

## For strained labs, hematology analyzers doing more

Karen Southwick

**D**iagnostics manufacturers, serving labs that have to do more work with less staff and money, are responding with instruments that automate increasingly complex tasks.

The latest round of hematology analyzers from five vendors—Abbott Laboratories, ABX Diagnostics, Bayer Diagnostics, Beckman Coulter, and Roche Diagnostics—offers such features as autoverification, low maintenance, and simpler interfaces.

"The focus for hematology is on workflow improvement and increased efficiencies," says Mary Beth Johnson, product manager for Beckman Coulter, Brea, Calif. "We want to decrease interaction of the technologist with the analyzer" to streamline workflow.

Ruth Becker, marketing manager for quality control and automation with Abbott's hematology unit in Santa Clara, Calif., says one aim is to reduce review rates and the need for manual intervention, "decreasing your need to have a highly trained workforce."

"Having high-quality analyzers can help retain trained staff by reducing the tedium of having to repeat tests or do them manually," says Andy Hay, business alliance manager for the Sysmex instruments at Roche Diagnostics, Indianapolis.

In hematology, change has come quickly. "The state of the art has moved faster in hematology than any other [diagnostic] discipline," says Jim Mulry, director of marketing for ABX Diagnostics, Irvine, Calif. Thanks to improved software and optics, the linearity in new machines is almost doubled from previous years, he says.

Expanded linearity—wider ranges to interpret results from analyzers rather than resorting to a manual procedure—will allow an instrument to handle a high white cell count without the need for a medical technologist to do serial dilutions, a high-complexity test under CLIA '88. For blood banks, increased linearity makes it possible to process higher platelet counts, maximizing the production of platelets for transfusion.

Automated quality control is another advance. "You have ongoing readings that tell you how precise and accurate the results are," Mulry says. "You can do online verification of accuracy at any time." He credits Abbott with introducing automated QC several years ago, but, he says, "now that feature is getting better and better in all the machines."

### Distinguishing features

In the annual CAP TODAY survey of hematology analyzers (pages 39–52), vendors were asked what features distinguish their systems from those of competitors. All five manufacturers cited improvements in detecting reticulocytes and immature cells, onboard quality control monitoring, and better linearity. High-end analyzers typically offer add-on slide-maker capability.

ABX's Mulry singled out the autoverification feature in its high-end Pentra 120. "The operator can

program in an algorithm that allows the system to auto repeat" if the results are not within defined parameters, he says. For instance, if a patient shows a high white blood cell count, the analyzer will find the tube, resample, and rerun the test.

The next generation of ABX hematology instruments is due out in summer 2002. The Pentra 80 hematology analyzer will have an onboard internal diluting system. The onboard dilution is a reflex test that will be performed automatically on the Pentra 80 should the sample require it, Mulry says.

Beckman Coulter stressed its autoverification technology, as well as "zero routine daily maintenance" and its remote monitoring and service technology.

"We look at certain parameters from the instrument and analyze trends to see if something is going wrong," says Naomi Culp, senior product manager, cellular analysis. "Then we call the customer to schedule service before it becomes an issue. We're the first in the industry to implement this proactive customer care."

Earlier this year, Beckman Coulter signed an agreement with eMation, which makes Internet-enabled remote diagnostic technology. In 2002, Beckman Coulter plans to implement the eMation technology on its hematology systems to improve the remote-monitoring capabilities of those instruments.

Within the next year, Beckman Coulter also expects to introduce an instrument that can perform other body fluids, including spinal fluid. "It's a matter of picking the tests that are automatable," Culp says, and obtaining Food and Drug Administration clearance. Abbott, too, believes that automating body fluid analysis is essential for future hematology systems.

Roche's Hay says the Sysmex line is moving forward using automated flow cytometry, which makes it possible to "probe cellular contents more accurately, identify abnormalities more clearly, and enumerate the abnormal events." Sysmex has introduced nucleated red cell counting, which can be a major source of manual review. "The new machine will automatically recalculate white cells and the differential," he says.

Abbott also stressed its flow cytometry capability. With its top-level analyzer, the Cell-Dyn 4,000, which contains an argon ion laser, "nucleated red blood cell counting is automatic as part of any routine WBC count and differential," says John Cieslewicz, marketing manager for the Abbott hematology business unit. Abbott, he adds, pioneered the use of fully automated monoclonal antibodies in routine hematology.

Another Cell-Dyn product, the Cell-Dyn Work-Cell, has automated data-review capability. Says Abbott's Becker, "You can program in certain criteria and the system will determine whether repeat testing is required." For example, "if you had a resistant red cell, you could set the criteria to automatically reflex to that mode. The operator wouldn't have to do anything," she says.

Bayer Diagnostics, Tarrytown, NY, has expanded its product line with a mid-range analyzer, the Advia 70, which can be used as a backup or as the primary instrument for smaller laboratories, says Leslie

McVeigh, marketing manager for hematology at Bayer. The Advia 70 offers such features as zero daily maintenance, automatic recounts, and micro-sampling for pediatrics. "You can select the sample-saver mode, which uses half the volume to perform the testing," she says.

Bayer also recently upgraded its Advia 120 hematology analyzer. The company received FDA clearance for the Advia 120 to analyze cells in cerebrospinal fluid. And Bayer plans to roll out a new automated quality control package for hematology in early 2002. The product, accessible via the Internet, will allow users to review quality control in real time.

With the wide range of available instruments, "it's important for customers to determine and prioritize their goals," McVeigh says. "Some questions to ask are: Are you looking to expand your laboratory services? What new areas do you want your lab to enter? What are the issues with your current systems? Do you have a need to reduce costs, labor, et cetera?"

### Shopping the systems

In making the purchase decision, the lab must understand its operational costs for handling blood analysis, McVeigh says. "You need to look at more than just price. Look at your long-term operational goals rather than just short-term price savings." Most laboratories will be able to assess their cost per test, "but that's not the whole story," she says. "You need to look at the labor involved, replacement costs, your review rates, and supply costs."

Evaluating competing analyzers in your laboratory can be helpful, but it consumes time and resources. A better option may be to talk to peers who use specific analyzers before making a purchase.

"I would give more credence to peer group review—contacting other users—than to bringing an instrument in and testing it," says Roche's Hay. The problem with an evaluation is that often no one has been trained on the analyzer, "so the results can be haphazard," he says. A more effective method is "to talk on the phone with everyone who has the instrument."

Ask users of the analyzer: Why did you pick this instrument? How has it increased productivity? How has it affected workflow? Has it reduced review rates? How easily can one be trained on it? How does it impact the patient?

"If you're going to test it yourself, make sure you do it right by running through a series of standard protocols," Hay advises.

ABX's Mulry recommends empirical testing. "Let the operators who are going to run the system establish the criteria to buy a system, and bring the instrument in for an in-house evaluation," he says.

Among the questions laboratorians should ask themselves: Does the analyzer do all the tests that I need? What processes will I have to change to use the machine? And they need to ask the vendor: As technology improves, can the analyzer add functionality? What is the frequency of maintenance and the cost? □

Karen Southwick is a writer in San Francisco.



Johnson



Culp



Mulry



Hay

## High-volume hematology analyzers

<b>Part 1 of 8</b>	Abbott Diagnostics Steven T. Dethlefsen steven.dethlefsen@abbott.com 100 Abbott Park Rd., Bldg. AP6C-5, Dept. 02KL Abbott Park, IL 60064 800-323-9100 ext. 7-8134 www.abbott.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	Cell-Dyn 3200 1997/1997 >700/>1,500/\$165,000
Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, % neut, mono, lymph, eos, baso FDA-cleared tests but not clinically released Tests not avail. but submitted for clearance Tests in development For research-use-only Tests unique to analyzer	•Chartable •Laboratory •Flags standard menu (left) plus: RDW, MPV band #%, IG #%, variant lymph #%, blast #%, PCT, PDW, NRBC #% band, IG, variant lymph, blast, NRBC, NWBC, RRBC, FWBC, RBC morph., high/low interp. message, LRI, URI, LURI, WBC none none none none 3-dimensional optical RBC analysis with advanced MCV measurement
Differential method(s) used Linearity: Precision: Accuracy of automated diff. compared with manual diff., per NCCLS H-20A Interfering substances: Interfering substances: differential	MAPSS (Multi-Angle Polarized Scatter Sep.) 0–250/0–8 0–25/0–1,750 35–180 (MCV) ≤2.7%/≤1.5% ≤1.0%/≤4.0% ≤1.0% (MCV) neut #%: ≥0.95, lymph #%: ≥0.94, mono #%: ≥0.86, eos #%: ≥0.84, baso#% ≥0.73 NRBCs, lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrinogen, fragile WBCs elevated WBC count, increased numbers of giant Plts, autoagglutination, in vitro hemolysis MCV: elevated WBC count, hyperglycemia, in vitro hemolysis, increased no. of giant Plts WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulins, Plt clumping, increased no. giant Plts elev. WBC count, incr. plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resist. RBCs n/a
Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended avg. frequency of calib. 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 avail., no. installed/list price	yes 78/78 6 mos verification open &/or closed/WBC, RBC, Hb, MCV, Plt, MPV 2 levels every 8 hrs/n/a 130 µL/250 µL/1 mL (sample loader) yes no yes yes 80/\$125,000
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 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 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 &/or result info. displayed	yes yes 10,000 results 10,000 results 10,000 results yes yes yes yes no yes user or vendor yes yes yes yes
LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results Optional data mgmt. or collation system Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per NCCLS standard Auto2A	proprietary numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast yes yes, avail. in 2002; price TBD; proprietary enhanced QC, data archiving, data collation from multiple instruments Lab-Interlink, MDS/Autolab, Beckman Coulter (planned), Roche (planned), Labotix Codabar, codes 39 & 128, interl. 2 of 5 yes
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 Mftr. can perform diagnostics via modem	daily: 30 sec; weekly: 5 min; monthly: 10 min yes avg. <4 hrs yes/no in development
Acquisition program based on cost-per-reportable result	yes
Distinguishing features	MAPSS cell-by-cell analysis provides a better diff; focused flow 2-dimensional optical RBC & Plt anal. provides better separation betw. microcytic RBCs & large Plts; uses only 3 reagents; 3D MCV

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

Survey editor: Raymond D. Aller, MD

## High-volume hematology analyzers

<p><i>Part 2 of 8</i></p> <p><i>See related article, page 38</i></p>	<p><b>Abbott Diagnostics</b>                  Steven T. Dethlefsen steven.dethlefsen@abbott.com                  100 Abbott Park Rd., Bldg. AP6C-5, Dept. 02KL                  Abbott Park, IL 60064                  800-323-9100 ext. 7-8134                  www.abbott.com</p>	<p><b>Abbott Diagnostics</b>                  Steven T. Dethlefsen steven.dethlefsen@abbott.com                  100 Abbott Park Rd., Bldg. AP6C-5, Dept. 02KL                  Abbott Park, IL 60064                  800-323-9100 ext. 7-8134                  www.abbott.com</p>
<p>Name of instrument                  First year sold—installed in U.S./outside U.S.                  No. units installed in U.S./outside U.S./list price</p>	<p>Cell-Dyn 3700                  1999/1999                  &gt;300/&gt;500/\$180,000 SL Model, \$140,000 CS Model</p>	<p>Cell-Dyn 4000                  1997/1997                  &gt;350/&gt;500/\$250,000</p>
<p>Test menu:                  •Chartable                  All instruments have:                  WBC, RBC, Hb, Hct, MCV, •Laboratory                  MCH, MCHC, Plt, %&amp;# neut,                  mono, lymph, eos, baso                  •Flags</p>	<p>standard menu (left) plus: RDW, MPV, retic #&amp;%, IRF                  band, IG, variant lymph, blast, PCT, PDW, NRBC #&amp;% &amp; retic scatter                  profile                  suspect populations, band, blast, variant lymph, IG, NRBC, RRBC, NWBC,                  LRI, URI, LURI, RBC morph., FWBC, high/low interp. message, WBC</p>	<p>standard menu (left) plus: RDW, MPV, NRBC #&amp;%, retic #&amp;%, IRF, CD61                  (immuno-Plt), CD 3/4, CD 3/8 (immuno T-cell)                  #&amp;% for segs, bands, IG, blasts, variant lymphs; PDW, PCT, white cell                  viability fraction (WVF)                  band, IG, blast, variant lymph, nvWBC, rstRBC, IR, Plt clump, ASYM,                  high/low interp. msg., PCT, PDW</p>
<p>FDA-cleared tests but not clinically released                  Tests not avail. but submitted for clearance                  Tests in development                  For research-use-only                  Tests unique to analyzer</p>	<p>none                  none                  none                  none                  IRF</p>	<p>none                  none                  none                  none                  reportable NRBC #&amp;%, CD61 for Plts, WVF, CD 3/4, CD 3/8 (immuno T-cell)</p>
<p>Differential method(s) used                  Linearity:                  •WBC count (10<sup>9</sup>/L)/RBC count (10<sup>12</sup>/L)                  •Hemoglobin (g/dL)/platelet (10<sup>9</sup>/L)                  •MCV (fL) or Hct (%)                  Precision:                  •WBC count/RBC count                  •Hb/platelet                  •MCV or Hct</p>	<p>MAPSS (Multi-Angle Polarized Scatter Sep.)                  0–99.9/0–8                  0–24/0–2,000                  50–200 (MCV)                  ≤2.5%/≤1.5%                  ≤1.2%/≤5.0%                  ≤1.0% (MCV)</p>	<p>Optical scatter &amp; fluorescence technology                  0–250/0–7.5                  1.0–25/0–2,000                  37–197 (MCV)                  ≤2.5%/≤1.5%                  ≤1.0%/≤4.0%                  ≤1.0% (MCV)</p>
<p>Accuracy of automated diff. compared with manual diff.,                  per NCCLS H-20A                  Interfering substances:•WBC</p>	<p>neut #&amp;%: ≥0.95, lymph #&amp;%: ≥0.94, mono #&amp;%: ≥0.86, eos #&amp;%: ≥0.84,                  baso #&amp;%: ≥0.73                  NRBCs (WIC only), lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofib-                  rinogen, fragile WBCs                  increased no. giant Plts, auto-agglut, in vitro hemolysis</p>	<p>%neut 0.94, %lymph 0.93, %mono 0.84, %eos 0.91, %baso 0.40,                  NRBC/WBC 0.91, retic 0.95                  lyse-resistant RBCs, Plt clumps</p>
<p>•RBC                  •MCV or Hct                  •Platelet                  •Hb</p>	<p>MCV: elevated WBC count, increased no. giant Plts, hyperglycemia, in vitro                  hemolysis</p> <p>WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulin, Plt                  clumps, increased no. giant Plts                  increased plasma substances (triglycerides, bilirubin, in vivo hemolysis),                  lytic-resistant RBCs                  n/a</p>	<p>autoagglutinins, cold agglutinins, hemolysis, small leukocytes (in cases                  where leukocyte count is high [&gt;100 K/μL] and MCV is high)                  MCV: in vitro hemolysis, auto- &amp; cold agglutinins, hyperglycemia, leukocytosis                  with macrocy. anemia</p> <p>Plt clumps, WBC &amp; RBC fragments, microcytic RBCs, auto- &amp; cold                  agglutinins, Plt satellitosis                  high lipids (&gt;700 mg/dL), high WBCs (&gt;250 K/μL, based on concentrated,                  normal WBCs), high bilirubin (&gt;33 mg/dL)                  n/a</p>
<p>Interfering substances: differential</p>	<p>n/a</p>	<p>n/a</p>
<p>Age- and sex-specific reference ranges                  Max. CBCs per hr/max. CBCs &amp; diffs. per hr                  Recommended avg. frequency of calib.                  •Modes calibrated/parameters 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 avail., no. installed/list price</p>	<p>yes                  90/90                  6 mos                  open &amp; closed/WBC, RBC, Hb, MCV, Plt                  2 levels every 8 hrs/n/a                  130 μL/355 μL/1.0 mL                  yes (13x75 mm)                  yes                  yes                  yes (flags only)                  80/\$125,000</p>	<p>yes                  106/106                  6 mos verification                  open-closed one proc./WBC, RBC, Hb, MCV, Plt, MPV                  2 levels every 8 hrs/n/a                  112.5 μL—aspir. vol./same/387 μL—dead vol.                  yes                  no                  yes (250 μL) in Sarstedt Multivette &amp; Becton Dickinson Microtainer tubes                  yes (flags only)                  80/\$125,000</p>
<p>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                  •Stored in conjunction with CBC data                  •Histo/cytogram images &amp; 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 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 &amp;/or result info. displayed</p>	<p>yes                  yes                  10,000 results                  10,000 results                  10,000 results                  yes                  yes                  yes                  yes                  no                  yes                  user or vendor                  yes                  yes                  yes                  yes</p>	<p>yes                  yes                  10,000 results                  10,000 results                  10,000 results                  yes                  yes                  yes                  yes                  yes                  user or vendor                  yes                  yes                  yes                  yes</p>
<p>LIS interface formats supported                  Information transferred on LIS interface                  LOINC codes transmitted with results                  Optional data mgmt. or collation system                  • Software features                  Interface avail. or planned to auto. specimen-handling system                  Bar-code symbologies read on tube                  Accommodates bar-code placement per NCCLS standard Auto2A</p>	<p>proprietary                  numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS; patient                  demographics, orders, LIS to instrument—broadcast                  yes                  yes, available in 2002; price TBD; proprietary                  enhanced QC, data archiving, data collation from multiple instruments                  Lab-Interlink (planned), MDS/AutoLab, Beckman Coulter (planned), Roche                  (planned), Labotix (planned)                  Codabar, codes 39 &amp; 128, interl. 2 of 5                  yes</p>	<p>proprietary                  num. &amp; flag results, histograms &amp; scatterplots, inst. to LIS; patient                  demographics, orders, LIS to inst.—broadcast; host query for demographics &amp;                  orders                  yes                  yes, available in 2002; price TBD; proprietary                  enhanced QC, data archiving, data collation from multiple instruments                  Lab-Interlink, MDS/AutoLab, Beckman Coulter (planned), Roche                  (planned), Labotix (planned)                  Codabar, codes 39 &amp; 128, interl. 2 of 5                  yes</p>
<p>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                  Mfr. can perform diagnostics via modem</p>	<p>daily: 30 sec; bi-weekly: 5 min; monthly: 10 min                  yes                  avg. &lt;4 hrs                  yes/no                  in development</p>	<p>daily: 30 sec; weekly: 5 min; monthly: 10 min                  yes                  avg. &lt;4 hrs                  yes/no                  in development</p>
<p>Acquisition program based on cost-per-reportable result</p>	<p>yes</p>	<p>yes</p>
<p>Distinguishing features</p>	<p>MAPSS cell-by-cell analysis provides a better diff; retic with reportable                  IRF (immature retic. fraction); 60-species veterinary package</p>	<p>reportable NRBC count, monoclonal antibody capability, fluoresc. random                  access retic w/ reportable IRF, WBC viability index, Argon laser</p>

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

## High-volume hematology analyzers

<p><b>Part 3 of 8</b></p> <p><i>See related article, page 38</i></p>	<p><b>ABX Diagnostics Inc.</b>                  Jim Mulry jmulry@us.abx.fr                  34 Bunsen                  Irvine, CA 92618                  888-903-5001 x 259 www.abx.fr</p>	<p><b>ABX Diagnostics Inc.</b>                  Jim Mulry jmulry@us.abx.fr                  34 Bunsen                  Irvine, CA 92618                  888-903-5001 x 259 www.abx.fr</p>
<p><b>Name of instrument</b>                  First year sold—installed in U.S./outside U.S.                  No. units installed in U.S./outside U.S./list price</p>	<p><b>Pentra 60<sup>+</sup> Hematology Analyzer</b>                  2000/2000                  100/300/\$49,500</p>	<p><b>Pentra 120 Retic Hematology Analyzer</b>                  1999/1997                  18/550/\$125,000</p>
<p><b>Test menu:</b></p> <ul style="list-style-type: none"> <li>•Chartable</li> <li>All instruments have:                      WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&amp;# neut, mono, lymph, eos, baso</li> <li>•Laboratory</li> <li>•Flags</li> </ul>	<p>standard menu (left) plus: RDW, MPV                  atyp. lymph, atyp. lymph %, LIC, LIC %                  complete operator selectable flagging</p>	<p>standard menu (left) plus: RDW, RTC, IRF, MPV                  LIC, atyp. lymph, PCT, PDW, CRC%                  82 quantitative &amp; qualitative flags</p>
<p>FDA-cleared tests but not clinically released                  Tests not avail. but submitted for clearance                  Tests in development                  For research-use-only                  Tests unique to analyzer</p>	<p>none                  none                  none                  none                  none</p>	<p>none                  none                  none                  none                  none</p>
<p><b>Differential method(s) used</b></p>	<p>DHSS technology combining cytochemistry, focused flow impedance, &amp; light absorbance principles of measurement</p>	<p>cytochemistry, focused flow impedance, light absorbance</p>
<p><b>Linearity:</b></p> <ul style="list-style-type: none"> <li>•WBC count (10<sup>9</sup>/L)/RBC count (10<sup>12</sup>/L)</li> <li>•Hemoglobin (g/dL)/platelet (10<sup>9</sup>/L)</li> <li>•MCV (fL) or Hct (%)</li> </ul>	<p>0.1–90/0.5–8.1                  2.5–23/10–1,000                  10–70 (Hct)</p>	<p>0.1–85/0.5–8.1                  2–25/10–1,000                  10–70 (Hct)</p>
<p><b>Precision:</b></p> <ul style="list-style-type: none"> <li>•WBC count/RBC count</li> <li>•Hb/platelet</li> <li>•MCV or Hct</li> </ul>	<p>&lt;2%/&lt;2%                  &lt;1%/&lt;5%                  &lt;1% (Hct)</p>	<p>3%/2%                  2%/5%                  2% (Hct)</p>
<p><b>Accuracy of automated diff. compared with manual diff., per NCCLS H-20A</b></p>	<p>neut 0.9997, lymph 0.9897, mono 0.9645, eos 0.8910, baso 0.5490</p>	<p>neut 0.99, lymph 0.99, mono 0.92, eos 0.97, baso 0.71</p>
<p><b>Interfering substances:</b></p> <ul style="list-style-type: none"> <li>•WBC</li> <li>•RBC</li> <li>•MCV or Hct</li> <li>•Platelet</li> <li>•Hb</li> </ul>	<p>NRBCs, Plt clumps, large Plts, lyse-resistant RBCs                  cold agglut, Plt clumps, WBC overlinearity                  lipemic samples, high WBC, lipemic specimens, aggluts</p> <p>RBC &amp; WBC frags                  lipemia, high WBC</p>	<p>unlysed RBCs, NRBCs, cryoglob.                  cold agglut, agglut RBCs                  RBC agglut, large Plts</p> <p>giant Plts, microcytes, Plt agglut                  elevated WBC, elevated lipids</p>
<p><b>Interfering substances: differential</b></p>	<p>NRBC, resistant RBCs, lipemia</p>	<p>lyse-resistant RBCs</p>
<p><b>Age- and sex-specific reference ranges</b>                  Max. CBCs per hr/max. CBCs &amp; diffs. per hr                  Recommended avg. frequency of calib.                  •Modes calibrated/parameters 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 avail., no. installed/list price</p>	<p>yes                  60/60                  6 months                  open/WBC, RBC, Hb, MCV, PCT                  daily/none                  53 µL/53 µL/0.5 mL                  yes (multiple sizes)                  yes                  no                  no                  —</p>	<p>yes                  120/120                  with major PM or part replacement                  open by cust., others by svc./WBC, RBC, Hb, Hct, Plt per CLIA standards/not required                  130 µL/200 µL/1 mL                  yes                  yes                  yes                  yes                  avail. May 2002/list price \$40,000</p>
<p><b>Archives patient data for later comparison</b>                  Patient-specific archiving                  Max. archived data accessible when system online                  Memory capacity—numeric results—no. specimens                  Memory capacity—histo/cytograms—no. specimens                  •Stored in conjunction with CBC data                  •Histo/cytogram images &amp; 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 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 &amp;/or result info. displayed</p>	<p>yes                  no                  —                  10,000                  10,000                  yes                  yes                  yes                  yes                  yes                  yes                  user                  yes                  no                  yes                  —</p>	<p>yes                  yes                  90,000                  90,000                  90,000                  —                  —                  yes                  yes                  yes                  yes                  user                  yes (operator programmable)                  no                  yes                  yes</p>
<p><b>LIS interface formats supported</b>                  Information transferred on LIS interface</p>	<p>ASTM 1394 &amp; 1238, HL7, IEEE MIB                  numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS; patient demographics, LIS to instrument—broadcast</p>	<p>proprietary, ASTM 1394 &amp; 1238, HL7, IEEE MIB                  num. &amp; flag results, histograms &amp; scatterplots, instr. to LIS; patient demographics, orders, LIS to instr.—broadcast; host query for demographics &amp; orders</p>
<p><b>LOINC codes transmitted with results</b>                  Optional data mgmt. or collation system                  • Software features</p>	<p>yes                  yes                  enhanced QC, data archiving</p>	<p>no                  yes                  enhanced QC, data archiving, data collation from multiple instruments</p>
<p><b>Interface avail. or planned to auto. specimen-handling system</b>                  Bar-code symbologies read on tube                  Accommodates bar-code placement per NCCLS standard Auto2A</p>	<p>no                  Codabar, codes 39 &amp; 128, ASTM, interl. 2 of 5                  yes</p>	<p>no                  Codabar, codes 39 &amp; 128, ASTM, interl. 2 of 5                  yes</p>
<p><b>Time required for maintenance by lab personnel</b>                  Onboard maintenance records                  Time from communication of problem to engineer on-site                  Onboard diagnostics/limited to software problems                  Mfr. can perform diagnostics via modem</p>	<p>weekly: 15 min                  yes                  12 hrs                  yes/no                  no</p>	<p>weekly: 10 min; monthly: 10 min                  yes                  4 hrs avg., 24 hrs guaranteed                  yes/no                  no</p>
<p><b>Acquisition program based on cost-per-reportable result</b></p>	<p>yes</p>	<p>yes, ABX prefers CPT acquisitions</p>
<p><b>Distinguishing features</b></p>	<p>reliable 5-part WBC diff technology—MTBF over 200 days; small footprint; small sample size of 53 µL</p>	<p>automatic repeats for sample verification, 48 hr WBC diff stability, random access retic enumeration</p>

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

## High-volume hematology analyzers

<p><b>Part 4 of 8</b></p> <p><i>See related article, page 38</i></p>	<p><b>Bayer Diagnostics</b>                  Nancy Lavon nancy.lavon.b@bayer.com                  555 White Plains Rd., Tarrytown, NY 10591                  800-431-1970                  www.bayerdiag.com</p>	<p><b>Bayer Diagnostics</b>                  Nancy Lavon nancy.lavon.b@bayer.com                  555 White Plains Rd., Tarrytown, NY 10591                  800-431-1970                  www.bayerdiag.com</p>
<p><b>Name of instrument</b>                  First year sold—installed in U.S./outside U.S.                  No. units installed in U.S./outside U.S./list price</p>	<p><b>Advia 120 Hematology System</b>                  1998/1998                  600/2,500/\$169,000–\$189,000</p>	<p><b>Advia 70</b>                  2001/2001                  —/—/\$89,000</p>
<p><b>Test menu:</b> •Chartable</p> <p>All instruments have:                  WBC, RBC, Hb, Hct, MCV,                  MCH, MCHC, Plt, %neut, mono, lymph, eos, baso</p> <p>•Laboratory</p> <p>•Flags</p> <p>FDA-cleared tests but not clinically released                  Tests not avail. but submitted for clearance                  Tests in development                  For research-use-only                  Tests unique to analyzer</p>	<p>standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&amp;#, retic %&amp;#, Chr, CHCMr, MCVR</p> <p>%: hypo, hyper, macro, micro; calc. Hb, MPXI;                  %: blasts, PMN, MN; large Plt count; RBC frag. count; RBC ghost count</p> <p>left shift, atyp. lymph, blasts, immature grans, myeloperox. deficiency, aniso, micro, macro, Hb variation, hypo, hyper, NRBC, RBC frag., RBC ghost, large Plt, Plt clumps</p> <p>none                  none                  IRF, MPC, MPM                  none                  CHCM, HDW, Chr, CHCMr, MPC, MPM</p>	<p>standard menu (left) plus: RDW, MPV</p> <p>none</p> <p>diff., WBC, N, B, L, RBC, ABN, PL, Cl, Plt/RBC</p> <p>—                  —                  —                  Pct, PDW                  —</p>
<p><b>Differential method(s) used</b></p> <p><b>Linearity:</b> •WBC count (10<sup>9</sup>/L)/RBC count (10<sup>12</sup>/L)                  •Hemoglobin (g/dL)/platelet (10<sup>9</sup>/L)                  •MCV (fL) or Hct (%)</p> <p><b>Precision:</b> •WBC count/RBC count                  •Hb/platelet                  •MCV or Hct</p> <p><b>Accuracy of automated diff. compared with manual diff., per NCCLS H-20A</b></p> <p><b>Interfering substances:</b>•WBC                  •RBC                  •MCV or Hct</p> <p>•Platelet                  •Hb</p> <p><b>Interfering substances: differential</b></p>	<p>perox–peroxidase cytochem. staining w/ light scatter &amp; absorption; baso–cytochem. stripping with 2-angle laser light scatter</p> <p>0.02–400/0–7.0                  0–22.5 /5–3,500                  30–180 (MCV)                  2.7%/1.2%                  0.93%/2.93%                  0.78% (MCV)                  neut 0.997r, lymph 0.997r, mono 0.943r, eos 0.979r, baso 0.772r, luc 0.944r</p> <p>incomplete RBC lysis (perox only)                  cold agglut, extreme sickle cell                  none</p> <p>none                  high WBC, lip., extremely high bili., interfere w/ cyanmethb only, none w/ direct cellular Hb (CHCM)                  incomplete lysis of RBCs, complete myeloperox. def.</p>	<p>optical &amp; enhanced impedance</p> <p>0.1–99/0.02–9.99                  1.5–30/10–2,000                  30–150 (MCV)                  2.0%/1.2%                  1.0%/3–10%                  1.0% (MCV)                  neut% r&gt;0.9, lymph% r&gt;0.9, mono% &gt;0.7, eos% r&gt;0.8, baso% &gt;0.5</p> <p>incomplete RBC lysis                  cold agglutinins                  extremely high white blood cell count (HCT)</p> <p>RBC fragments                  lipemia, elevated WBC</p> <p>NRBCs, unlysed RBC, platelet clumps</p>
<p><b>Age- and sex-specific reference ranges</b>                  Max. CBCs per hr/max. CBCs &amp; diffs. per hr                  Recommended avg. frequency of calib.                  •Modes calibrated/parameters calibrated</p> <p><b>Frequency of blood/latex controls</b>                  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 avail., no. installed/list price</p>	<p>yes                  120/120                  6 mos                  open, closed, autosampler/all measured params                  once per shift/not required                  157 µL/157 µL/&lt;300 µL (tube size dependent)                  yes (2, 3, 5, 7 mL—all sizes—open tube)                  yes                  yes                  yes                  n/a</p>	<p>yes                  70/70                  every 6 mos per governmental requirements                  open &amp; closed/all measured parameters                  one level per shift/not required                  90 µL/180 µL/120 µL                  yes (12x75)                  no                  yes                  yes                  Advia 560, just released/\$35,000</p>
<p><b>Archives patient data for later comparison</b>                  Patient-specific archiving                  Max. archived data accessible when system online                  Memory capacity—numeric results—no. specimens                  Memory capacity—histo/cytograms—no. specimens                  •Stored in conjunction with CBC data                  •Histo/cytogram images &amp; CBC data printed as 1 report</p> <p><b>Saved results can be recalled and retransmitted</b>                  Saved data can be sorted for reprocessing 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 LIS while others held                  Scattergram display: cell-specific color                  Histogram display: color with threshold                  Choice of desired specimen &amp;/or result info. displayed</p>	<p>yes                  no                  10,000 samples                  10,000                  10,000                  yes                  yes                  yes                  yes                  yes                  yes                  user or vendor                  yes                  yes                  yes                  yes</p>	<p>yes                  yes                  100,000                  100,000                  100,000                  yes                  yes                  yes                  yes                  yes                  user                  all results for that sample are transmitted at once                  yes                  yes                  yes</p>
<p><b>LIS interface formats supported</b>                  Information transferred on LIS interface</p> <p><b>LOINC codes transmitted with results</b>                  Optional data mgmt. or collation system                  • Software features</p> <p><b>Interface avail. or planned to auto. specimen-handling system</b>                  Bar-code symbologies read on tube                  Accommodates bar-code placement per NCCLS standard Auto2A</p>	<p>proprietary (Spec 79)                  num. &amp; flag results, histograms &amp; scatterplots, instr. to LIS; patient demographics, orders, LIS to instr.— broadcast; host query for demographics &amp; orders</p> <p>no                  in development</p> <p>MXS (Japan), LabCell (Bayer)                  Codabar, codes 39 &amp; 128, ASTM, interl. 2 of 5                  yes</p>	<p>proprietary, ASTM 1394, E 1381                  num. &amp; flag results, instr. to LIS; patient demographics, patient orders, LIS to instr.— broadcast</p> <p>—                  in development</p> <p>—                  Codabar, code 39, interl. 2 of 5                  yes</p>
<p><b>Time required for maintenance by lab personnel</b>                  Onboard maintenance records                  Time from communication of problem to engineer on-site                  Onboard diagnostics/limited to software problems                  Mftr. can perform diagnostics via modem</p>	<p>daily: 15 min; weekly: 15 min; monthly: 15 min                  yes                  territory dependent                  yes/no                  yes</p>	<p>daily: 0; weekly: 0; monthly: 20 min                  yes                  territory dependent                  yes/no                  in development</p>
<p><b>Acquisition program based on cost-per-reportable result</b></p>	<p>yes</p>	<p>yes</p>
<p><b>Distinguishing features</b></p>	<p>unique laser technology provides cellular Hb for RBCs &amp; retics; 2-dimensional Plt analysis that eliminates interference from RBC fragments &amp; exclusion of large PIts; dual WBC counts w/ a linearity of up to 400,000</p>	<p>microsampling; auto recount; dual WBCs; automatic wakeup &amp; shutdown; no daily or weekly maintenance</p>

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

## High-volume hematology analyzers

<p><i>Part 5 of 8</i></p> <p><i>See related article, page 38</i></p>	<p>Beckman Coulter Inc. Martha M. Diaz/Cellular Analysis Marketing 200 S. Kraemer Blvd., Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com</p>	<p>Beckman Coulter Inc. Martha M. Diaz/Cellular Analysis Marketing 200 S. Kraemer Blvd., Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com</p>
<p>Name of instrument First year sold—installed in U.S./outside U.S. No. units installed in U.S./outside U.S./list price</p>	<p>Coulter LH 700 Series 2001 —/—/LH 750: \$195,000; LH 755: \$367,500</p>	<p>Coulter GEN•S System 1996 &gt;1,100/&gt;2,000/\$177,500; w/ SlideMaker-stainer, \$327,000</p>
<p>Test menu: •Chartable</p> <p>All instruments have: WBC, RBC, Hb, Hct, MCV, •Laboratory MCH, MCHC, Plt, %&amp;# neut, •Flags mono, lymph, eos, baso</p> <p>FDA-cleared tests but not clinically released Tests not avail. but submitted for clearance Tests in development For research-use-only Tests unique to analyzer</p>	<p>standard menu (left) plus: RDW, MPV, retic #&amp;%, IRF, MPV, graded RBC morph, NRBC %&amp;#/100 WBC PCT, PDW user-definable age-, gender-, &amp;/or location-based ref.; intervals, action &amp; critical limits; user-def. RBC morph.; gradient msgs. (=+, ++, +++); user-selectable sensitivity for diff abnormal pop, suspect messages</p> <p>none none none high light scatter retics, mean spherical cell vol. NRBC, mean spherical cell vol.</p>	<p>standard menu (left) plus: RDW, MPV, retic #&amp;%, graded RBC morph., MRV, IRF PCT, PDW user-definable age-, gender- &amp;/or location-based ref. intervals, action &amp; critical limits; user-def. RBC morph. gradient msgs. (=+, ++, +++); user-selectable sensitivity for diff abnormal pop. suspect msgs.</p> <p>none — none high light scatter retics, mean spherical cell vol. mean spherical cell vol.</p>
<p>Differential method(s) used</p> <p>Linearity: •WBC count (10<sup>9</sup>/L)/RBC count (10<sup>12</sup>/L) •Hemoglobin (g/dL)/platelet (10<sup>9</sup>/L) •MCV (fL) or Hct (%)</p> <p>Precision: •WBC count/RBC count •Hb/platelet •MCV or Hct</p> <p>Accuracy of automated diff. compared with manual diff., per NCCLS H-20A Interfering substances:•WBC</p> <p>•RBC •MCV or Hct</p> <p>•Platelet</p> <p>•Hb</p> <p>Interfering substances: differential</p>	<p>Coulter's 3-D VCS technology, AccuCount technology, AccuFlex technology w/ IntelliKinetics &amp; AccuGate</p> <p>0-400/0-8.0 0-25/0-3,000 50-200 (MCV) &lt;1.7%/&lt;0.8% &lt;0.8%/&lt;3.3% &lt;0.8% (MCV) lymph%= ±1.5%, neut%= ±2.0%, mono%= ±1.0%, eos%= ±0.5%, baso%= ±0.5% unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle &gt;35 fL, large Plt very high WBC, high conc. large Plt, autoagglutinins MCV &amp; Hct: very high WBC, high conc. large Plt, autoagglutinins</p> <p>very small RBCs &amp; WBC frags. may interfere; chemotherapy may affect certain samples. very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing</p>	<p>Coulter's 3-D VCS technology, AccuFlex technology w/ IntelliKinetics &amp; AccuGate</p> <p>0-140/0-8.0 0-25/0-1,500 50-200 (MCV) &lt;1.7%/&lt;0.8% &lt;0.8%/&lt;3.3% &lt;0.8% (MCV) lymph%= ±3.0%, mono%= ±2.0%, neut%= ±3.0%, eos%= ±1.0%, baso%= ±1.0% unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle &gt;35 fL, large Plt very high WBC, high conc. large Plt, autoagglutinins MCV &amp; Hct: very high WBC, high conc. large Plt, autoagglutinins</p> <p>very small RBCs &amp; WBC frags. may cause no-fit; chemotherapy may affect certain samples very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing</p>
<p>Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs &amp; diffs. per hr Recommended avg. frequency of calib. •Modes calibrated/parameters calibrated</p> <p>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 avail., no. installed/list price</p>	<p>yes 105/105 2 times/yr primary/RBC, WBC, Hb, MCV, Plt, MPV once per shift/once per day 200 µL/300 µL/550 µL with Slidemaker/1.0 mL yes (multiple sizes &amp; styles) no yes yes, both &gt;100 U.S./\$175,000</p>	<p>yes 105/105 2 times/yr primary/RBC, WBC, Hb, MCV, Plt, MPV once per shift/once per day 200 µL/300 µL/550 µL with SlideMaker/1.0 mL yes (multiple sizes &amp; styles) no yes yes, both &gt;100 U.S./\$175,000</p>
<p>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 •Stored in conjunction with CBC data •Histo/cytogram images &amp; 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 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 &amp;/or result info. displayed</p>	<p>yes yes 20,000 samples 20,000 5,000 yes yes yes yes yes yes yes yes yes yes yes yes yes</p>	<p>yes yes 20,000 samples 20,000 5,000 yes yes yes yes yes yes yes yes yes yes yes yes yes</p>
<p>LIS interface formats supported</p> <p>Information transferred on LIS interface</p> <p>LOINC codes transmitted with results Optional data mgmt. or collation system • Software features</p> <p>Interface avail. or planned to auto. specimen-handling system</p> <p>Bar-code symbologies read on tube Accommodates bar-code placement per NCCLS standard Auto2A</p>	<p>proprietary</p> <p>numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no yes enhanced QC, data archiving, common database, extensive decision rules, delta checking Beckman Coulter</p> <p>Codabar, codes 39 &amp; 128, interl. 2 of 5, NW-7 no</p>	<p>proprietary</p> <p>numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no yes enhanced QC, data archiving, common database, extensive decision rules, delta checking Beckman Coulter</p> <p>Codabar, codes 39 &amp; 128, interl. 2 of 5, NW-7 no</p>
<p>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 Mftr. can perform diagnostics via modem</p>	<p>monthly: 2 min yes — yes/no yes</p>	<p>monthly: 2 min yes — yes/no yes</p>
<p>Acquisition program based on cost-per-reportable result</p>	<p>yes</p>	<p>yes</p>
<p>Distinguishing features</p>	<p>VCS technol., lowest review rate in class, zero daily maint., triplicate counting, aperture burn circuit, sweepflow, SmartStart, AccuGate, AccuFlex, IntelliKinetics application, WBC in near native state, 3-D diff. display, online training &amp; help, random access, AccuCount technology for extended linearity and enhanced WBC and Plt counts</p>	<p>VCS technol., lowest review rate in class, zero daily maint., triplicate counting, aperture burn circuit, sweepflow, SmartStart, AccuGate, AccuFlex, IntelliKinetics application, WBC in near native state, 3-D diff. display, online training &amp; help</p>

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

## High-volume hematology analyzers

<p><i>Part 6 of 8</i></p> <p><i>See related article, page 38</i></p>	<p>Beckman Coulter Inc. Martha M. Diaz/Cellular Analysis Marketing 200 S. Kraemer Blvd., Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com</p>	<p>Beckman Coulter Inc. Martha M. Diaz/Cellular Analysis Marketing 200 S. Kraemer Blvd., Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com</p>
<p>Name of instrument First year sold—installed in U.S./outside U.S. No. units installed in U.S./outside U.S./list price</p>	<p>Coulter HmX 1999 HmX AL, 1999 HmX CP &gt;100/&gt;250/\$135,000 AL; \$120,000 CP</p>	<p>Coulter MAXM with Reticulocytes 1991 MAXM; 1992 MAXM AL &gt;2,100/2,400/MAXM with retics \$90,000; MAXM AL with retics \$105,000</p>
<p>Test menu: •Chartable All instruments have: WBC, RBC, Hb, Hct, MCV, •Laboratory MCH, MCHC, Plt, %&amp;# neut, mono, lymph, eos, baso •Flags</p>	<p>standard menu (left) plus: RDW, MPV, retic #&amp;%, graded RBC morph., IRF, MRV PCT, PDW  comprehensive high/low, definitive &amp; suspect messages</p>	<p>standard menu (left) plus: RDW, MPV, retic #&amp;%, graded RBC morph. PCT, PDW  comprehensive high/low, definitive &amp; suspect messages</p>
<p>FDA-cleared tests but not clinically released Tests not avail. but submitted for clearance Tests in development For research-use-only Tests unique to analyzer</p>	<p>none none none none none</p>	<p>none none none mean retic vol., maturation index none</p>
<p>Differential method(s) used</p>	<p>Coulter's 3-D VCS technology</p>	<p>Coulter's 3-D VCS technology</p>
<p>Linearity: •WBC count (10<sup>9</sup>/L)/RBC count (10<sup>12</sup>/L) •Hemoglobin (g/dL)/platelet (10<sup>9</sup>/L) •MCV (fL) or Hct (%)</p>	<p>0–99.9/0–7.0 0–25/0–999 50–150 (MCV)</p>	<p>0–99.9/0–7.0 0–25/0–999 50–150 (MCV)</p>
<p>Precision: •WBC count/RBC count •Hb/platelet •MCV or Hct</p>	<p>&lt;2.5%/&lt;2.0% &lt;1.5%/&lt;5.0% &lt;2.0% (MCV)</p>	<p>&lt;2.5%/&lt;2.0% &lt;1.5%/&lt;5.0% &lt;2.0% (MCV)</p>
<p>Accuracy of automated diff. compared with manual diff., per NCCLS H-20A</p>	<p>lymph%= ±3.0%, mono%= ±2.0%, neut%= ±3.0%, eos%= ±1.0%, baso%= ±1.0%</p>	<p>lymph%= ±3.0%, mono%= ±2.0%, neut%= ±3.0%, eos%= ±1.0%, baso%= ±1.0%</p>
<p>Interfering substances:•WBC  •RBC •MCV or Hct  •Platelet  •Hb</p>	<p>unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle &gt;35 fL, large Plt  very high WBC, high conc. of very large Plt, autoagglutinins MCV &amp; Hct: very high WBC, high conc. of large Plt, autoagglutinins  very small RBCs &amp; WBC frags. may cause no-fit; chemotherapy may affect certain samples very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs</p>	<p>unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle &gt;35 fL, large Plt  very high WBC, high conc. of very large Plt, autoagglutinins MCV &amp; Hct: very high WBC, high conc. of large Plt, autoagglutinins  very small RBCs &amp; WBC frags. may cause no-fit; chemotherapy may affect certain samples very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs</p>
<p>Interfering substances: differential</p>	<p>high triglycerides may affect lysing</p>	<p>high triglycerides may affect lysing</p>
<p>Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs &amp; diffs. per hr Recommended avg. frequency of calib. •Modes calibrated/parameters 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 avail., no. installed/list price</p>	<p>gender-specific printout 75/75 2 times/yr primary/RBC, WBC, Hb, MCV, Plt, MPV once per shift/once per day 125 µL/185 µL/50 µL predilute/0.5 mL yes (multiple sizes &amp; styles) no yes no n/a</p>	<p>gender-specific printout 75/75 4 times/yr primary/RBC, WBC, Hb, MCV, Plt, MPV once per shift/once per day 125 µL/185 µL/50 µL predilute/0.5 mL yes (multiple sizes &amp; styles) no yes no n/a</p>
<p>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 •Stored in conjunction with CBC data •Histo/cytogram images &amp; 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 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 &amp;/or result info. displayed</p>	<p>yes yes 5,000 samples 5,000 5,000 yes yes yes yes no yes user or vendor yes, through a selective batch process 4 colors/cell types colors without thresholds no</p>	<p>no yes 5,000 samples 5,000 5,000 yes yes yes yes no yes user or vendor no (all held) 4 colors/cell types colors without thresholds no</p>
<p>LIS interface formats supported  Information transferred on LIS interface LOINC codes transmitted with results Optional data mgmt. or collation system • Software features  Interface avail. or planned to auto. specimen-handling system  Bar-code symbologies read on tube Accommodates bar-code placement per NCCLS standard Auto2A</p>	<p>proprietary numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no yes enhanced QC, data archiving, common database, extensive decision rules, delta checking Beckman Coulter  Codabar, codes 39 &amp; 128, interl. 2 of 5, NW-7 no</p>	<p>proprietary numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no yes enhanced QC, data archiving, common database, extensive decision rules, delta checking Beckman Coulter  Codabar, codes 39 &amp; 128, interl. 2 of 5, NW-7 no</p>
<p>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 Mfr. can perform diagnostics via modem</p>	<p>monthly: 2 min no — yes/no no</p>	<p>monthly: 2 min no — yes/no no</p>
<p>Acquisition program based on cost-per-reportable result</p>	<p>yes</p>	<p>yes</p>
<p>Distinguishing features</p>	<p>VCS technology, lowest review rate in class, zero routine daily maint., triplicate counting, aperture burn circuit, sweepflow, SmartStart system, autoloader &amp; single sample models</p>	<p>VCS technology, lowest review rate in class, zero routine daily maint., triplicate counting, aperture burn circuit, sweepflow, autoloader &amp; single sample models</p>

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

## High-volume hematology analyzers

<p><i>Part 7 of 8</i></p> <p><i>See related article, page 38</i></p>	<p><b>Beckman Coulter Inc.</b> Martha M. Diaz/Cellular Analysis Marketing 200 S. Kraemer Blvd., Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com</p>	<p><b>Roche Diagnostics Corp.</b> Peggy Barranco 9115 Hague Rd., Indianapolis, IN 46250-0475 800-428-5074 www.roche.com</p>
<p>Name of instrument First year sold—installed in U.S./outside U.S. No. units installed in U.S./outside U.S./list price</p>	<p>Coulter Act 5diff Family 2001/2000 75/300/\$43,500 cap pierce model; \$38,500 open vial model</p>	<p>Sysmex SF-3000 1996/— 100/2,300/\$120,000</p>
<p>Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&amp;# neut, mono, lymph, eos, baso</p>	<p>•Chartable •Laboratory •Flags</p>	<p>standard menu (left) plus: RDW, MPV atyp. lymph # (ATL#), atyp. lymph % (ATL%), immature cells # (IMM#), immature cells % (IMM%), PCT, PDW complete operator selectable flagging</p>
<p>FDA-cleared tests but not clinically released Tests not avail. but submitted for clearance Tests in development For research-use-only Tests unique to analyzer</p>	<p>none none none PCT, PDW, IMM, ATL none</p>	<p>standard menu (left) plus: RDW-SD, RDW-CV, MPV none RBC agglut, turbidity/Hb interference, WBC abn scattergram, RBC abn distrib, Plt abn distrib, NRBC/Plt clumps, blasts, immature grans, left shift, atyp./abn lymph PDW, P-LCR none none none none</p>
<p>Differential method(s) used</p>	<p>A<sup>c</sup>V technology combining cytochemistry, focused flow impedance, and light absorbance principles of measurement</p>	<p>flow cyto with semiconductor laser for lymph, mono, neut, eos, baso</p>
<p>Linearity: Precision: Accuracy of automated diff. compared with manual diff., per NCCLS H-20A Interfering substances: •WBC •RBC •MCV or Hct •Platelet •Hb Interfering substances: differential</p>	<p>•WBC count (10<sup>9</sup>/L)/RBC count (10<sup>12</sup>/L) •Hemoglobin (g/dL)/platelet (10<sup>9</sup>/L) •MCV (fL) or Hct (%) •WBC count/RBC count •Hb/platelet •MCV or Hct</p> <p>0.1–90/0.5–8.1 2.5–23/10–1,000 10–70 (Hct) &lt;2%/&lt;2% &lt;1%/&lt;5% &lt;1.0% (Hct) not available in NCCLS H-20A format</p> <p>NRBCs, Plt clumps, large Pits, lyse-resistant RBCs cold agglut, Plt clumps, WBC overlinearity</p> <p>Hct: lipemic samples, high WBC, cold aggluts</p> <p>RBC and WBC fragments</p> <p>elevated WBC, lipemia</p> <p>lyse-resistant RBCs, NRBCs, lipemia</p>	<p>1–99.99/1–9.99 2–25/10–999 10–60 (Hct) 3% (WBC&gt;4)/1.5% (RBC&gt;4) 1.5%/5% (Pit&gt;100) 1.5% (Hct) neut% R&gt;0.90, lymph% R&gt;0.90, mono% R&gt;0.75, eos% R&gt;0.80, baso% R&gt;0.50 cold agglut, Plt clumps, NRBCs, cryoglobulins cold agglut, severe microcytosis, frag. RBCs, WBC &gt; 100,000/μL cold agglut, WBC&gt;100,000/μL, abn RBC fragility Plt satellitism, Plt clumps, increased microcytosis, giant Pits WBC&gt;100,000/μL, lipemia, abn proteins lyse-resistant RBCs</p>
<p>Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs &amp; diffs. per hr Recommended avg. frequency of calib. •Modes calibrated/parameters 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 avail., no. installed/list price</p>	<p>yes 60/60 6 mos open/RBC, WBC, Hb, Hct, Plt daily/none 53 μL/53 μL/0.5 mL yes (multiple sizes) no yes no n/a</p>	<p>no 80/80 with major PM or parts replacement open by customer, others by svc./WBC, RBC, Hb, Hct, Plt 2 levels per 8 hrs operation/service calibration only 170 μL/270 μL/1 mL yes (3 mL, 5 mL, 7 mL) no yes no &gt;100/—</p>
<p>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 •Stored in conjunction with CBC data •Histo/cytogram images &amp; 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 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 &amp;/or result info. displayed</p>	<p>yes no 10,000 samples 10,000 10,000 yes yes yes yes yes no yes yes, through user-defined criteria no yes yes yes</p>	<p>yes no 1,000 samples (additional on disk) 1,000 1,000 yes yes yes yes yes yes user or vendor yes yes yes yes</p>
<p>LIS interface formats supported</p>	<p>proprietary</p>	<p>RS-232C</p>
<p>Information transferred on LIS interface</p>	<p>numeric &amp; flag results, histograms &amp; diff plots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast</p>	<p>numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics &amp; orders</p>
<p>LOINC codes transmitted with results Optional data mgmt. or collation system • Software features</p>	<p>no yes enhanced QC, data archiving, common database, optional data mgmt., extensive decision rules, delete checking</p>	<p>— yes, proprietary enhanced QC, data archiving, data collation from multiple instruments</p>
<p>Interface avail. or planned to auto. specimen-handling system</p>	<p>no</p>	<p>no</p>
<p>Bar-code symbologies read on tube Accommodates bar-code placement per NCCLS standard Auto2A</p>	<p>Codabar, codes 39 &amp; 128, interl. 2 of 5, EAN 8 &amp; 13 yes</p>	<p>— yes</p>
<p>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 Mftr. can perform diagnostics via modem</p>	<p>weekly: 5 min yes — yes/no no</p>	<p>daily: 15 min; weekly: 20 min; monthly: 15 min yes territory dependent no/no no</p>
<p>Acquisition program based on cost-per-reportable result</p>	<p>yes</p>	<p>yes</p>
<p>Distinguishing features</p>	<p>only quant. 5-part WBC diff inst. that lists for &lt;\$40,000; aspirates only 53 μL of sample; requires small space footprint and runs quietly</p>	<p>Adaptive Cluster Anal. System (ACAS), semiconductive diode laser, bidirectional communications</p>

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



## High-volume hematology analyzers

<p><i>Part 8 of 8</i></p> <p><i>See related article, page 38</i></p>	<p>Roche Diagnostics Corp. Andy Hay 9115 Hague Rd., Indianapolis, IN 46250-0475 800-428-5074 www.roche.com</p>	<p>Roche Diagnostics Corp. Andy Hay 9115 Hague Rd., Indianapolis, IN 46250-0475 800-428-5074 www.roche.com</p>
<p>Name of instrument First year sold—installed in U.S./outside U.S. No. units installed in U.S./outside U.S./list price</p>	<p>Sysmex XE 2100/XE 2100-L 2000 100/1,000/\$225,000</p>	<p>Sysmex XE 2100 Alpha/HST 2000 10/140/\$360,000–\$1,000,000</p>
<p>Test menu: •Chartable All instruments have: WBC, RBC, Hb, Hct, MCV, •Laboratory MCH, MCHC, Plt, %&amp;# neut, mono, lymph, eos, baso •Flags</p> <p>FDA-cleared tests but not clinically released Tests not avail. but submitted for clearance Tests in development For research-use-only Tests unique to analyzer</p>	<p>standard menu (left) plus: NRBC %&amp;#, retic %&amp;#*, RDW-SD, RDW-CV, IRF* none Pit clumps, RBC agglut, turbidity, WBC abn scattergram, RBC abn distrib, PIt abn distrib, RBC lyse resistance, NRBC/PIt clumps, blasts, immature grans, atyp./abn lymphs, abn lymph/aged sample none HPC %&amp;#, IG %&amp;# MPV, P-LCR, PCT, PDW NRBC, IMI channel</p>	<p>standard menu (left) plus: NRBC %&amp;#, retic %&amp;#, RDW-SD, RDW-CV, IRF none Pit clumps, RBC agglut, turbidity, WBC abn scattergram, RBC abn distrib, PIt abn distrib, RBC lyse resistance, NRBC/PIt clumps, blasts, immature grans, atyp./abn lymphs, abn lymph/aged sample none HPC %&amp;#, IG %&amp;# MPV, P-LCR, PCT, PDW NRBC, IMI channel</p>
<p>Differential method(s) used Linearity: Precision: Accuracy of automated diff. compared with manual diff., per NCCLS H-20A Interfering substances:•WBC</p>	<p>flow cytometry using semiconductor laser RF/DC detecting method 0–170/0–8 0–25/0–5,000 0–60 (Hct) &lt;3%/&lt;1.5% &lt;1.0%/&lt;4.0% &lt;1.0% (Hct) neut% R=0.95, lymph% R=0.95, mono% R=0.79, eos% R=0.92, baso% R=0.82, NRBC% R=0.96 cold agglut, PIt aggreg, nucl. RBCs, cryoglob., lyse-resistant RBCs in patients w/ hemoglobinopathies, severe liver disease, or neonates cold agglut, severe microcytosis, frag. RBCs, large no. giant PIts, in vitro hemolysis Hct: cold agglut, leukocytosis (&gt;100,000/μL), abn red cell fragility, spherocytosis pseudothrombocytopenia, PIt aggreg, incr. microcytosis, megalocytic PIts lipemia, abn proteins in blood plasma, severe leukocytosis (&gt;100,000/μL)</p> <p>lyse-resistant RBCs</p>	<p>flow cytometry using semiconductor laser RF/DC detecting method 0–170/0–8 0–25/0–5,000 0–60 (Hct) &lt;3%/&lt;1.5% &lt;1.0%/&lt;4.0% &lt;1.0% (Hct) neut% R=0.95, lymph% R=0.95, mono% R=0.79, eos% R=0.92, baso% R=0.82, NRBC% R=0.96 cold agglut, PIt aggreg, nucl. RBCs, cryoglob., lyse-resistant RBCs in patients w/ hemoglobinopathies, severe liver disease, or neonates cold agglut, severe microcytosis, frag. RBCs, large no. giant PIts, in vitro hemolysis Hct: cold agglut, leukocytosis (&gt;100,000/μL), abn red cell fragility, spherocytosis pseudothrombocytopenia, PIt aggreg, incr. microcytosis, megalocytic PIts lipemia, abn proteins in blood plasma, severe leukocytosis (&gt;100,000/μL)</p> <p>lyse-resistant RBCs</p>
<p>Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs &amp; diffs. per hr Recommended avg. frequency of calib. •Modes calibrated/parameters 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 avail., no. installed/list price</p>	<p>yes 150/150 annually open, closed, capillary/WBC, RBC, Hb, Hct, PIt per CLIA requirements/not required 130 μL/200 μL/1 mL yes no yes yes w/ Alpha or HST upgrade &gt;100/TBD</p>	<p>yes 150/600 annually open, closed, capillary/WBC, RBC, Hb, Hct, PIt per CLIA requirements/not required 130 μL/200 μL/1 mL yes no yes yes yes</p>
<p>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 •Stored in conjunction with CBC data •Histo/cytogram images &amp; 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 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 &amp;/or result info. displayed</p>	<p>yes yes 10,000 samples 10,000 10,000 yes yes yes yes yes yes yes yes yes yes yes yes yes</p>	<p>yes yes 10,000 samples 10,000 10,000 yes yes yes yes yes yes yes yes yes yes yes yes</p>
<p>LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results Optional data mgmt. or collation system • Software features Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per NCCLS standard Auto2A</p>	<p>RS-232C/TCP IP numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics &amp; orders — yes, proprietary enhanced QC, data archiving, data collation from multiple instruments, online QC Roche, Labotix, IDS, A&amp;T Codabar, codes 39 &amp; 128, interl. 2 of 5, ITF, NW-7, EAN 8 &amp; 13 yes</p>	<p>RS-232C/TCP IP numeric &amp; flag results, histograms &amp; scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics &amp; orders — yes, proprietary enhanced QC, data archiving, data collation from multiple instruments, online QC Roche, Labotix, IDS, A&amp;T Codabar, codes 39 &amp; 128, interl. 2 of 5, ITF, NW-7, EAN 8 &amp; 13 yes</p>
<p>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 Mftr. can perform diagnostics via modem</p>	<p>daily: 15 min yes territory dependent yes/no yes</p>	<p>daily: 15 min yes territory dependent yes/no yes</p>
<p>Acquisition program based on cost-per-reportable result</p>	<p>yes</p>	<p>yes</p>
<p>Distinguishing features</p>	<p>enumeration of NRBCs, throughput of 150 CBCs/hr, random access, discrete testing, network capability and extended linearities  * not available on XE 2100-L</p>	<p>multiple configurations available</p>

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