Hematology analyzers—efficiency through automation

Predicting the future used to be a much more exciting enterprise. Underwater cities, robot maids, commuting via jetpack—the guiding principle seemed to be “Make it up, and it might come true.” These days, nobody’s holding out for androids in aprons, and predicting the future of high-volume hematology analyzers, at least, is much less fanciful. “The needs of tomorrow’s laboratory aren’t going to be all that different from the needs of today,” says Mary Beth Johnson, Beckman Coulter hematology marketing manager. “The lab of the future is still going to need to be equipped with systems that are ready to deliver an accurate result at a moment’s notice. That’s one of the reasons more-automated systems are growing in popularity.” Hence the profusion of automated systems and capabilities in this month’s instrumentation survey (see next page), which features high-volume hematology analyzers from five vendors.

Abbott, for example, “has focused its research and development efforts on providing automated instrument systems that maximize the efficiency of the analytical phase of the hematology workflow process,” says James Schwartz, director of global public affairs and marketing communications. New from his company: the Cell-Dyn Sapphire, which performs CBC analyses via Abbott’s Multi-Angle Polarized Scatter Separation technology “plus three-color fluorescence,” Schwartz says. He adds, “Industry-leading first-pass CBC efficiency, even in the face of challenging pathologies, is our primary goal.” The Sapphire also offers automated random-access monochrom antibody analysis. In 2006, the company plans to introduce a sister instrument, the Cell-Dyn Ruby, aimed at mid-size laboratories; it will, Schwartz says, “streamline operations within the laboratory by offering reduced manual interventions in an easy-to-use, Windows-based customizable operating software package.” Already available is Abbott’s Accelerator Decision Manager software, which “provides postanalytical connectivity and functionality across the entire laboratory in an open architecture.”

Automation’s latest incarnation at Beckman Coulter has taken the shape of the LH 1500 series, a completely integrated hematology system. The LH 1500 was previously available only as a custom system, says Johnson, who adds that it’s designed to help high-volume laboratories “manage the purple tubes with automated preanalytical processing, testing, and analysis of results, and postanalytical sorting and storage.” Available in 12 configurations, the LH 1500 includes an automation track line that can connect up to four of the company’s LH 750 hematology analyzers or LH 755 workcells. “Technologists place samples directly in the inlet module,” Johnson explains. “The tubes are then routed automatically to a connected hematology analyzer or sorted.”

Meanwhile, Bayer has increased the automated capabilities of its Advia 2120 hematology system with the advent of the Advia Autoslide, a fully automated slide maker and stainer that is available as an integrated option for the system. Processing up to 120 slides per hour, the Autoslide lets the user “define reflexive slide sampling criteria based on morphology, ranges, flags, and demographics for the right results the first time,” says worldwide hematology marketing manager Pat Frank. Also new is the Advia 2120 MultiSpecies software package, which offers fully automated hematology testing on up to 21 species and strains and lets users identify 30 additional species. With Advia hematology sys- tems, “laboratories can optimize their workflow and deliver a patient-focused approach to results management,” Frank says. Additionally, outside the United States, the company has introduced the NRBC method for its Advia 2120 systems. (The method has been submitted to the FDA and is pending 510(k) clearance.)

Horiba ABX is anticipating the release of a double differential matrix with three immature cell line indices—IMC, IMM, and IML—on its Pentra DX 120 analyzer. The Pentra DX 120 features more than 40 other parameters as well, such as reticulocyte analysis and NRBC enumeration, and can perform automated reticulocyte testing in real time. Another new offering, the SPS Evolution, is “an integration slide maker/stainer available for both Pentra DX and DF systems,” says Jim Knowles, U.S. hematology marketing manager. Finally, Sysmex is celebrating the recent FDA clearance of two parameters, reticulocyte hemoglobin and immature platelet fraction, on its XE-2100 hematology analyzer. Body fluids on the analyzers in the XT series remain under investigation for FDA submission, says senior market manager Brian Verne. Also forthcoming, he says, is the result of his company’s partnership with Bio-Rad Laboratories: the availability of Bio-Rad’s Variant II Turbo hemoglobin testing system on the Sysmex HST-N hematology automation line. Expected to be available in 2006, “this initiative brings all testing of lavender-top sample tubes into the hematology laboratory,” Verne says. “Some of the benefits are automated processing, elimination of sample splitting, and increases in operational efficiency with cost reductions.”

Anne Ford is a writer in Chicago.
### Differential method(s) used

- **Color:** optical scatter & 3-color fluorescence
- **Linear:**
  - WBC count (10^9/L):
    - N: 0.0–250.0 x 10^9/L
    - I: 0.0–7.5 x 10^9/L
    - Q: 7.5–10 x 10^9/L
  - Hemoglobin (g/dL):
    - N: 12.0–16.0 g/dL
    - I: 12.0–18.0 g/dL
    - Q: 18.0–20.0 g/dL
  - Hematocrit (%): N: 37.0–50.0
  - MCV or Hct
- **Precision:**
  - WBC count: N: 2.7% ± 1.5%
  - Hemoglobin: N: 1.0% ± 0.8%
  - Hematocrit: N: 0.5% ± 0.3%
- **Accuracy of automated diff. compared with manual diff.**
  (per NCHL B-208A, regression equation):
  - neut: r = 0.962 slope = 0.947 y = 0.446 (y = 0.936 slope = 0.943 y = 0.21);
  - lymph: r = 0.938 slope = 0.947 y = 0.985; r = 0.464 slope = 0.228 base r = 0.932 slope = 0.250
- **Interfering substances:**
  - **WBC**
    - RBC: autoagglutination, elevated WBC, elevated hemoglobin, smears
  - **MCV or Hct**
    - MCV: autoagglutination, elevated WBC, giant PL, hemolysis, hypergammaglobulinemia
  - **Platelet**
    - Hb: autoagglutination, cold agglutination, elevated WBC, cryoglobulinemia, cryofibrinogenemia, FBC, RBC
  - **Hb**
    - Autoagglutination, cold agglutination, elevated WBC, giant PL, hemolysis, hypergammaglobulinemia
  - **Interfering substances: differential**
    - see WBC

### Age- and sex-specific reference ranges

- Max. CBCs per h/mass.: CBCs & diff.s per h
- Recommended average frequency of CBCs:
- **Monod calibrated/parametrized calibrated**
- **Frequency of blood/latex controls**
  - per regulatory requirement/na
- **Min. specimen vol. open/closed sample dead vol. closed**
  - 177 µL/176 µL/5.6 mL, 0.3 mL for 10.25 × 64 mm tubes
- **Tube sampling supported**
  - yes (115–125 × 65–75 mm, 10.25 × 64 mm, 9 × 66 mm [Starlab Monovette])
  - no
  - yes
  - yes
- **Microsample capability**
- **Prepares microscopic slides automatically or flags problems for slide prep**
- **If auto. slide maker available, No. installed/list price**
  - n/a/215,000

### LIS interface formats supported

- **Information transferred on LIS interface**
  - ASTM 1394: n/a
- **LIS/CMS codes transmitted with results**
  - no
- **Optional data mgmt. or collection system**
  - yes, Abbott Accelerator DH
- **Software features**
  - Accelerator APS
  - Color, codes 30 & 139, Intert. 2 of 5
- **Time required for maintenance by lab personnel**
  - daily: 30 sec; weekly: 10 min; monthly: 5 min
- **On-board maintenance records**
  - yes
- **Time from communication of problem to engineer on site**
  - n/a
- **On-board diagnostic/limited to software problems**
  - yes/no
- **Fr. can perform diagnostics via modem**
  - no
- **Acquisition program based on cost-per-sample report**

### Distinguishing features

- 4 optical and 3 fluorescent detectors providing Multiple Scatterpoint Analysis: 2-D optical detectors that avoids interference; fluorescent analysis of reflectometers, nRBCs, and 3-color mass-signal analysis on a routine hematologic analyzer
- Unique laser technology provides cellular Hb for RBCs and retic; 2-D PR analysis that eliminates interference; fluorescent analysis of reflectometers, nRBCs, and 3-color mass-signal analysis on a routine hematologic analyzer

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**Tabulation does not represent an endorsement by the College of American Pathologists**
<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>Bayer Healthcare Diagnostics</th>
<th>Name of instrument</th>
<th>Bayer Healthcare Diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td>First year sold-installed in U.S./outside U.S.</td>
<td>Advia 70</td>
<td>Year sold/installation</td>
<td>2000/2001</td>
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<td>100/300/$98,000</td>
<td>Cost/price</td>
<td>Advia 2120 Hematology System</td>
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<td>Charitable standard menu (left fee): RDM, MPV</td>
<td>Test menu:</td>
<td>Charitable standard menu (left fee): RDM, MPV</td>
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<td>All instruments have:</td>
<td>WBC, RBC, MCV, Ht, Hct, Hct, WBC,</td>
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<tr>
<td>MDA, MDA, PLT, lymph, eos, liso.</td>
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<td>MDA, MDA, PLT, lymph, eos, liso.</td>
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</tr>
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<td>• Flaps</td>
<td>dPL, WBC, N, B, L, RBC, ABN, PL, CI, PR/RBC</td>
<td>• Flaps</td>
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<td>---</td>
<td>FDA-cleared tests but not clinically released</td>
<td>---</td>
</tr>
<tr>
<td>Tests not available but submitted for clearance</td>
<td>---</td>
<td>Tests not available but submitted for clearance</td>
<td>---</td>
</tr>
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<td>Tests in development</td>
<td>MBC</td>
<td>Tests in development</td>
<td>MBC</td>
</tr>
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<td>Pol, PDM</td>
<td>For research use only</td>
<td>Pol, PDM</td>
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<td>---</td>
<td>Tests unique to analyzer</td>
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<tr>
<td>Differential method(s) used</td>
<td>Optical &amp; enhanced impedance</td>
<td>Differential method(s) used</td>
<td>Optical &amp; enhanced impedance</td>
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<td>Linearity:</td>
<td>WBC count (10^4/L)/RBC count (10^6/L): 0.1-9.9/0.0-6.99</td>
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<tr>
<td></td>
<td>Hemoglobin (g/dl)/plated (10^6/L)</td>
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<td>Hemoglobin (g/dl)/plated (10^6/L)</td>
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<td>1.5-3.0/10-2000</td>
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<td>30-100 (MCV)</td>
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<td>1.5%±10%</td>
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<td>Accuracy of automated diff. compared with manual diff. (per NCCLS H-204), regression equation</td>
<td>Total n=9,863, p=0.02-3.3; lymphocyte n=9,863, p=0.941-0.64; monocyte n=9,797,</td>
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<tr>
<td></td>
<td>p=0.12±0.18; eosinophi n=9,863, p=0.47±0.1; basophil n=9,322, p=0.3±0.1</td>
<td></td>
<td>p=0.12±0.18; eosinophi n=9,863, p=0.47±0.1; basophil n=9,322, p=0.3±0.1</td>
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<td>Platelet</td>
<td>RBC fragments</td>
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<td>lipemia, elevated WBC</td>
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<td>Interfering substances: differential</td>
<td>NMCs, unlysed RBC, platelet clumps</td>
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<td>Age- and sex-specific reference ranges</td>
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<td>Recommended avg. frequency of calibr.</td>
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<td>Microsample capability</td>
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<td>Previews microscopic slides automatically or flags problems for slide prep</td>
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<td>Archivs patient data for later comparison</td>
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<td>Memory capacity—numeric results-No. specimens</td>
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<td>• Histo/CFGram images &amp; CBC data printed as 1 report</td>
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<td>Saved results can be recalled and retransmitted</td>
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<td>Performs delta checks</td>
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<td>Performs delta checks</td>
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<tr>
<td>Tags and holds results for followup, confirm, testing, or rerun</td>
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<td>Tags and holds results for followup, confirm, testing, or rerun</td>
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<td>Parameters for flags for holding samples are defined by user</td>
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<td>Histogram display: color with threshold</td>
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<td>LIS interface formats supported</td>
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<td>LOINC codes transmitted with results</td>
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<td>How lab uses LOINC codes for reagent kits</td>
<td>online documentation</td>
<td>How lab uses LOINC codes for reagent kits</td>
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<td>Optimal data management or collaboration system</td>
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<td>Optimal data management or collaboration system</td>
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<td>• Software features</td>
<td>---</td>
<td>• Software features</td>
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<td>Interface avail. or planned to auto. specimen-handling system</td>
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<td>Codabar, code 39, interl. 2 of 5</td>
<td>Bar-code symbologies read on tube</td>
<td>Codabar, code 39, interl. 2 of 5</td>
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<td>Accommodates bar-code placement per NCCLS standard Autocode</td>
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<td>Time required for maintenance by lab personnel</td>
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<td>Onboard maintenance records</td>
<td>territorial dependent</td>
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<td>Time from communication of problem to engineer on site</td>
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<td>Time from communication of problem to engineer on site</td>
<td>yes/no in development</td>
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<tr>
<td>Onboard diagnostics/limited to software problems</td>
<td>yes/no in development</td>
<td>Onboard diagnostics/limited to software problems</td>
<td>yes/no in development</td>
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<td>Mfrs. can perform diagnostics via modem</td>
<td>---</td>
<td>Mfrs. can perform diagnostics via modem</td>
<td>---</td>
</tr>
<tr>
<td>Acquisition program based on cost-per-reportable result</td>
<td>yes</td>
<td>Acquisition program based on cost-per-reportable result</td>
<td>yes</td>
</tr>
<tr>
<td>Distinquishing features</td>
<td>microsampling; auto recoint; dual WBCs; automatic wakup and shutdown; no daily or weekly maintenance</td>
<td>Distinquishing features</td>
<td>unique laser technology provides direct collagen Hb for RBCs and retics; 2-D Pld analysis that eliminates RBC fragments and exclusion of large Pts; dual WBC counts with a linearly of up to 400,000; ---</td>
</tr>
</tbody>
</table>

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High-volume hematology analyzers

Part 4 of 11

Name of instrument

First year sold—installed in U.S./outside U.S.

No. units installed in U.S./outside U.S./list price

Test menu:

+Charterable

• Logs

• PCA

+Signs:

• Test not available but submitted for clearance

• Tests in development

• For research use only

• Unique to analyzer

Differential method(s) used

Linear:

+WBC count (10^9/L) +RBC count (10^12/L)

+Neutrophils (μL)/platelet (10^9/L)

• MCV (fl) or Hct (%) or other

• WBC count/RBC count

• Ht/platelet

• MCV or Hct

Access to automated diff. compared to manual diff.

(par MCLL H-20A, regression equation

Interfering substances:

• WBC

• RBC

• Mcv or Hct

• Platelet

• Hb

Interfering substances: differential

Age- and sex-specific reference ranges

Max. CBCs per brocsm.

CBC or diff's per hr

Recommended avg. freq. of calibr.

+Monos calibrated/parameter calibrated

Frequency of blood/controls tests

Min. specimen vol. open/closed sample/ded vol. closed

Tube sampling supported

Veterinary capability

Microsample capability

Prepares microsample slides automatically or flags problems for slide prep

If auto. slideviewer available, No. installed/list price

Archives patient data for later comparison

Patient-specific archiving

Max. archived data accessible when system online

Memory capacity—numeric results—No. specimens

Memory capacity—histo/cyto/deg—No. specimens

+Shared in conjunction with CBC data

+Histology/cytogen images & CBC data printed as 1 report

Saved results can be recalled and retransmitted

Saved data can be sorted for reprocessing or report transmission

Performs dets checks

Tags and holds results for followup, confirm. testing, or rerun

Parameters for flags for holding specimens 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 &/or result info. displayed

LI3 interface format supported

Information transferred on LI3 interface

LORIC codes transmitted with results

New labs get LORIC codes for reagent kits

Optional data magnet. or collection system

+ Software features

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

Bar-code symbologies read on tube

Accreditation bar-code placement per NCLIS standard Automatic

Time required for maintenance by lab personnel

Onboard maintenance record

Time from communication of problem to engineer on site

Onboard diagnostics/limited to software problems

Mtr. can perform diagnostics via modem

Accession program based on cost-per-reportable result

Distinguishing features

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Tabulation

High-volume hematology analyzers

December 2005

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Beckman Coulter Inc.
Martha M. Szisz/Cellular Analysis Marketing
200 S. Krasner Blvd.
Brea, CA 92822-8000
714-993-8467 www.beckmancoulter.com

Name of instrument

Coulter LH 500
330000
>5000/1000/1450/600

Test methods used:

- *Charlott*
- Laboratory

Test instruments:

- BEC, BC, 4%, IDEX, MEN, MEC, PC, PT, WBC, red/b
- Palce, lymph, eos, neut

FDA-cleared tests 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

Coulter's 3-D biophysical flow cytometry with AccuGate 500, Reaction Manager technologies

Linearity:

- WBC count (1000/L) [RBC count (1000/L)
- Hemoglobin (g/dL)/platelet (10^4/mL)
- MCV (fl) or Hct (%)

Precision:

- WBC count/RBC count/Platelet
- MCV or Hct
- %

Accuracy of automated diff. compared with manual diff. (per NCLLS H-200, emission equation:

Interfering substances:

- WBC
- RBC
- MCV or Hct
- Platelet

Interfering substances: differential

- *Age* and sex-specific reference ranges
- Max. BCs per hirman, CBCs & diff. per hr
- Recommended avg. frequency of calls.
- *Medos calibrated* / calibrated
- Frequency of blood/latex controls
- Min. specimen vol. open/closed/sample dead vol. closed
- Tube sampling supported
- Veterinary capability
- Microsample capability
- Prepares microscopic slides automatically or flags problems for slide prep
- If auto. slidemaker available, No. installed/list price

Archives patient data for later comparison

- Patient-specific archiving

Max. archived data accessible when system online

Memory capacity—numeric results—Nos. specimens

Memory capacity—histo/lymph-Nos. specimens

*Shared* in conjunction with CBC data
*Histos/cytogram images & CBC printed data as 1 report

Saved results can be recalled and retransmitted

Saved data can be sorted for reporting or report transmission

Performs differential checks

Tags and holds results for follow-up, confirm, testing, or rerun

Parameters for flags for holding samples are defined by

Some results can be transmitted to LIS while others held

Scattergram display: color-specific filter

Histogram display: color with threshold

Choice of desired specimen & or result info. displayed

LIS interface formats supported

Information transferred on LIS interface

LIS codes transmitted with results

SC/plots codes for coagulation

Data capture input, output, report

Software features

- LABS codes transmitted with results

- New labs get LIS codes for coagout

- Optimal data capture, report

- *System features*

- RS-232, proprietary

- Numeric & flag results, histograms & scattergrams, instrument to LIS: patient demographics, orders, LIS to instrument—broadcast

- Technical support

- RS-232, proprietary

- Numeric & flag results, histograms & scattergrams, instrument to LIS: patient demographics, orders, LIS to instrument—broadcast

- Technical support

- Coder, codes 39 & 128, ASTM, Intert. 2 of 5, NW7

Time required for maintenance by lab personnel

On-site maintenance records

Time from communication of problem to engineer on site

On-site diagnosis/limited to software problems

Mfr. can perform diagnostics via modem

Acquisition program based on cost-per-reportable result

Distinguishiing features

- VCS technology: lowest review rate in class; no routine daily maintenance

- Thresholds counting, automated bar circuit, sweeping downstream

- SmartStart system: autocalibrate and single sample modules
Part 6 of 11

Beckman Coulter Inc.
Martha M. Diaz/Cellular Analysis Marketing
34 Bunker St.
Bra, CA 92202-8000
714-993-8447
www.beckman.com

Heraeus Diagnostics Inc.
Jim Konowal
34 Bunnos
Irvine, CA 92616
888-900-5601 ext. 553
www.aba.com

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

CoULTer AV+® Shift Family: AV+® Shift AL
1,200,000,500,000 cap/pipe model; $38,500 open vial model; AC, 340; $45,450autoloader

Pencot®-60C—Hematology Analyzer
2003/2000
325/440/$49,500

Test menu:
- Charitable
  - All instruments have
    - WBC, RBC, Hb, MCH, MCHC, platelet.
    - Laboratory
      - BCA, Covalent, Fy, Tnt, met.
    - Flags

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

Differential method(s) used
- A V technology combining cytometry, focused flow impedance, and light absorption principles of measurement
- DHRS technology combining cytometry, focused flow impedance, & light absorption principles of measurement

Accuracy of automated diff. compared with manual diff.
- (per NCCLS H-20A, regression equation
- Interferring substances—WBC
  - MCRs, PM, large PHs, lye-resistant RBs
  - RBC
    - cold agglutin
  - MCH or MCHT
    - cold agglutin
  - Platelet
    - RBC and WBC fragments
  - Hb
    - elevated WBC, Sponia

Interferring substances: differential

Archives patient data for later comparison
- Patient-specific archiving
- Max. archived data accessible when system online
- Memory capacity—numeric results—No. specimens
- Memory capacity—histo/lymograms—No. specimens
- Stored in conjunction with CBC data
- Histology/lymogram images & CBC data printed as 1 report
- 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, confirm, testing, or repeat
- Various parameters for flags holding samples are defined
- Some results can be transmitted to LIS while others held
- Scattergram display: cell-specific color
- Histogram display: color with threshold
- Choice of desired specimen &/or result units displayed

LIS interface formats supported
- Information transferred on LIS interface
  - proprietary, proprietary ASTm
  - proprietary
  - proprietary & flag results, histo/lymograms & diff. plts, instrument to LIS: patient demographics, orders, LIS to instrument—broadcast
  - proprietary & flag results, histo/lymograms & diff. plts, instrument to LIS: patient demographics, orders, LIS to instrument—broadcast
  - proprietary & flag results, histo/lymograms & diff. plts, instrument to LIS: patient demographics, orders, LIS to instrument—broadcast

LIS codes transmitted with results
- Not specified
t

How lab gets LOINC codes for reagent kits
- technical support
- technical support
- technical support

Optimal data regent. or collation system
- Programmed
- Enhanced OC, data archiving with Henry’s Data Manager
- Enhanced OC, data archiving with Henry’s Data Manager

Interface avail. or planned to auto. specimen-handling system
- Bar-code symbologies read on tube

Bar-code symbologies read on tube
- Cog达尔, codes 39 & 128, interf. of 2, 5, EAN 8 & 13

Cog达尔, codes 39 & 128, interf. of 2, 5, EAN 8 & 13

Time required for maintenance by lab personnel
- Weekly: 15 min

Onboard maintenance records
- Yes

Time from communication of problem to enginere on site
- 24 hrs

Onboard diagnostics/limited to software problems
- Yes/No

Onboard maintenance records
- Yes/Yes

Onboard diagnostics/limited to software problems
- Yes/Yes

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

Distinguishing features
- quant. 5-part WBC diff.: aspirates only 30 µL of sample; requires small space footprint and runs quietly.
- Ac has auto repeat based on decision rules
- Reliable 5-part WBC diff. technology—MTFR over 200 days; small footprint; small sample size of 53 µL; Hematology Data Manager

* Manufacturer stated for AV+® Shift EP.

Tabulation does not represent endorsement by the College of American Pathologists.
High-volume hematology analyzers

<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>Pentra 120 RefleX Hematology Analyzer</th>
<th>Pentra 90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>HumaX Diagnostics Inc.</td>
<td>HumaX Diagnostics Inc.</td>
</tr>
<tr>
<td>List price</td>
<td>$710,000</td>
<td>$130,000</td>
</tr>
</tbody>
</table>

Test menus:
- Standard menu (left) plus: RDW, IMF, MPV
- Standard menu (left) plus: RDW, MPV
- **Charter**
  - WBC, RBC, MCV, MCH, MCHC, PLT
  - Laboratory tests
  - **+Flags**
  - Operator selectable flagging

DSO classified tests but not clinically released:
- None
- None
- None

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

Tests in development:
- None
- None
- None

For research use only:
- None
- None
- None

Tests unique to analyzer:
- None
- None
- None

Differential method(s) used:
- Chemotaxis, focused flow impendence, light absorbance
- DHS technology combining chemotaxis, focused flow impendence & light absorbance principles of measurement

Accuracy of automated diff. compared with manual diff.:
- (per MCHL-1020a) regression equation
  - Results: n<0.99, n/a; lymph%<0.99, n/a; monocytes<0.92, n/a; eosinophils<0.97, n/a; basophils<0.71, n/a
- MBRGs, PT clumps, lymph-resistant RBCs
- MBRGs, PT clumps, lymph-resistant RBCs

Age- and sex-specific reference ranges:
- Yes
- Yes

Max. CBCs per/1000, CBCs & diff. per hr:
- Yes
- Yes

Recommended average frequency of calibr:
- 1/2/120
- 6/100

Max. calibrated/parameters calibrated:
- Yes
- Yes

Frequency of blood/blood cells controls:
- Yes
- Yes

Min. specimen vol. open/closed/switched:
- 100 µL/200 µL/1 mL
- 50 µL/100 µL/0.5 mL

Tube sampling supported:
- Yes
- Yes

Veterinary capability:
- Yes
- Yes

Microsample capability:
- Yes
- Yes

Prepares microscopic slides automatically or flags problems for slide prep:
- Yes
- Yes

If auto. slide maker available, No. installed/list price:
- $40,000
- N/A

LIS interface formats supported:
- Proprietary, ASTM 1394 & 1238, HL7, IEEE 8808
- Proprietary, ASTM 1394 & 1238, HL7, IEEE 8808

Information transferred on LIS interface:
- Numerical & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument — broadcast
- Numerical & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument — broadcast

RSNC codes transmitted with results:
- N/A
- N/A

Optional data agent or cancellation system:
- Enhanced GC, data archiving (HumaX Data Manager), data deletion from multiple instruments
- Enhanced GC, data archiving, data deletion from multiple instruments

Interface avail. or planned for auto. specimen-handling system:
- N/A
- N/A

Bar-code symbologies read on tube:
- Adobe Acrobat bar-code placement per NCCLS standard 1238
- Adobe Acrobat bar-code placement per NCCLS standard 1238

Time required for maintenance by lab personnel:
- Weekly: 10 min; monthly: 10 min
- Weekly: 15 min

Onsite maintenance records:
- Yes
- Yes

Time from communication of problem to engineer on site:
- 4 hrs average, 24 hrs guaranteed
- N/A

Onsite diagnostic/limited to software problems:
- Yes
- Yes

Htopl. can perform diagnostics via modem:
- Yes
- Yes

Acquisition program based on cost-per-reportable result:
- CMC, reliable 5-part diff technology, auto loader, 100 samples per hour, auto rerun feature
- CMC, reliable 5-part diff technology, auto loader, 100 samples per hour, auto rerun feature

[Note: Tabulation does not represent endorsement by the College of American Pathologists]
### Tabulation

#### Distinguishing features

- **High-volume hematology analyzers**

- **Part 1 of 11**

- **Name of instrument**

- **First year sold-installed in U.S./outside U.S.**

- **No. units installed in U.S./outside U.S./list price**

- **Test menu:**

  - **Chartable:**

    - Standard menu (left) plus: automatic dilution of overrange results (NCB $3, RBC/hg/Ht in R, MDW, MPV)

    - **Laboratory:**

      - Operator selectable flagging

      - Differential (pC) 100% (Ht)

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

    - Tests not available but submitted for clearance

    - Tests in development

    - For research use only

    - Tests unique to analyzer

    - **Cytochemistry (citromedic black and absobence)**

    - **Linearly:**

      - **WBC count (10/l):**

        - 0-1200-8

      - **Hemoglobin (g/dl)/pleatlet (10e12):**

        - 0.6-7 (0.9-2.600 e2 g/dl, Hb)

      - **MCV (fl):**

        - 80-80

      - **Hct (%):**

        - 0.4-2

      - **PCV (Hct):**

        - 0.4-2

    - **Precision:**

      - **WBC count/NCB count:**

        - ±%<1%<2%

      - **Hb/pleatlet:**

        - ±%<1%<2%

      - **MCV or Hct:**

        - ±%<1%<2%

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

      - (par MCLTH 200A, regression equation)

      - **Hct:**

        - 0.4-2

      - **WBC:**

        - 0.4-2

      - **RBC:**

        - 0.4-2

      - **Platelet:**

        - 0.4-2

      - **Frequency:**

        - 0.4-2

      - **Interfering substances:**

        - **WBC:**

          - Cold agglutination

        - **RBC:**

          - Hemolyzed

        - **Platelet:**

          - Microscopic, PR clumps

        - **Hb:**

          - Extreme hemolysis

        - **Interfering substances: differential**

          - Microscopic, PR clumps

          - Extreme hemolysis

          - Extreme, hyperbilirubinemia

          - Hyperbilirubinemia

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

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>4–12 × 10^9/L</td>
</tr>
<tr>
<td>RBC</td>
<td>4.0–5.5 × 10^12/L</td>
</tr>
<tr>
<td>Hb</td>
<td>130–170 g/L</td>
</tr>
<tr>
<td>Platelets</td>
<td>100–300 × 10^9/L</td>
</tr>
</tbody>
</table>

- **Recommended average frequency of calib:**

  - Weekly: 100 reports/day

- **Medline calibrated/parameters calibrated**

  - CLIA standards/nos

  - 30 for CBC/53 for CBC & diff/0.5 mL

- **Tube sampling supported**

  - (Autolab 13 x 75; closed tube 16 sizes + micro)

- **Preparation of samples for testing**

  - Preparatory: 0.5 h

  - Repair: 0.5 h

- **Archives patient data for later comparison**

  - Yes

  - Yes

- **Patient-specific archiving**

  - Yes

  - Yes

- **Max. archival data accessible when system on-line**

  - Unlimited with Hematik Data Manager; 10,000 instrument only

  - Unlimited with Hematik Data Manager; 10,000 instrument only

  - Unlimited with Hematik Data Manager; 10,000 instrument only

  - Unlimited with Hematik Data Manager; 10,000 instrument only

- **Memory capacity—history/cytoimages—No. specimens**

  - 30,000

  - 30,000

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

  - Yes

  - Yes

- **Histogram display: color with threshold**

  - Yes

  - Yes

- **LIS interface formats supported**

  - Proprietary, ASTM 1394 & 1236, H2, IEEE 1101

  - Proprietary, ASTM 1394 & 1236, H2, IEEE 1101

- **LOINC codes transmitted with results**

  - N/A

  - N/A

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

  - Yes

  - Yes

- **Time required for maintenance by lab personnel**

  - Weekly: 15 min

  - Weekly: 15 min

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

  - Yes

  - Yes

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

  - Yes

  - Yes

- **Distinguishing features**

  - Compact 5-part differential instrument with autoloader and autodilution capability, autorun feature, auto validation

  - High-throughput cell counter with integrated reticuloocyte methodology and wavelengths/fluorescent NWBC counting, auto renin and renin testing, auto validation

---

**Tabulation does not represent an endorsement by the College of American Pathologists**
### High-volume hematology analyzers

**Part 9 of 11**

**Table:**

<table>
<thead>
<tr>
<th>Test menu:</th>
<th>Standard Method</th>
<th>FDA-cleared tests but not clinically released</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pit traps, RBC agglutination, turbidity, WBC ABN scattergram, RBC ABN dilution, Pit ABN dist., RBC po lysm resistance, left shift, atypical, ABN lymph, blast, ret. ABN scattergram</td>
<td>none</td>
</tr>
<tr>
<td></td>
<td>Pit traps, Pit ABN distribution, WBC ABN scattergram, blast, left shift, atypical lymph, ABN lymph/plots, RBC ABN distribution, RBC lysm resistance, RBC agglutination, turbidity</td>
<td>none</td>
</tr>
</tbody>
</table>

**Examples of parameters testing:**

- **Examples of parameters testing:**
  - **WBC count (10^3)/RBC count (10^6)/**
  - **Hemoglobin (g/dl)/platelet (10^9)/**
  - **MCV (fl) or Hct (%)/**
  - **MCH (pg)/MCV (fl)/**
  - **MCHC (g/dl)/**
  - **Mean cell haemoglobin (g/dl)/**
  - **Mean cell volume (fl)/**
  - **Platelet (10^9)/**
  - **Interfering substances:**
    - **WBC: RBC: Hb: platelet: MCV =**
    - **Accuracy of automated diff. compared with manual diff.**
  - **Interfering substances: differential**

### Age- and sex-specific reference ranges:

- **Max. CBCs per hr/max. CBCs & diffs per hr**
- **Recommended average frequency of calibr./**
- **(per NQCS N-204), regression equation**
- **Frequency of blood/plates control**
- **Min. specimen vol. specimens/sample does vol. closed**
- **Tube sampling supported**
- **Veterinary capability**
- **Microsample capability**
- **Prepares microscopic slides automatically or flags problems for slide prep**
- **If auto. slidechanger available, No. installed/kit price**

### Test results:

- **Archives patient data for later comparison**
- **Patient-specific archiving**
- **Max. archived data accessible when system online**
- **Memory capacity—numeric results—No. specimens**
- **Memory capacity—histo/lymphograms—No. specimens**
- **Stored in conjunction with CBC data**
- **Histology/lymphograms & CBC data printed as 1 report**
- **Save results can be recalled and retransmitted**
- **Save data to be sorted for reprocessing or report transmission**
- **Performs delta checks**
- **Tags and results flags for followup, confirm, testing, or review**
- **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 thresholding**

### LIS interface formats supported:

- **LIS Interface formats supported**
- **Information transmitted on an LIS interface**
- **LION codes transmitted with results**
- **How long do LION codes for reagent kits last?**
- **Optional data report, or collection system**
- **Software features**
- **Interface avail. or planned to auto. specimen-handling system**

### Bar-code systems:

- **Bar-code symbology used on tube rack**
- **Accommodates bar-code placement per NQCS standard Auto 20A**

### Time required for maintenance by lab personnel:

- **Time required for maintenance by lab personnel**
- **Onboard maintenance records**
- **Time from communication of problem to engineer on site**
- **Onboard diagnostic/limited to software problems**
- **MHC. can perform diagnostics via modem**

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

- **Distinguishing features**
- **Remote diagnostics: online QC; random access; HPC testing; testing on multiple instruments; LIS enumeration, body fluid analysis; patient interface; key benefits to six million, RP, and RET Ne**

---

Tabulation does not represent an endorsement by the College of American Pathologists.
<table>
<thead>
<tr>
<th>Name of instrument</th>
<th>First year sold-installed in U.S./outside U.S.</th>
<th>No. units installed in U.S./outside U.S./List price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tabulationr</td>
<td>Sybron America Inc.</td>
<td>2004/2004</td>
</tr>
<tr>
<td></td>
<td>Peggy Barracone</td>
<td>—/—/250,000</td>
</tr>
</tbody>
</table>

**Test menu:**

- **CharterLine**
  - standard menu (left) plus: RDW-SD, RDW-CV, 10%, IMA
- **Hematology**, **Hct, Hb, MCV, MCH, MCHC, **LMP**
  - none
- **Plaque**
  - PIT clumps, PIT ABN distribution, BAC ABN scattergram, klast, left shift, atlp. lymph., ABN lymph/klast, RBC ABN distribution, BAC lymph resistance, JBC Aggl., turbidity

**Pitfalls**

- PIT clumps, RBC aggl., turbidity, BAC ABN scattergram, RBC ABN distrib., PIT ABN distr., BAC lymph resistance, klast, left shift, atlp. lymph., ABN lymph/klast, mkt. ABN scattergram
- New release PF & RET He

**Tests not available but submitted for clearance**

- none

**Tests in development**

- RET-He, PH

**For research use only**

- P-LCR, PCT, PWSW

**Tests unique to analyzer**

- IMA & IGA

**Differential method(s) used**

<table>
<thead>
<tr>
<th>Linearity:</th>
<th>Fluorescent flow cytometry</th>
</tr>
</thead>
</table>
| WBCC count | 0-1500 <-
| Hemoglobin (g/dL)/platelet (10^12/L) | 0-255 <-
| MCV (fl) or Hct (%) | 0-40 (%)<-
| MCHC (g/dL) | 1.2-1.8 (%)<-

**Popularity**

<table>
<thead>
<tr>
<th>Accuracy of automated diff. compared with manual diff.</th>
<th>Fluorescent flow cytometry, FDC detecting method</th>
</tr>
</thead>
<tbody>
<tr>
<td>(per NCCLS H-20A), regression equation</td>
<td></td>
</tr>
</tbody>
</table>

**Interfering substances**

- **WBCC**
  - MCV or Hct
  - Cold agglut., RBC red cell fragility, spherocytosis, leukocytosis

- **Plaque**
  - Pseudotuberculosis, PIT aggr., incr. microcytosis, macrocytosis

- **Hb**
  - Lipemia, ABN proteins, leukocytosis

**Preparation of specimen**

- For slides prep, with Alpha or HST upgrade

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

- $1,000—

**List of features**

- Archives patient data for later comparison
- Patient-specific archiving
- Max. archived data accessible when system offline
- Memory capacity—numeric results—No. specimens
- Memory capacity—histo/cytophys—No. specimens
- Shared in conjunction with CBC data
- Video/photograph images & CBC data printed as 1 report
- Saved results can be recalled and reformatted
- Saved data can be sorted for reprocessing or transmission
- Performs platelet check
- Tags and holds results for followup, confirm, testing, or review
- Parameters for flags for holding results are defined by
- Some results can be transmitted to LIS while others held
- Scattergram display: cell-specific color
- Histogram display: color with thresholding
- Choice of desired specimen & result info. displayed

**LIS interface formats supported**

<table>
<thead>
<tr>
<th>Information transferred on LIS interface</th>
<th>RS-232C, TCP/IP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numeric &amp; flag results, histograms &amp; scattergrams, instrument to LIS, patient demographics, orders, LIS to instrument—broadcast, host query for patient demographics</td>
<td></td>
</tr>
</tbody>
</table>

**LOINC codes transmitted with results**

- How labs get LOINC codes for reagent kits
- Optional data elements or collection system
- • Software features

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

| Lab InterLink, MBD/AutoLab, Bencken Currant, Roche, Labdoc, &T Covalus, codes 36 & 12A, ASTM, Intert. 2 of 5, ITF, NWT, EAN 8 & 13 |

**Time required for maintenance by lab personnel**

<table>
<thead>
<tr>
<th>On-site maintenance records</th>
<th>10 min walkaway with autoready</th>
</tr>
</thead>
<tbody>
<tr>
<td>On-board diagnostics/limited to software problems</td>
<td>15 min walkaway with autoready</td>
</tr>
<tr>
<td>Mfr. can perform diagnostics via modem</td>
<td>15 min walkaway with autoready</td>
</tr>
</tbody>
</table>

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

| yes | yes |

**Distinguishing features**

| provides high throughput sample analysis; small footprint; configurable & available; patient literacy—6 million |
| multiple configurations available as are all distinguishing features of the E-2100S, patient literacy—5 million, new parameters for patient monitoring—PF & retic Hb measurement & RET He |
### Part 11 of 11

#### Name of instrument

**First year sold-installed in U.S./outside U.S.**

<table>
<thead>
<tr>
<th>System</th>
<th>XT-2000i 2002</th>
<th>XT-8000i 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Units installed in U.S./outside U.S./list price</td>
<td>$400,000/140,000</td>
<td>$400,000/25,000</td>
</tr>
</tbody>
</table>

#### Test menu:

- **Charitable**: standard menu (left) plus: retic % ±R, RBC, Ht, MPV, RDW-S, RDW-CV
- **Laboratory**: PIT clumps, PIT ABN distribution, WBC ABN scattergram, blast imm. gran., left shift, atyp lymph., ABN lymph/blast, RBC ABN distribution, RBC haemoglobin, RBC agglut., turbidity, ret ABN scattergram, NRBC
- **Phagocyte clearance tests but not clinically released**: none
- **Tests not available but submitted for clearance**: none
- **Tests in development**: body fluids, immature gran. %
- **For research use only**: body fluids, immature gran.

#### Differential method(s) used

- **Linearly**: fluorescent flow cyto
- **Nonlinearly**: fluorescent flow cyto

#### Accuracy of automated diff. compared with manual diff. (per MCLL H-202b, regression equation)

<table>
<thead>
<tr>
<th>Method</th>
<th>XT-2000i 2002</th>
<th>XT-8000i 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBC</td>
<td>0.80% ±0.02%</td>
<td>0.80% ±0.02%</td>
</tr>
<tr>
<td>Ht</td>
<td>0.80% ±0.02%</td>
<td>0.80% ±0.02%</td>
</tr>
<tr>
<td>MPV</td>
<td>0.80% ±0.02%</td>
<td>0.80% ±0.02%</td>
</tr>
<tr>
<td>RDW</td>
<td>0.80% ±0.02%</td>
<td>0.80% ±0.02%</td>
</tr>
</tbody>
</table>

#### Differential ranges

- **Age- and sex-specific reference ranges**
- **Max. CBCs per hrm, CBCs & diff. per hr**
- **Recommended average frequency of calls**
- **Erythrocyte calibrated/parameters calibrated**
- **Frequency of blood/latex controls**
- **Min. specimen volume: open/closed/sample dead vol. closed**
- **Tube sampling supported**
- **Other**
- **Prepares microscopic slides automatically or flags problems for slide prep**
- **If auto. smearmaker available, No. installed/list price**

#### Archives patient data for later comparison

- **Patient-specific archiving**
- **Max. archived data accessible when system online**
- **Memory capacity—numeric results—No. specimens**
- **Memory capacity—histo/cytograms—No. specimens**
- **Shared in conjunction with CBC data**
- **Histology/cytograms images & CBC data printed as 1 report**
- **Saved results can be recalled and retransmitted**
- **Saved data can be sorted for reporting or report transmission**
- **Performs delta checks**
- **Tags and holds results for followup, confirm, testing, or rerun**
- **Parameters for flags for holding samples are defined by**
- **Some results can be transmitted to LUS while others held**
- **Scattergram display: cell-specific color**
- **Histogram display: color with threshold**
- **Choice of desired specimen &/or result info. displayed**

#### LUS interface formats supported

<table>
<thead>
<tr>
<th>Information transmitted on LUS interface</th>
<th>XT-2000i 2002</th>
<th>XT-8000i 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>RS-232C, TCP IP, ASTM</td>
<td>RBC, Ht, MPV</td>
<td></td>
</tr>
<tr>
<td>numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS patient demographics &amp; orders</td>
<td>RBC, Ht, MPV</td>
<td></td>
</tr>
</tbody>
</table>

#### LUS codes transmitted with results

<table>
<thead>
<tr>
<th>How labs get LUSC codes for requisit tests</th>
<th>XT-2000i 2002</th>
<th>XT-8000i 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Software features</strong></td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Interface avail. or planned to auto. specimen-handling system</strong></td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Bar-code symbologies read on tube</strong></td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

#### Time required for maintenance by lab personnel

- **Onsite maintenance records**
- **Time from communication of problem to engineer on site**
- **Onsite diagnosis/limited to software problems**
- **Mtr. can perform diagnostics via modem**

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

- **Remote diagnostics: online QC; random access; fluorescent optical plating/technique; discrete testing; reactant monitoring; customized charitable report formats; XT-9 unit for use in toxicology & research**
- **Remote diagnostics: online QC; random access; discrete testing; reactant monitoring; charitable report formats; XT-9 unit for use in toxicology & research; unique specimen-coloring BM is FDA Part II compliant**

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

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**Survey of high-volume hematology analyzers**

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**50 / CAP TODAY**

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**December 2005**