - yes
  - yes
  - contact vendor
  - yes, Sysmex WM (Work Area Manager)
  - enhanced GC, data archiving, data collection from multiple instruments, rules setting
  - Roche Diagnostics, and Labotix, A & T, Thermo, IDS

#### Time required for maintenance by lab personnel
- **Onboard diagnostic records to engineer on site**
  - **Onboard diagnostics limited to software problems**
    - no/no
  - **Manufacturer can perform diagnostics via moden**
    - no

#### Acquisition program based on cost-per-reportable result
- **Automatic floating discriminators**
  - low-end linearity for all body fluids; two-part differential (mono nuclear % & # and polymorphonuclear % & # or body fluid; reticulocyte hemoglobin content; immature platelet fraction; throughout of 100 GBCs per hour; random access; discrete testing; online GC; routine diagnostics, body fluid analysis; platelet linearity to 5 million, hematocrit linear to 75 percent; hematopoietic progenitor cell testing; immature granulocyte enumeration; immature platelet fraction; reticulocyte hemoglobin equivalent; standardized reagents, controls, and operations with other Sysmex X series analyzers

#### Notes:
- a dash in lieu of an answer means company did not answer question or question is not applicable
### Hematology analyzers

**System:** Sysmex America  
**Address:** 1 Nelson C. White Pkwy. Mundelein, IL 60060  
**Phone:** 847-379-7639 www.sysmex.com/usa

| Part 12 of 14 | Sysmex America  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of instrument</td>
<td>Sysmex XE-2100</td>
</tr>
<tr>
<td>First year installed in U.S./outside U.S./No. of units installed in 2009</td>
<td>1999/19/390</td>
</tr>
<tr>
<td>No. units installed in U.S./outside U.S./List price</td>
<td>1,325/5,000/$240,000</td>
</tr>
<tr>
<td>Test menu:</td>
<td>standard menu (left plus): RDW-SD, RDW-CV</td>
</tr>
<tr>
<td>- Laboratory</td>
<td>PLT clumps, RBC agglut, turbidity, WBC AIN scattergram, RBC AIN distribution, PLT AIN distribution, RBC lyse resistance, blasts, left shift, atyp. lymph., AIN lymph./blast., reticulocyte AIN scattergram</td>
</tr>
<tr>
<td>- Flags</td>
<td></td>
</tr>
<tr>
<td>FDA-cleared tests but not clinically released</td>
<td>-</td>
</tr>
<tr>
<td>Tests not available but submitted for clearance</td>
<td>-</td>
</tr>
<tr>
<td>Tests in development</td>
<td>-</td>
</tr>
<tr>
<td>For research use only</td>
<td>P-LCR, PCT, PDW</td>
</tr>
<tr>
<td>Tests unique to analyzer</td>
<td>HPC%, Hct, ISG, RET%, HFP</td>
</tr>
</tbody>
</table>

### Differential method(s) used:
- Linearly: **WBC count (10/L)**  
- Hemoglobin (g/dL)/platelet (10/L)  
- MCV (fL) or Hct (%)

### Precision:
- **WBC count/RBC count**  
- Hemoglobin/platelet  
- MCH (pg)/MCHC (%)

### Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation

### Interfering substances:
- **WBC**  
- **RBC**  
- **MCV or Hct**  
- **Platelet**  
- **Hemoglobin**

### Interfering differential:

### Age- and sex-specific reference ranges
- **Maximum CBCs per hour/Maximum CBCs and differentials per hour**  
- **Recommended average frequency of calibration**  
- **Modes calibrated/parameters calibrated**  
- **Frequency of blood/latex controls**

### Minimum specimen volume open/closed/Sample dead volume closed
- 130 µL/200 µL/mL

### Tube sampling supported
- yes

### Veterinary capability
- no

### Microsample capability
- yes

### Preparations for slide slides automatically or flags problems for slide prep
- yes (with Alpha or HST upgrade)

### IF automatic slide maker available, No. installed/list price
- >1,000/price depends on configuration

### Archives patient data for later comparison
- yes

### Patient-specific tracking
- yes

### Maximum archived data accessible when system online
- 100,000

### Memory capacity—numeric results-No. specimens
- 100,000

### Memory capacity—histo-/cytograms-No. specimens
- 100,000

### Stored in conjunction with CBC data
- yes

### History/cytogram images and CBC data printed as one report
- yes

### Saved results can be recalled and retransmitted
- yes

### Saved data can be sorted for reprocessing or report transmission
- yes

### Performs delta checks
- yes

### Tags and holds results for followup, confirmatory testing, or rerun
- yes

### Parameters for flags for holding samples are defined by
- user or vendor

### Some results can be transmitted to LIS while others held
- yes

### Scattergram display: cell-specific color
- yes

### Histogram display: color with threshold
- yes

### Choice of desired specimen and/or result information displayed
- yes

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

### Information transferred on LIS interface
- Numeric and flag results, histograms and scatterplots, patient demographics, orders

### LOINC codes transmitted with results
- yes

### How labs get LOINC or Hct
- contact vendor

### Optional data management or collation system
- yes, Sysmex WAM (Work Area Manager)

### Enhanced QC, data archiving, data collation from multiple instruments, multiple sites
- on automation platform

### Interface available or planned to automate specimen-handling system
- Codabar, codes 39 and 128, interleaved 2 of 5, ITF, NW7, EAN 8 and 13

### Time required for maintenance by lab personnel
- daily: <3 minutes

### Onboard maintenance records
- yes

### Time from communication of problem to engineer on site
- <24 hours

### Onboard diagnostics/limited to software problems
- yes/no

### User can perform diagnostics via modem
- yes, also via Internet

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

### Distinguishing features (supplied by company)
- throughput of 150 CBCs per hour; random access; discrete testing; online QC; remote diagnostics, body fluid analysis; platelet linearity to 5 million, hematocrit linear to 75 percent; 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 per hour; platelet linearity—6 million, hematocrit extended to 75 percent; standardized technology, reagents, controls and operations; ISBT-compliant; FDA-cleared application for blood component products in specified anticoagulants
### Hematology analyzers

**Part 13 of 14**

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

**Name of instrument**
Sysmex XE-Alpha N/HST-N

**First year installed in U.S./outside U.S./No. of units sold in 2009**
2000/—/>160

**List price**
>$275/1,300/$300,000—$1,000,000

**Test menu**
- **Charitable (standard menu):** WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&dagger; neut, monocyte, lymph, eosin, baso;
- **Laboratory**
- **Flags**
- **Distinguishing features (supplied by company)**
  - Acquisition program based on cost-per-reportable result
  - Manufacturer can perform diagnostics via modem
  - Time from communication of problem to engineer on site <24 hours
  - Onboard maintenance records
  - Time required for maintenance by lab personnel
  - Accommodates bar-code placement per CLSI standard
  - Bar-code symbologies read on tube
  - Interface available or planned to automate specimen-handling system
  - How labs get LOINC codes for reagent kits
  - LOINC codes transmitted with results
  - LIS interface formats supported
  - Scattergram display: cell-specific color
  - Parameters for flags for holding samples are defined by user or vendor
  - Tags and holds results for followup, confirmatory testing, or rerun
  - Saved results can be recalled and retransmitted
  - Memory capacity—histo/cytograms–No. specimens
  - Maximum archived data accessible when system online
  - Patient-specific archiving
  - Maximum archived data accessible when system online
  - Memory capacity—numeric results—No. specimens
  - Memory capacity—histo/cytograms—No. specimens
  - Stored in conjunction with CBC data
  - Histocytogram images and CBC data printed as one report
  - Saved results can be recalled and retransmitted
  - Saved data can be sorted for reprocessing or report transmission
  - Performs data checks
  - Tags and holds results for followup, confirmatory testing, or rerun
  - Parameters for flags for holding samples are defined by:
  - Some results can be transmitted to LIS while others held
  - Scattogram display: cell-specific color
  - Histogram display: color with threshold
  - Choice of desired specimen and/or result information displayed
  - LIS interface formats supported
  - Information transmitted on LIS interface
  - LOINC codes transmitted with results
  - How labs get LOINC codes for reagent kits
  - Optional data management or collation system
  - Software features
  - Interface available or planned to automate specimen-handling system
  - Bar-code symbologies read on tube
  - Accommodates bar-code placement per CLSI standard Auto2A

**Performance**
- **Linearity:** WBC count
- **Precision:** WBC count/RBC count
- **Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation
- **Interfering substances:**
  - WBC
  - RBC
  - MCV or Hct
  - Platelet
  - Hemoglobin

**Differential methods**
- **Fluorescent flow cytometry, RF/DC detecting method**

**Part 14 of 14**

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

**Name of instrument**
Sysmex XT-2000i

**First year installed in U.S./outside U.S./No. of units sold in 2009**
2002/2001/>235

**List price**
>$900/>2,200/$149,500

**Test menu**
- **Charitable (standard menu):** WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&dagger; neut, monocyte, lymph, eosin, baso;
- **Laboratory**
- **Flags**
- **Distinguishing features (supplied by company)**
  - Acquisition program based on cost-per-reportable result
  - Manufacturer can perform diagnostics via modem
  - Time from communication of problem to engineer on site <24 hours
  - Onboard maintenance records
  - Time required for maintenance by lab personnel
  - Accommodates bar-code placement per CLSI standard
  - Bar-code symbologies read on tube
  - Interface available or planned to automate specimen-handling system
  - How labs get LOINC codes for reagent kits
  - LOINC codes transmitted with results
  - LIS interface formats supported
  - Scattergram display: cell-specific color
  - Parameters for flags for holding samples are defined by user or vendor
  - Tags and holds results for followup, confirmatory testing, or rerun
  - Saved results can be recalled and retransmitted
  - Memory capacity—histo/cytograms–No. specimens
  - Maximum archived data accessible when system online
  - Patient-specific archiving
  - Maximum archived data accessible when system online
  - Memory capacity—numeric results—No. specimens
  - Memory capacity—histo/cytograms—No. specimens
  - Stored in conjunction with CBC data
  - Histocytogram images and CBC data printed as one report
  - Saved results can be recalled and retransmitted
  - Saved data can be sorted for reprocessing or report transmission
  - Performs data checks
  - Tags and holds results for followup, confirmatory testing, or rerun
  - Parameters for flags for holding samples are defined by:
  - Some results can be transmitted to LIS while others held
  - Scattogram display: cell-specific color
  - Histogram display: color with threshold
  - Choice of desired specimen and/or result information displayed
  - LIS interface formats supported
  - Information transmitted on LIS interface
  - LOINC codes transmitted with results
  - How labs get LOINC codes for reagent kits
  - Optional data management or collation system
  - Software features
  - Interface available or planned to automate specimen-handling system
  - Bar-code symbologies read on tube
  - Accommodates bar-code placement per CLSI standard Auto2A

**Performance**
- **Linearity:** WBC count/RBC count
- **Precision:** WBC count/RBC count
- **Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation
- **Interfering substances:**
  - WBC
  - RBC
  - MCV or Hct
  - Platelet
  - Hemoglobin

**Differential methods**
- **Fluorescent flow cytometry, RF/DC detecting method**

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**Note:** A dash in lieu of an answer means company did not answer question or question is not applicable.
### Hematology analyzers

**Sysmex America**

**Communications@sysmex.com**

**1 Nelson C. White Pkwy.**

**Mundelein, IL 60060**

**800-379-7639**

**www.sysmex.com/usa**

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**Name of instrument**

First year installed in U.S./Outside U.S./No. of units sold in 2009

<table>
<thead>
<tr>
<th>Region</th>
<th>Model</th>
<th>No. units installed in U.S./Outside U.S./List price</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>Sysmex XT-180i</td>
<td>&gt;900/1,600/$128,750</td>
</tr>
<tr>
<td>Outside U.S.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of units sold in 2009</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Test menu**

<table>
<thead>
<tr>
<th>Test menu</th>
<th>Charitable (standard menu: WBC, RBC, Hct, MCV, MCHC, MCH, PLT, Tdil neut, neut, mono, lymph, eos, baso)</th>
<th>Flags</th>
<th>FDA-cleared tests but not clinically released</th>
<th>Tests unique to analyzer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>standard menu (left) plus: MPV, RDW-SD, RDW-CV, immature granulocytes %&amp;</td>
<td>PLT clumps, PLT ABN distribution, WBC ABN scattergram, blast imm. gran., left shift, atyp. lymph., ALC, lymph/blast, RBC ABN distribution, RBC lymph resistance, RBC agglutinins, turbidity, MBC, body fluids</td>
<td>---</td>
<td>immature granulocytes (65%&amp;/%)</td>
</tr>
</tbody>
</table>

**Hematology analyzers**

**Part 14 of 14**

**Sysmex America**

**Communications@sysmex.com**

**1 Nelson C. White Pkwy.**

**Mundelein, IL 60060**

**800-379-7639**

**www.sysmex.com/usa**

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**Test menu**

<table>
<thead>
<tr>
<th>Linearity</th>
<th>Precision</th>
<th>Accuracy of automated differential compared with manual (per CLSI H-20A), regression equation</th>
<th>Interfering substances:</th>
<th>Interfering substances: differential</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC count (10^9/L)/RBC count (10^12/L)</td>
<td>WBC count/RBC count</td>
<td>neut%: r=0.95, y=0.85x+3.38; lymph%: r=0.96, y=0.95x+1.67; mono%: r=0.90, y=11.37x+1.99; eos%: r=0.94, y=0.97x+0.04; baso%: r=0.76, y=0.48x+0.24</td>
<td>WBC: cold agglutinins, PLT aggregation, cryoglobulins, lyse-resistant RBCs, NRBCs</td>
<td>WBC: cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis</td>
</tr>
<tr>
<td>Hemoglobin (g/dL)/platelet (10^11/L)</td>
<td>Hemoglobin/platelet</td>
<td>r=0.90, y=0.80x+3.94; lymph%: r=0.87, y=0.90x+2.41; mono%: r=0.78, y=0.82x+3.93; eos%: r=0.94, y=0.97x+0.38; baso%: r=0.79, y=0.83x+0.21</td>
<td>MCV or Hct: cold agglutinins, PLT aggregation, cryoglobulins, lyse-resistant RBCs, NRBCs</td>
<td>MCV or Hct: cold agglutinins, ABR red cell fragility, spherocytosis, leukocytosis</td>
</tr>
<tr>
<td>MCV (fl) or Hct (%)</td>
<td>MCV or Hct</td>
<td>neut%: r=0.96, y=0.90x+3.94; lymph%: r=0.87, y=0.90x+2.41; mono%: r=0.78, y=0.82x+3.93; eos%: r=0.94, y=0.97x+0.38; baso%: r=0.79, y=0.83x+0.21</td>
<td>Platelet: cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis</td>
<td>Platelet: cold agglutinins, ABR red cell fragility, spherocytosis, leukocytosis</td>
</tr>
<tr>
<td>MCH, MCHC, PLT, % neut, mono, lymph, eos, baso</td>
<td>MCV or Hct</td>
<td>neut%: r=0.96, y=0.90x+3.94; lymph%: r=0.87, y=0.90x+2.41; mono%: r=0.78, y=0.82x+3.93; eos%: r=0.94, y=0.97x+0.38; baso%: r=0.79, y=0.83x+0.21</td>
<td>Hemoglobin: cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis</td>
<td>Hemoglobin: cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis</td>
</tr>
</tbody>
</table>

---

**Information transferred on LIS interface**

<table>
<thead>
<tr>
<th>Numeric and flag results, histograms and scatterplots, patient demographics,</th>
<th>Information transferred on LIS interface numeric and flag results, histograms and scatterplots, patient demographics,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Choices of desired specimen and/or result information displayed     | **Hematology analyzers**

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**Time required for maintenance by lab personnel**

<table>
<thead>
<tr>
<th>Maintenance activity</th>
<th>Time required by lab personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily: three minutes</td>
<td>yes</td>
</tr>
<tr>
<td>Weekly: none; monthly: nine minutes</td>
<td>yes</td>
</tr>
</tbody>
</table>

---

**Distinguishing features (supplied by company)**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>remote diagnostics; online QC; random access; discrete testing; reagent monitoring; charitable report formats; unique specimen-gating, software is FDA Part II compliant; body fluids now FDA cleared; standardized technology, reagents, controls, and operations with other X series analyzers; XT-V for use in toxicology, research, and veterinary reference labs</td>
<td>standardize technology, reagents, controls, and operations to other X series analyzers; small sample volume requirements for CBC and five-part differential; remote diagnostics; online QC; discrete analysis, reagent monitoring, charitable report; online calibration verification</td>
</tr>
</tbody>
</table>

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