Vendors selling simplicity and banking on the basics

Anne Ford

In today's global market, everyone seems to be thinking big, and high-volume hematology labs are no exception. Yet practicality still prevails.

"One area that is no longer in high demand is monoclonal antibody testing integrated into a routine hematology analyzer," says Bayer spokeswoman Nancy Lavon. "Although very attractive at first, these esoteric tests are not always practical for the routine hematology analyzer and may actually have a negative impact on workflow. There has been a return to the basics—quality, simplicity, reliability."

Case in point: Beckman Coulter's electronic Interlaboratory Quality Assurance Program, or eIQAP. Whereas enrollees in the program's previous incarnation had to mail in diskettes containing their QA information so Beckman Coulter could upload the information to a master database, now laboratories can submit and access hematology QA data via the Internet. "It's proving to be a huge time-saver and is much more efficient for labs," says Alan Burton, Beckman's marketing director for cellular analysis products. "This program eliminates numerous clerical hassles and processing time."

The company is now launching Command Central, a combination of software and hardware. "Command Central is a particularly exciting development as it provides a single point of contact with all the connected instruments," says Burton. "Now a single user can access and monitor up to 12 Beckman Coulter instruments—including hematology, chemistry, and immunoassay analyzers—all from one central workstation." Burton adds

that Beckman Coulter will soon introduce a new version of its DL 2000 data manager, which "allows labs to consolidate and manage test information and apply decision rules from multiple hematology analyzers."

With Bayer's Advia CentraLink networking solution, meanwhile, labs that own multiple Advia 2120 analyzers can consolidate data management. "This provides the ability to review and edit results at any workstation, to review patient results and cytograms at any microscope station with electronic diff pad entry," Lavon says. "Additional workstations can be placed wherever necessary—for example, in the hematology supervisor's or pathologist's office."

The Advia 2120 system, released in April, is the company's newest hematology analyzer. Next year, Bayer plans to introduce the Advia Autoslide, which will integrate with the 2120 and provide automated slide making and staining. With regard to future trends, Lavon says she sees an increased demand for Web-based services.

Sysmex hematology marketing manager Brian Verne agrees. His company plans to launch a new online customer support service—SNCS, or Sysmex Network Customer Support—in 2005. SNCS "offers remote maintenance and quality control by linking customers using Sysmex products with the Sysmex technical assistance center via the Internet," he says. Laboratories will be able to instantly access their daily QC and peer group comparisons. They'll also be able to monitor equipment trouble and receive online remote-access support. SNCS, Verne adds, will be available for all Sys-

mex instruments.

Several companies have recently launched or plan to launch new applications on their existing analyzers or brand-new products. Beckman Coulter, for example, expected to release a new body fluid application on its Coulter LH 700 series analyzers at CAP TODAY press time. The new application, Burton says, "will allow labs to analyze cerebrospinal fluid, s e rous fluids, and synovial fluids that have been treated with hyaluronidase."

Sysmex, meanwhile, has received FDA clearance for its body fluids application, which includes synovial, plurals, and CSF, on its XE series of instruments. It also plans to add new capabilities in 2005, such as immature platelet fraction and reticulocyte hemoglobin equivalent on the XE instruments. Already on the market is Sysmex's IG Master software, which provides enumerated immature granulocyte counts.

Pending regulatory approval, Abbott Diagnostics will launch a high-volume hematology analyzer, called the Cell-Dyn Sapphire, in 2005, says Abbott public affairs manager Amy Woodworth. Abbott currently markets, as part of its Cell-Dyn series, the Cell-Dyn 4000, which offers measurements of argon-ion laser light scatter and focused-flow impedance and supports high-volume workloads. The company is developing additional Cell-Dyn instruments.

ABX reports that it is developing leukocyte differential staining using thiazole orange and flow cytometry analysis. At the same time, the company continues its integration with Horiba; it now represents the medical diagnostics branch of Horiba and is

officially known as Horiba ABX Diagnostics. But the company's aim remains the same, says marketing director Tom Brown: "The goal at Horiba ABX is to continue to simplify the preanalytical, analytical, and post-analytical phases of the hematology process. We believe that expensive track systems can be eliminated th rough onboard auto-re run and auto-reflex capabilities, streamlining the workflow process."

Finally, while Six Sigma and Lean principles are nothing new, the increasing demand for them is. Bayer's Lavon characterizes the rise in Six Sigma's popularity as "a more sophisticated approach to instrument selection," while Sysmex's Verne says the interest in Lean principles stems from cost constraints and the continuing shortage of qualified medical technologists. That, too, is why "customers continue to demand reliability and performance in the instruments they acquire," he adds. "More and more customers are not able to acquire a comparable backup analyzer. Reliable, feature-rich analyzers have become a need, whereas before they were a luxury. What was once thought of as a 'nice-to-have' feature will now become mandatory."

CAP TODAY's survey of high-volume hematology analyzers on pages 24–44 includes products from the aforementioned manufacturers. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities. □

Anne Ford is a writer in Chicago.

SURVEY OF INSTRUMENTS

High-volume hematology analyzers

	Abbott Diagnostics Hematology Business Unit 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbott.com	Abbott Diagnostics Hematology Business Unit 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbott.com
Part 1 of 11 *See related article, page 22*		
Name of instrument	Cell-Dyn 3200	Cell-Dyn 3700
First year sold–installed in U.S./outside U.S.	1997/1997	1999/1999
No. units installed in U.S./outside U.S./list price	>700/>1,500/$165,000	>300/>500/$180,000 SL Model, $140,000 CS Model
Test menu: •**Chartable**	standard menu (left) plus: RDW, MPV	standard menu (left) plus: RDW, MPV, retic #&%, IRF
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •**Laboratory** •**Flags**	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	band, IG, variant lymph, blast, PCT, PDW, NRBC #&% and retic scatter profile suspect populations, band, blast, variant lymph, IG, NRBC, RRBC, NWBC, LRI, URI, LURI, RBC morph., FWBC, high/low interp. message, WBC
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	none
For research use only	atypical depolarization flag outside U.S.	none
Tests unique to analyzer	3-dimensional optical RBC analysis with advanced MCV measurement	IRF
Differential method(s) used	MAPSS (Multi-Angle Polarized Scatter Sep.)	MAPSS (Multi-Angle Polarized Scatter Sep.)
Linearity: •**WBC count (10⁹/L)/RBC count (10¹²/L)**	0–250/0–8	0–250/0–8
•**Hemoglobin (g/dL)/platelet (10⁹/L)**	0–25/0–1,750	0–24/0–2,000
•**MCV (fL) or Hct (%)**	34–172 (MCV)	50–200 (MCV)
Precision: •**WBC count/RBC count**	2.7%/1.5%	2.5%/1.5%
•**Hb/platelet**	1.0%/4.0%	1.2%/5.0%
•**MCV or Hct**	1 .0% (MCV)	1.0 % (MCV)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	neut #&%: 0.9 5, lymph #&%: 0.94, mono #&%: 0.8 6, eos #&%: 0.8 4, baso #%: 0.7 3	neut #&%: 0 .95, lymph #&%: 0.9 4, mono #&%: 0 .86, eos #&%: 0 .84, baso #&%: 0 .73
Interfering substances:•**WBC**	NRBCs, lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrinogen, fragile WBCs	NRBCs (WIC only), lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrino-gen, fragile WBCs
•**RBC**	elevated WBC count, increased No. of giant Plts, autoagglutination, in vitro hemolysis	increased No. giant Plts, autoagglutination, in vitro hemolysis
•**MCV or Hct**	MCV: elevated WBC count, hyperglycemia, in vitro hemolysis, increased No. of giant Plts	MCV: elevated WBC count, increased No. giant Plts, hyperglycemia, in vitro hemolysis
•**Platelet**	WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulins, Plt clumping, increased No. giant Plts	WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulin, Plt clumps, increased No. giant Plts
•**Hb**	elevated WBC count, incr. plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs	increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs
Interfering substances: differential	n/a	n/a
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	71/71	90/90
Recommended average frequency of calib.	6 months verification	6 months
•**Modes calibrated/parameters calibrated**	open & closed/WBC, RBC, Hb, MCV, Plt, MPV	open & closed/WBC, RBC, Hb, MCV, Plt
Frequency of blood/latex controls	as per regulatory requirement/n/a	as per regulatory requirement/n/a
Min. specimen vol. open/closed/sample dead vol. closed	150 µL/250 µL/1 mL (sample loader)	130 µL/355 µL/1.0 mL
Tube sampling supported	yes	yes (13x75 mm)
Veterinary capability	no	yes
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes	yes (flags only)
If auto. slidemaker available, No. installed/list price	80/$125,000	80/$125,000
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes
Max. archived data accessible when system online	10,000 results	10,000 results
Memory capacity—numeric results–No. specimens	10,000 results	10,000 results
Memory capacity—histo/cytograms–No. specimens	10,000 results	10,000 results
•**Stored in conjunction with CBC data**	yes	yes
•**Histo/cytogram images & CBC data printed as 1 report**	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	no	no
Tags and holds results for followup, confirm. testing, or rerun	yes	yes
Parameters for flags for holding samples are defined by	user or vendor	user or vendor
Some results can be transmitted to LIS while others held	yes	yes
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	proprietary	proprietary
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast
LOINC codes transmitted with results	yes	yes
How labs get LOINC codes for reagent kits	package insert; www.e-abbott.com; 800-323-9100	package insert; www.e-abbott.com; 800-323-9100
Optional data mgmt. or collation system	yes, proprietary	yes, proprietary
• **Software features**	enhanced QC, data archiving, data collation from multiple instruments	enhanced QC, data archiving, data collation from multiple instruments
Interface avail. or planned to auto. specimen-handling system	Lab-InterLink, MDS/Autolab, Roche (planned), Labotix	Lab-InterLink (planned), MDS/AutoLab, Roche (planned), Labotix (planned)
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5	Codabar, codes 39 & 128, interl. 2 of 5
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	daily: 30 sec; weekly: 5 min; monthly: 10 min	daily: 30 sec; bi-weekly: 5 min; monthly: 10 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	same day	same day
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	in development	in development
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	MAPSS cell-by-cell analysis provides a better diff.; focused flow 2-D optical RBC and Plt analysis provides better separation between microcytic RBCs and large Plts; uses only 3 reagents; 3-D MCV	MAPSS cell-by-cell analysis provides a better diff.; retic with reportable IRF (immature retic. fraction); 60-species veterinary package

Tabulation does not represent an endorsement by the College of American Pathologists   Survey editor: Raymond D. Aller, MD

High-volume hematology analyzers

Part 2 of 11 See related article, page 22	Abbott Diagnostics Hematology Business Unit 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbott.com	Bayer Diagnostics Nancy Lavon nancy.lavon.b@bayer.com 555 White Plains Rd. Tarrytown, NY 10591 800-431-1970 www.bayerdiag.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 4000 1997/1997 >350/>500/$250,000	Advia 120 Hematology System 1998/1998 800/3,500/$169,000–$189,000

Test menu: •Chartable
   All instruments have:
WBC, RBC, Hb, Hct, MCV,
MCH, MCHC, Plt, %&# neut, •Laboratory
mono, lymph, eos, baso
  •Flags
	standard menu (left) plus: RDW, MPV, NRBC #&%, retic #&%, IRF, CD61 (immuno-Plt), CD 3/4, CD 3/8 (immuno T-cell)
	
	#&% for segs., bands, IG, blasts, variant lymph; PDW, PCT, white cell viability fraction (WVF)
	band, IG, blast, variant lymph, nvWBC, rstRBC, IR, Plt clump, ASYM, high/low interp. msg., PCT, PDW
		standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, CHr, CHCMr, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono; cellular Hgb
		%: hypo, hyper, macro, micro; calc. Hb, MPXI;
		%: blasts, PMN, MN; large Plt count; RBC frag. count; RBC ghost count
		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

FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	IRF, MPC, MPM
For research use only	none	CSF, eos
Tests unique to analyzer	reportable NRBC #&%, CD61 for Plts, WVF, CD 3/4, CD 3/8 (immuno T-cell)	CHCM, HDW, CHr, CHCMr, MPC, MPM; CSF: WBC, RBC, PMN, neut, lymph, mono
Differential method(s) used	optical scatter & fluorescence technology	perox–peroxidase cytochem. staining with light scatter & absorption; baso–cytochem. stripping with 2-angle laser light scatter
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0–250/0–8	0.02–400/0–7.0; CSF WBC 0–5,000/μL; CSF RBC 0–1,500/μL
•Hemoglobin (g/dL)/platelet (10^9/L)	1.0–25/0–2,000	0–22.5 /5–3,500
•MCV (fL) or Hct (%)	37–197 (MCV)	30–180 (MCV)
Precision: •WBC count/RBC count	2.5%/1.5%	2.7%/1.2%
•Hb/platelet	1.0%/4.0%	0.93%/2.93%
•MCV or Hct	1 .0% (MCV)	0.78% (MCV)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	neut% 0.94, lymph% 0.93, mono% 0.84, eos% 0.91, baso% 0.40, NRBC/WBC 0.91, retic% 0.95	neut% R=0.997, lymph% R=0.997, mono% R=0.943, eos% R=0.979, baso% R=0.772, luc% R=0.944
Interfering substances:•WBC	lyse-resistant RBCs, Plt clumps	incomplete RBC lysis (perox only)
•RBC	autoagglutinins, cold agglutinins, hemolysis, small leukocytes (in cases where leukocyte count is high [>100 K/μL] and MCV is high)	cold agglutinins, extreme sickle cell
•MCV or Hct	MCV: in vitro hemolysis, autoagglutinins, cold agglutinins, hyperglycemia, leukocytosis with macrocy. anemia	none
•Platelet	Plt clumps, WBC & RBC fragments, microcytic RBCs, autoagglutinins, cold agglutinins, Plt satellitosis	none
•Hb	high lipids (>700 mg/dL), high WBCs (>250 K/μL, based on concentrated, normal WBCs), high bilirubin (>33 mg/dL)	high WBC, lip., extremely high bili., interfere with cyanmethb. only, none with direct cellular Hb (CHCM)
Interfering substances: differential	n/a	incomplete lysis of RBCs, complete myeloperox. deficiency
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	106/106	120/120
Recommended average frequency of calib.	6 months verification	6 months
•Modes calibrated/parameters calibrated	open-closed one proc./WBC, RBC, Hb, MCV, Plt, MPV	open, closed, autosampler/all measured parameters
Frequency of blood/latex controls	as per regulatory requirement/n/a	once per shift/not required
Min. specimen vol. open/closed/sample dead vol. closed	112.5 μL–aspir. vol./same/387 μL–dead vol.	157 μL/157 μL/<300 μL (tube size dependent)
Tube sampling supported	yes	yes (2, 3, 5, 7 mL—all sizes–open tube)
Veterinary capability	no	yes
Microsample capability	yes (250 μL) in Sarstedt Multivette & Becton Dickinson Microtainer tubes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes (flags only)	yes
If auto. slidemaker available, No. installed/list price	80/$125,000	Advia S60, >100/$35,000
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	no
Max. archived data accessible when system online	10,000 results	10,000 samples
Memory capacity—numeric results–No. specimens	10,000 results	10,000
Memory capacity—histo/cytograms–No. specimens	10,000 results	10,000
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	yes	yes
Tags and holds results for followup, confirm. testing, or rerun	yes	yes
Parameters for flags for holding samples are defined by	user or vendor	user or vendor
Some results can be transmitted to LIS while others held	yes	yes
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	proprietary	proprietary (Spec 79)
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics & orders	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast; host query for demographics & orders
LOINC codes transmitted with results	yes	no
How labs get LOINC codes for reagent kits	www.e-abbott.com; package insert; 800-323-9100	online documentation
Optional data mgmt. or collation system	yes, proprietary	in development
• Software features	enhanced QC, data archiving, data collation from multiple instruments	—
Interface avail. or planned to auto. specimen-handling system	Lab-InterLink, MDS/AutoLab, Roche (planned), Labotix (planned)	MXS (Japan), LabCell (Bayer)
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5	Codabar, codes 39 & 128, ASTM, interl. 2 of 5
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	daily: 30 sec; weekly: 5 min; monthly: 10 min	daily: 15 min; weekly: 15 min; monthly: 15 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	same day	territory dependent
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	in development	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	reportable NRBC count; monoclonal antibody capability; fluorescent random access retic with reportable IRF; WBC viability index; Argon laser	unique laser technology provides cellular Hb for RBCs and retics; 2-D Plt analysis that eliminates interference from RBC fragments and exclusion of large Plts; dual WBC counts with a linearity of up to 400,000; CSF assay

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High-volume hematology analyzers

Part 3 of 11	Bayer Diagnostics Nancy Lavon nancy.lavon.b@bayer.com 555 White Plains Rd. Tarrytown, NY 10591 800-431-1970 www.bayerdiag.com	Bayer Diagnostics Nancy Lavon nancy.lavon.b@bayer.com 555 White Plains Rd. Tarrytown, NY 10591 800-431-1970 www.bayerdiag.com
See related article, page 22		
Name of instrument	Advia 70	Advia 2120 Hematology System
First year sold–installed in U.S./outside U.S.	2001/2001	2004/2004
No. units installed in U.S./outside U.S./list price	100/300/$89,000	>60/>70/$225,000
Test menu: •Chartable	standard menu (left) plus: RDW, MPV	standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, CHr, CHCMr, cellular Hgb, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	none	% hypo, hyper, macro, micro; MPXI, % blast, PMN, MN, large PLT count, RBC fragment count; RBC ghost count
•Flags	diff., WBC, N, B, L, RBC, ABN, PL, CI, Plt/RBC	—
FDA-cleared tests but not clinically released	—	none
Tests not available but submitted for clearance	—	none
Tests in development	—	NRBC, MPC, MPM
For research use only	Pct, PDW	IRF, CSF, eos
Tests unique to analyzer	—	CHCM, HDW, CHr, CHCMr, cellular Hgb, MPC, MPM, CSF: WBC, RBC, PMN, MN, neut, lymph, mono
Differential method(s) used	optical & enhanced impedance	peroxidase WBC—peroxidase cytochem. staining w/ light scatter & absorption; baso—cytochem. stripping w/ 2-angle laser light scatter
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0.1–99/0.02–9.99	0.02–400; CSF WBC 0–5,000/0–7.0; CSF RBC 0–1,500
•Hemoglobin (g/dL)/platelet (10^9/L)	1.5–30/10–2,000	0–22.5/5–3,500
•MCV (fL) or Hct (%)	30–150 (MCV)	30–180 (MCV)
Precision: •WBC count/RBC count	2.0%/1.2%	2.7%/1.2%
•Hb/platelet	1.0%/3–10%	0.93%/2.93%
•MCV or Hct	1.0% (MCV)	0.78% (MCV)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	neut% R>0.9, lymph% R>0.9, mono% R>0.7, eos% R>0.8, baso% R>0.5	neut% R=0.997, lymph% R=0.997, mono% R=0.943, eos% R=0.979, baso% R=0.772, luc% R=0.944
Interfering substances:•WBC	incomplete RBC lysis	incomplete RBC lysis (peroxidase only)
•RBC	cold agglutinins	cold agglutinins, extreme sickle cell
•MCV or Hct	extremely high white blood cell count (Hct)	none
•Platelet	RBC fragments	none
•Hb	lipemia, elevated WBC	extreme lipemia, high WBC, extreme high bili. interference w/ colorimetric Hgb only, none with cellular Hgb
Interfering substances: differential	NRBCs, unlysed RBC, platelet clumps	inclomplete RBC lysis, complete myeloperox. deficiency
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	70/70	120/120
Recommended avg. frequency of calib.	every 6 months per governmental requirements	6 months
•Modes calibrated/parameters calibrated	open & closed/all measured parameters	autosampler, closed, open/all measured parameters
Frequency of blood/latex controls	one level per shift/not required	once per shift/not required
Min. specimen vol. open/closed/sample dead vol. closed	90 µL/180 µL/120 µL	175 µL/175 µL/<300 (tube size dependent)
Tube sampling supported	yes (12x75)	yes (2, 3, 5, 7 mL—all sizes open)
Veterinary capability	no	available 2005
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes	if integrated to Advia Autoslide
If auto. slidemaker available, No. installed/list price	Advia S60,>100/$35,000	—
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	no
Max. archived data accessible when system online	100,000	10,000
Memory capacity—numeric results–No. specimens	100,000	10,000
Memory capacity—histo/cytograms–No. specimens	100,000	10,000
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	no	yes
Tags and holds results for followup, confirm. testing, or rerun	yes	yes
Parameters for flags for holding samples are defined by	user	user or vendor
Some results can be transmitted to LIS while others held	all results for that sample are transmitted at once	yes
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	proprietary, ASTM 1394, E 1381	proprietary
Information transferred on LIS interface	numeric & flag results, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders (when bar code is read, host is queried for orders)
LOINC codes transmitted with results	—	no
How labs get LOINC codes for reagent kits	online documentation	online documentation
Optional data mgmt. or collation system	in development	yes (Bayer HealthCare)
• Software features		enhanced QC, data archiving, data collation from multiple instruments, auto validation, integrated diff. pad, remote diagnostics, remote workstations
Interface avail. or planned to auto. specimen-handling system	—	Bayer
Bar-code symbologies read on tube	Codabar, code 39, interl. 2 of 5	Codabar, codes 39 & 128, interl. 2 of 5
Accommodates bar-code placement per NCCLS standard Auto2A	yes	—
Time required for maintenance by lab personnel	daily: 0; weekly: 0; monthly: 20 min	daily: 0; weekly: 15 min; monthly: 15 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	territory dependent	territory dependent
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	in development	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	microsampling; auto recount; dual WBCs; automatic wakeup and shutdown; no daily or weekly maintenance	unique laser technology provides direct cellular Hgb for RBCs and retics; 2-D Plt analysis that eliminates interference from RBC fragments and exclusion of large Plts; dual WBC counts with a linearity of up to 400,000; CSF assay

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

High-volume hematology analyzers

Part 4 of 11 **See related article, page 22**	Beckman Coulter Inc. **Martha M. Diaz/Cellular Analysis Marketing** mmdiaz@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com	Beckman Coulter Inc. **Martha M. Diaz/Cellular Analysis Marketing** mmdiaz@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.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**	LH 1500 Hematology Automation Series 2002/2003 >25/3/varies	Coulter LH 700 Series 2001 1,000/>1,100/LH 750: $195,000; LH 755: $367,500
Test menu: •**Chartable** **All instruments have:** WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •**Laboratory** •**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**	standard menu (left) plus: RDW, MPV, retic %&#, IRF, graded RBC morph, NRBC %&#, TNC & RBC on CSF, synovial and serous fluids — user-definable age-, gender-, &/or location-based ref.; intervals, action & critical limits; user-def. RBC morph.; user-selectable sensitivity for diff., abnormal population suspect messages none none n/a PCT, PDW, high light scatter retics, mean sphered cell volume (MSCV) NRBC, MSCV, body fluids	standard menu (left) plus: RDW, MPV, retic #&%, IRF, MPV, graded RBC morph, NRBC %&#, TNC & RBC on CSF, synovial and serous fluids — user-definable age-, gender-, &/or location-based ref.; intervals, action & critical limits; user-def. RBC morph.; gradient msgs. (=+, ++, +++); user-selectable sensitivity for diff. abnormal population suspect messages — none none PCT, PDW, high light scatter retics, mean sphered cell volume NRBC, mean sphered cell volume

Differential method(s) used
 	
Linearity: •**WBC count (10⁹/L)/RBC count (10¹²/L)**
  •**Hemoglobin (g/dL)/platelet (10⁹/L)**
  •**MCV (fL) or Hct (%)**
Precision: •**WBC count/RBC count**
  •**Hb/platelet**
  •**MCV or Hct**
	Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate & Accuflex technologies
	0–400/0–8.0
	0–25/0–3,000
	50–200 (MCV)
	<1.7%/<0.8%
	<0.8%/<3.3%
	<0.8% (MCV)
		Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate & Accuflex technologies
		0–400/0–8.0
		0–25/0–3,000
		50–200 (MCV)
		<1.7%/<0.8%
		<0.8%/<3.3%
		<0.8% (MCV)

Accuracy of automated diff. compared with manual diff.,
  per NCCLS H-20A
Interfering substances:•**WBC**
 	
  •**RBC**
 	
  •**MCV or Hct**
  •**Platelet**
  •**Hb**
Interfering substances: differential
	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 >35 fL, large Plt
	very high WBC, high conc. large Plt, autoagglutinins
	very high WBC, high conc. large Plt, autoagglutinins
	very small RBCs & WBC frags. may interfere
	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs
	high triglycerides may affect lysing
		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 >35 fL, large Plt
		very high WBC, high conc. large Plt, autoagglutinins
		MCV & Hct: very high WBC, high conc. large Plt, autoagglutinins
		very small RBCs & WBC frags. may interfere
		very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs
		high triglycerides may affect lysing

Age- and sex-specific reference ranges
Max. CBCs per hr/max. CBCs & 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 available, No. installed/list price
	yes
	105 per analyzer on automation system/105 per analyzer on automation sys.
	twice per year
	primary/RBC, WBC, Hgb, MCV, Plt, MPV
	per CLIA, CAP, JCAHO, state or lab SOP/once per day
	200 µL/300 µL, 550 µL with slidemaker/1.0 mL
	yes
	no
	yes
	yes
	
	>350 U.S./$110,000
		yes
		105/105
		2 times per yr
		primary/RBC, WBC, Hb, MCV, Plt, MPV
		per CLIA, CAP, JCAHO, state or lab SOP/once per day
		200 µL/300 µL, 550 µL with slidemaker/1.0 mL
		yes (multiple sizes & styles)
		no
		yes
		yes, both
		
		>350 U.S./$110,000

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
  •**Stored in conjunction with CBC data**
  •**Histo/cytogram 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 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 threshhold
Choice of desired specimen &/or result info. displayed
	yes
	yes
	20,000
	20,000
	5,000
	yes
	yes
	yes
	yes
	yes
	yes
	user or vendor
	yes
	yes
	yes
	yes
		yes
		yes
		20,000 samples
		20,000
		5,000
		yes
		yes
		yes
		yes
		yes
		yes
		user or vendor
		yes
		yes
		yes
		yes

LIS interface formats supported **Information transferred on LIS interface** **LOINC codes transmitted with results** **How labs get LOINC codes for reagent kits** **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**	RS-232 numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast no — yes, Orchard Software Aqueduct enhanced QC, data archiving, data colleciton from multiple instruments, extensive decision rules, delta checking, patient results & graphics Beckman Coulter Codabar, codes 39 & 128, interl. 2 of 5, NW7 yes	RS-232, proprietary numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no technical support yes, DL 2000, Command Central, Orchard Software Aqueduct enhanced QC, data archiving, common database, extensive decision rules, delta checking, patient results & graphics, centralized management of all instruments Beckman Coulter Codabar, codes 39 & 128, interl. 2 of 5, NW7 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: automation system= 5 min, analyzer=0; weekly; automation=10 min, analyzer=0; monthly: automation=15 min, analyzer=2 min yes — yes/no yes	daily: 0; weekly: 0; monthly: 2 min yes — yes/no yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	the LH 1500 hematology automation system automatically loads and unloads cassettes, performs reflex and repeat testing, sorts tubes for offline tests, stores tubes with availability for retrieval for any type of test; multiple configurations available	extensive decision support; enumeration of NRBCs with every differential; random access; automation ready; extended linearity for WBC and platelets using AccuCount Technology; integrated slidemaker/staining options, ProService, electronic IQAP

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High-volume hematology analyzers

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Part 5 of 11 *See related article, page 22*		
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 LH 500 2003/2003 >200/0/$145,000	Coulter HmX 1999 HmX AL, 1999 HmX CP >400/>600/$135,000 AL; $120,000 CP
Test menu: •**Chartable**	standard menu (left) plus: retic #, retic %, MRV, IRF, RDW, MPV	standard menu (left) plus: RDW, MPV, retic #&%, graded RBC morph., IRF, MRV
All instruments have: •**Laboratory** WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut,	—	—
mono, lymph, eos, baso •**Flags**	user-definable age-, gender- &/or location-based ref. intervals, action & critical limits; user-def. RBC morph.; gradient msgs.	comprehensive high/low, definitive & suspect messages
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	none
For research use only	PCT, PDW	PCT, PDW
Tests unique to analyzer	none	none
Differential method(s) used	Coulter's 3-D biophysical flow cytometry with AccuGate 500, Reaction Manager technologies	Coulter's 3-D VCS technology
Linearity: •**WBC count (10⁹/L)/RBC count (10¹²/L)**	0–200/0–8.0	0–99.9/0–7.0
•**Hemoglobin (g/dL)/platelet (10⁹/L)**	0–25/0–2,000	0–25/0–999
•**MCV (fL) or Hct (%)**	50–150 (MCV)	50–150 (MCV)
Precision: •**WBC count/RBC count**	2 .5%/2 .0%	<2.5%/<2.0%
•**Hb/platelet**	1.5%/5.0%	<1.5%/<5.0%
•**MCV or Hct**	2 % (MCV)	<2.0% (MCV)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	lymph= ±1.5 % mean diff.; mono= ±1.5 % mean diff.; neut= ±2.0 % mean diff.; baso= ±0.5 % mean diff.; eos= ±0.5 % mean diff.	lymph%= ±3.0%, mono%= ±2.0%, neut%= ±3.0%, eos%= ±1.0%, baso%= ±1.0%
Interfering substances:•**WBC**	none	unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, large Plt
•**RBC**	none	very high WBC, high conc. of very large Plt, autoagglutinins
•**MCV or Hct**	none	MCV & Hct: very high WBC, high conc. of large Plt, autoagglutinins
•**Platelet**	none	very small RBCs & WBC frags. may cause no fit
•**Hb**	none	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs
Interfering substances: differential	not designated	high triglycerides may affect lysing
Age- and sex-specific reference ranges	yes	gender-specific printout
Max. CBCs per hr/max. CBCs & diffs. per hr	75/75	75/75
Recommended avg. frequency of calib.	timing not specified	timing not specified
•**Modes calibrated/parameters calibrated**	primary/RBC, WBC, Hb, MCV, Plt, MPV	primary/RBC, WBC, Hb, MCV, Plt, MPV
Frequency of blood/latex controls	not specified/once per day	not specified/once per day
Min. specimen vol. open/closed/sample dead vol. closed	125 µL/185 µL/tube dependent	125 µL/185 µL/50 µL predilute/0.5 mL
Tube sampling supported	yes (10.25 x 75 mm or less; 13 x 75 mm or less)	yes (multiple sizes & styles)
Veterinary capability	no	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	no	no
If auto. slidemaker available, No. installed/list price	—	n/a
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes
Max. archived data accessible when system online	20,000	5,000 samples
Memory capacity—numeric results–No. specimens	20,000	5,000
Memory capacity—histo/cytograms–No. specimens	5,000	5,000
•**Stored in conjunction with CBC data**	yes	yes
•**Histo/cytogram images & CBC data printed as 1 report**	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	yes	no
Tags and holds results for followup, confirm. testing, or rerun	yes	yes
Parameters for flags for holding samples are defined by	user	user or vendor
Some results can be transmitted to LIS while others held	yes	yes, through a selective batch process
Scattergram display: cell-specific color	yes	4 colors/cell types
Histogram display: color with threshhold	yes	colors without thresholds
Choice of desired specimen &/or result info. displayed	yes	no
LIS interface formats supported	RS-232, proprietary	RS-232, proprietary
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast
LOINC codes transmitted with results	no	no
How labs get LOINC codes for reagent kits	technical support	technical support
Optional data mgmt. or collation system	yes, DL 2000, Command Central, Orchard Software Aqueduct	yes, DL 2000, Orchard Software Aqueduct
• **Software features**	enhanced QC, data archiving, data collation from multiple instruments, common database, extensive decision rules, delta checking, patient results & graphics, centralized management of instruments	enhanced QC, data archiving, common database, delta checking, patient results & graphics
Interface avail. or planned to auto. specimen-handling system	—	Beckman Coulter
Bar-code symbologies read on tube	Codabar, codes 39 & 128, ASTM, interl. 2 of 5, NW7	Codabar, codes 39 & 128, interl. 2 of 5, NW7
Accommodates bar-code placement per NCCLS standard Auto2A	yes	no
Time required for maintenance by lab personnel	none	none
Onboard maintenance records	yes	no
Time from communication of problem to engineer on site	—	—
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	yes	no
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	extensive decision support, extended linearity for WBC & Plt, lowest review rate in class, small footprint, superior reliability, ProService, electronic IQAP	VCS technology; lowest review rate in class; no routine daily maintenance; triplicate counting; aperture burn circuit; sweepflow; SmartStart system; autoloader and single sample models

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High-volume hematology analyzers

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Part 6 of 11 *See related article, page 22*		

Name of instrument	Coulter Ac•T 5diff Family; Ac•T 5diff AL	Pentra 60C+ Hematology Analyzer
First year sold–installed in U.S./outside U.S.	2001/2000; 2003/2003	2000/2000
No. units installed in U.S./outside U.S./list price	400/600/$43,500 cap pierce model; $38,500 open vial model; AL: 30/—; $54,500 autoloader	286/400/$49,500

Test menu:	•Chartable	standard menu (left) plus: RDW, MPV	standard menu (left) plus: RDW, MPV
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso	•Laboratory	atyp. lymph. # (ATL#), atyp. lymph % (ATL%), immature cells # (IMM#), immature cells % (IMM%), PCT, PDW	atyp. lymph, atyp. lymph %, LIC, LIC %
	•Flags	complete operator selectable flagging	operator selectable flagging
FDA-cleared tests but not clinically released		none	none
Tests not available but submitted for clearance		none	none
Tests in development		none	none
For research use only		PCT, PDW, IMM, ATL	none
Tests unique to analyzer		none	none

Differential method(s) used		AcV technology combining cytochemistry, focused flow impedance, and light absorbance prinicples of measurement	DHSS technology combining cytochemistry, focused flow impedance, & light absorbance principles of measurement
Linearity:	•WBC count (10⁹/L)/RBC count (10¹²/L)	0.4–91.3/0.3–8.0*; AL: 0.4–120.0/0.3–8.0	0–120/0–8
	•Hemoglobin (g/dL)/platelet (10⁹/L)	0–22/10–1,000*; AL: 1.3–24.0/10.0–1,000	0.7–24/0–1,900
	•MCV (fL) or Hct (%)	1.8–63.8 (Hct)*	0.7–67% (Hct)
Precision:	•WBC count/RBC count	<2%/<2%	<2%/<2%
	•Hb/platelet	<1%/<5%	<1%/<5%
	•MCV or Hct	<1.0% (Hct); AL: <2.0% (Hct)	<2% (Hct)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A		not available in NCCLS H-20A format	neut% = 0.99, lymph% = 0.98, mono% = 0.96, eos% = 0.89, baso% = 0.54
Interfering substances:	•WBC	NRBCs, Plt clumps, large Plts, lyse-resistant RBCs	NRBCs, Plt clumps, lyse-resistant RBCs
	•RBC	cold agglutinins, Plt clumps, WBC overlinearity	cold agglutinins
	•MCV or Hct	Hct: lipemic samples, high WBC, cold aggluts	Hct: extreme leukocytosis
	•Platelet	RBC and WBC fragments	microcytes, Plt clumps
	•Hb	elevated WBC, lipemia	extreme lipemia/leukocytosis
Interfering substances: differential		lyse-resistant RBCs, NRBCs, lipemia	NRBC, lyse-resistant RBCs, extreme hyperbilirubinemia

Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	60/60; 80/80	60/60
Recommended average frequency of calib.	not specified by time	6 months
•Modes calibrated/parameters calibrated	open or closed/RBC, WBC, Hb, Hct, Plt	closed-open/WBC, RBC, Hb, Hct, Plt, MPV
Frequency of blood/latex controls	not specified/none	per CLIA standards/none
Min. specimen vol. open/closed/sample dead vol. closed	30 µL for CBC/30 µL/varies by tube size; 53 µL for CBC-diff/53 µL for CBC-diff./varies by tube size	53 µL/53 µL/0.5 mL
Tube sampling supported	yes (multiple sizes)	yes (multiple sizes)
Veterinary capability	no	yes
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	no	no
If auto. slidemaker available, No. installed/list price	n/a	—

Archives patient data for later comparison	yes	yes
Patient-specific archiving	no	yes, with Hemalink Data Manager
Max. archived data accessible when system online	10,000 samples	unlimited with Hemalink Data Manager
Memory capacity—numeric results–No. specimens	10,000	10,000, unlimited with Hemalink Data Manager
Memory capacity—histo/cytograms–No. specimens	10,000	10,000, unlimited with Hemalink Data Manager
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	no	yes
Tags and holds results for followup, confirm. testing, or rerun	yes	yes
Parameters for flags for holding samples are defined by	user or vendor	user
Some results can be transmitted to LIS while others held	yes, through user-defined criteria	yes
Scattergram display: cell-specific color	no	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes

LIS interface formats supported	proprietary; proprietary ASTM	ASTM 1394 & 1238, HL7, IEEE MIB
Information transferred on LIS interface	numeric & flag results, histograms & diff. plots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, LIS to instrument—broadcast
LOINC codes transmitted with results	no	yes
How labs get LOINC codes for reagent kits	technical support	—
Optional data mgmt. or collation system	yes, DL 2000, Command Central, Orchard Software Aqueduct	yes
• Software features	enhanced QC, data archiving, common database, optional data mgmt., extensive decision rules, delta checking, patient results & graphics available, centralized management of all instruments	enhanced QC, data archiving with Hemalink Data Manager
Interface avail. or planned to auto. specimen-handling system	no	no
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5, EAN 8 & 13	Codabar, codes 39 & 128, ASTM, interl. 2 of 5
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes

Time required for maintenance by lab personnel	none	weekly: 15 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	—	24 hrs
Onboard diagnostics/limited to software problems	yes/no	yes/yes
Mftr. can perform diagnostics via modem	no	yes, with Hemalink Data Manager

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

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

* linearity stated for Ac•T 5diff CP

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High-volume hematology analyzers

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Part 7 of 11 *See related article, page 22*		
Name of instrument	Pentra 120 Retic Hematology Analyzer	Pentra 80
First year sold–installed in U.S./outside U.S.	1999/1997	2003/2002
No. units installed in U.S./outside U.S./list price	89/650/$125,000	98/300/$70,000
Test menu: •Chartable	standard menu (left) plus: RDW, IRF, MPV	standard menu (left) plus: RDW, MPV
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	LIC#, LIC%, atyp lymph #&%, CRC%, RETL%, RETM%, RETH%, IMR%, MRV, MFI%	atyp. lymph, atyp. lymph%, LIC, LIC%
•Flags	operator selectable flagging	operator selectable flagging
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	none
For research use only	none	none
Tests unique to analyzer	—	none
Differential method(s) used	cytochemistry, focused flow impedance, light absorbance	DHSS technology combining cytochemistry, focused flow impedance & light absorbance principles of measurement
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0–150/0.5–8.1	0–120/0–8
•Hemoglobin (g/dL)/platelet (10^9/L)	2–25/0–2,000	1.3–24/0–1,900 (>2 g/dL Hgb)
•MCV (fL) or Hct (%)	0–80 (Hct)	2–67% (Hct)/0–2,800 (<2 g/dL Hgb)
Precision: •WBC count/RBC count	<2%/<2%	<2%/<2%
•Hb/platelet	<1%/<5%	<1%/<5%
•MCV or Hct	<2% (Hct)	<2% (Hct)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	neut% =0.99, lymph% =0.99, mono% =0.92, eos% =0.97, baso% =0.71	neut% =0.99, lymph% =0.99, mono% =0.36, eos% =0.61
Interfering substances: •WBC	NRBCs, Plt clumps/lyse-resistant RBCs	NRBCs, Plt clumps, lyse-resistant RBCs
•RBC	cold agglutinins	cold agglutinins
•MCV or Hct	Hct: extreme leukocytosis	Hct: extreme leukocytosis
•Platelet	microcytes, Plt clumps	microcytes, Plt clumps
•Hb	extreme lipemia/leukocytosis	extreme lipemia, leukocytosis
Interfering substances: differential	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	120/120	80/80
Recommended average frequency of calib.	6 months	6 months
•Modes calibrated/parameters calibrated	closed, open/WBC, RBC, Hb, Hct, Plt	closed rack/WBC, RBC, Hb, Hct, Plt, MPV
Frequency of blood/latex controls	per CLIA standards/not required	per CLIA standards/none
Min. specimen vol. open/closed/sample dead vol. closed	130 µL/200 µL/1 mL	53 µL/53 µL/0.5 mL
Tube sampling supported	yes	yes
Veterinary capability	yes	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes	no
If auto. slidemaker available, No. installed/list price	—/$40,000	n/a
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes, with Hemalink Data Manager
Max. archived data accessible when system online	90,000, unlimited with Hemalink Data Manager	unlimited with Hemalink Data Manager
Memory capacity—numeric results–No. specimens	90,000, unlimited with Hemalink Data Manager	10,000
Memory capacity—histo/cytograms–No. specimens	90,000, unlimited with Hemalink Data Manager	10,000
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	yes	yes
Tags and holds results for followup, confirm. testing, or rerun	yes	yes
Parameters for flags for holding samples are defined by	user	user
Some results can be transmitted to LIS while others held	yes (operator programmable)	yes
Scattergram display: cell-specific color	no	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	—
LIS interface formats supported	proprietary, ASTM 1394 & 1238, HL7, IEEE MIB	proprietary, ASTM 1394 & 1238, HL7, IEEE MIB
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast; host query for demographics & orders	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast
LOINC codes transmitted with results	no	n/a
How labs get LOINC codes for reagent kits	—	n/a
Optional data mgmt. or collation system	yes	yes (Medicus, Hemalink)
• Software features	enhanced QC, data archiving (Hemalink Data Manager), data collation from multiple instruments	enhanced QC, data archiving, data collation from multiple instruments
Interface avail. or planned to auto. specimen-handling system	no	—
Bar-code symbologies read on tube	Codabar, codes 39 & 128, ASTM, interl. 2 of 5	Codabar, codes 39 & 128, ASTM, interl. 2 of 5
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	weekly: 10 min; monthly: 10 min	weekly: 15 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	4 hrs average, 24 hrs guaranteed	—
Onboard diagnostics/limited to software problems	yes/yes	no/yes
Mftr. can perform diagnostics via modem	yes, with Hemalink Data Manager	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	automatic rerun for sample verification; MTBF>90 days; small footprint; integrated reticulocyte methodology and slidemaker/stainer; thiazole orange reticulocyte methodology	compact, reliable 5-part diff technology, autoloader, 80 samples per hour, auto rerun feature

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

High-volume hematology analyzers

Part 8 of 11 *See related article, page 22*	Horiba ABX Diagnostics Inc. **Tom Brown** tbrown@us.abx.fr 34 Bunsen Irvine, CA 92618 888-903-5001 ext. 535 www.abx.com	Horiba ABX Diagnostics Inc. **Tom Brown** tbrown@us.abx.fr 34 Bunsen Irvine, CA 92618 888-903-5001 ext. 535 www.abx.com
Name of instrument	Pentra XL 80	Pentra DX120/FDA SUBMISSION PENDING
First year sold–installed in U.S./outside U.S.	2004/2003	—/2004
No. units installed in U.S./outside U.S./list price	8/80/$90,000	0/25/—
Test menu: •Chartable	standard menu (left) plus: automatic dilution of overrange results (WBC x 3, RBC/hgb/Plt x 2), RDW, MPV	standard menu (left) plus: NRBCs, reticulocytes, IRF
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	atyp. lymph, atyp. lymph%, LIC, LIC%	LIC%&#, atyp lymphs %&#, IMG %&#, IML %&#, IMM %&#, RETL%, RETM%, RETH%, IMR%, MRU, MFI%, CRC%
•Flags	operator selectable flagging	—
FDA-cleared tests but not clinically released	none	pending 510(k)
Tests not available but submitted for clearance	none	pending 510(k)
Tests in development	—	pending 510(k)
For research use only	none	—
Tests unique to analyzer	automatic dilution protocol	—
Differential method(s) used	DHSS technology combining cytochemistry, focused flow impedance & light absorbance	cytochemistry (chlorazolic black) and absorbance
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0–120/0–8	0–150/0.5–8.1
•Hemoglobin (g/dL)/platelet (10^9/L)	0–24/0–1,900 (>2 g/dL Hgb)	2–25/0–2,000
•MCV (fL) or Hct (%)	0–67% (Hct)/0–2,800 (<2 g/dL Hgb)	0–80 (Hct)
Precision: •WBC count/RBC count	<2%/<2%	<2%/<2%
•Hb/platelet	<1%/<5%	<1%/<5%
•MCV or Hct	<2% (Hct)	<2% (Hct)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	neut% =0.99, lymph% =0.98, mono% =0.96, eos% =0.89, baso%=0.54	neut%=0.99, lymph% =0.98, mono% =0.92, eos% =0.97, baso%=0.71
Interfering substances:•WBC	NRBCs, Plt clumps, lyse-resistant RBCs	NRBCs, Plt clumps, lyse-resistant RBCs
•RBC	cold agglutinins	cold agglutinins
•MCV or Hct	Hct: extreme leukocytosis	Hct: extreme leukocytosis
•Platelet	microcytes, Plt clumps	microcytes, Plt clumps
•Hb	extreme lipemia, leukocytosis	extreme lipemia, leukocytosis
Interfering substances: differential	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	80/80	120/120
Recommended average frequency of calib.	6 months	6 months
•Modes calibrated/parameters calibrated	open, closed/WBC, RBC, Hb, Hct, Plt, MPV	open, closed/WBC, RBC, Hb, Hct, Plt, MPV
Frequency of blood/latex controls	per CLIA standards/none	per CLIA standards/none
Min. specimen vol. open/closed/sample dead vol. closed	30 for CBC/53 for CBC & diff/0.5 mL	130 µL/200 µL/1 mL
Tube sampling supported	yes (autoloader 13 x 75; closed tube 16 sizes + micro)	yes
Veterinary capability	yes	no
Microsample capability	yes	no
Prepares microscopic slides automatically or flags problems for slide prep	yes	yes
If auto. slidemaker available, No. installed/list price	—/—	—/—
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes, with Hemalink Data Manager	yes
Max. archived data accessible when system online	unlimited with Hemalink Data Manager; 10,000 instrument only	unlimited Data Manager; 10,000 instrument only
Memory capacity—numeric results–No. specimens	unlimited with Hemalink Data Manager; 10,000 instrument only	unlimited Data Manager
Memory capacity—histo/cytograms–No. specimens	unlimited with Hemalink Data Manager	unlimited Data Manager
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	yes	yes
Tags and holds results for followup, confirm. testing, or rerun	yes	yes
Parameters for flags for holding samples are defined by	user	user
Some results can be transmitted to LIS while others held	yes	—
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	—	yes
LIS interface formats supported	proprietary, ASTM 1394 & 1238, HL7, IEEE MIB	proprietary, ASTM 1394 & 1238, HL7, IEEE MIB
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast
LOINC codes transmitted with results	n/a	n/a
How labs get LOINC codes for reagent kits	n/a	n/a
Optional data mgmt. or collation system	yes (Medicus, Hemalink)	yes (Medicus, Hemalink)
• Software features	enhanced QC, data archiving, data collation from multiple instruments	enhanced QC, data archiving, data collation from multiple instruments
Interface avail. or planned to auto. specimen-handling system	—	—
Bar-code symbologies read on tube	Codabar, codes 39 & 128, ASTM, interl. 2 of 5	Codabar, codes 39 & 128, ASTM, interl. 2 of 5
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	weekly: 15 min	weekly: 15 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	—	—
Onboard diagnostics/limited to software problems	no/yes	no/yes
Mftr. can perform diagnostics via modem	yes	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	compact 5-part differential instrument with autoloader and auto-dilution capability, auto rerun feature, auto validation	high-throughput cell counter with integrated reticulocyte methodology and slidemaker/stainer; fluorescent NRBC counting, auto rerun and reflex testing, auto validation

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

High-volume hematology analyzers

	Sysmex America Inc. Barb Connell 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Inc. Barb Connell 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
Part 9 of 11 *See related article, page 22*		
Name of instrument	Sysmex XE-2100	Sysmex XE-2100L
First year sold–installed in U.S./outside U.S.	2000	2001
No. units installed in U.S./outside U.S./list price	650/2,000/$225,000	100/300/$200,000
Test menu: •**Chartable** All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •**Laboratory**	standard menu (left) plus: NRBC %&#, retic %&#*, RDW-SD, RDW-CV, IRF, Plt-O, HPC#, MPV, IG%, IG# none	standard menu (left) plus: MPV, RDW-SD, RDW-CV, NRBC %&#, HPC#, IG%, IG# none
•**Flags**	Plt clumps, RBC agglut, turbidity, WBC ABN scattergram, RBC ABN distrib., Plt ABN distrib., RBC lyse resistance, blasts, left shift, atyp. lymph., ABN lymph./blast., ret. ABN scattergram	Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast, left shift, atyp. lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	RET-He, IPF	none
For research use only	P-LCR, PCT, PDW	P-LCR, PCT, PDW
Tests unique to analyzer	NRBC, HPC#, IG%, IG#	HPC#, NRBC, IG%, IG#
Differential method(s) used	fluorescent flow cytometry, RF/DC detecting method	fluorescent flow cytometry, RF/DC detecting method
Linearity: •**WBC count (10⁹/L)/RBC count (10¹²/L)**	0–170/0–8	0–170/0–8
•**Hemoglobin (g/dL)/platelet (10⁹/L)**	0–25/0–5,000	0–25/0–5,000
•**MCV (fL) or Hct (%)**	0–60 (Hct)	0–60 (Hct)
Precision: •**WBC count/RBC count**	<3%/<1.5%	3%/1.5%
•**Hb/platelet**	<1.0%/<4.0%	1.0%/4.0%
•**MCV or Hct**	<1.0% (Hct)	1.0 % (Hct)
Accuracy of automated diff. compared with manual diff., **per NCCLS H-20A**	neut% R=0.95, lymph% R=0.95, mono% R=0.79, eos% R=0.92, baso% R=0.82, NRBC% R=0.96, IG% R=0.80	neut% R=0.95, lymph% R=0.96, mono% R=0.79, eos% R=0.92, baso% R=0.82, NRBC% R=0.96, IG% R=0.80
Interfering substances:•**WBC**	cold agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs	cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs
•**RBC**	cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts, in vitro hemolysis	cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/μL)
•**MCV or Hct**	Hct: cold agglutinins, leukocytosis (>100,000/μL), ABN red cell fragility, spherocytosis	Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL)
•**Platelet**	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts lipemia, ABN proteins in blood plasma, severe leukocytosis (>100,000/μL)	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts lipemia, ABN proteins, leukocytosis (>100,000/μL)
•**Hb**		
Interfering substances: differential	lyse-resistant RBCs	lyse-resistant RBCs
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	150/150	150/150
Recommended average frequency of calib.	twice per year	twice per year
•**Modes calibrated/parameters calibrated**	open, closed, capillary/WBC, RBC, Hb, Hct, Plt	open, closed, capillary/WBC, RBC, Hb, Hct, Plt
Frequency of blood/latex controls	per CLIA requirements/not required	per CLIA requirements/not required
Min. specimen vol. open/closed/sample dead vol. closed	130 μL/200 μL/1 mL	130 μL/200 μL/1 mL
Tube sampling supported	yes	yes
Veterinary capability	no	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags **problems for slide prep**	yes with Alpha or HST upgrade	yes with Alpha or HST upgrade
If auto. slidemaker available, No. installed/list price	>1,000	>1,000
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes
Max. archived data accessible when system online	10,000 samples	10,000 samples
Memory capacity—numeric results–No. specimens	10,000	10,000 samples
Memory capacity—histo/cytograms–No. specimens	10,000	10,000
•**Stored in conjunction with CBC data**	yes	yes
•**Histo/cytogram images & CBC data printed as 1 report**	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	yes	yes
Tags and holds results for followup, confirm. testing, or rerun	yes	yes
Parameters for flags for holding samples are defined by	user or vendor	user or vendor
Some results can be transmitted to LIS while others held	yes	yes
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	RS-232C/TCP IP	RS-232C, TCP IP
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders
LOINC codes transmitted with results	—	—
How labs get LOINC codes for reagent kits	n/a	n/a
Optional data mgmt. or collation system	yes, proprietary	yes, proprietary
• **Software features**	enhanced QC, data archiving, data collation from multiple instruments, online QC	enhanced QC, data archiving, data collation from multiple instruments, online QC
Interface avail. or planned to auto. specimen-handling system	Roche, Labotix, IDS, A&T	Roche, Labotix, A&T, IDS
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW7, EAN 8 & 13	Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW7, EAN 8 & 13
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	daily: 15 min walkaway	daily: 15 min walkaway
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	territory dependent	territory dependent
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	yes	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	enumeration of NRBCs; throughput of 150 CBCs per hour; random access; discrete testing; extended linearities; HPC testing; online QC; remote diagnostics, IG enumeration, body fluid analysis	remote diagnostics; online QC; random access; HPC testing; 150 CBC per hour throughput; discrete testing; NRBC enumeration, IG enumeration, body fluid analysis

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SURVEY OF INSTRUMENTS

High-volume hematology analyzers

	Sysmex America Inc. Barb Connell 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Inc. Nilam Patel 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
Part 10 of 11 *See related article, page 22*		
Name of instrument	Sysmex XE-2100D	Sysmex XE-Alpha N/HST-N
First year sold–installed in U.S./outside U.S.	2004/2004	2000
No. units installed in U.S./outside U.S./list price	—/—/$200,000	>1,000 worldwide/$360,000–$1,000,000
Test menu: •Chartable	standard menu (left) plus: RDW-SD, RDW-CV, IG%, IG#	standard menu (left) plus: NRBC %&#, retic %&#, RDW-SD, RDW-CV, IRF, Plt-O, HPC#, MPV, IG%, IG#
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	none	none
•Flags	Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast, left shift, atyp. lymph., ABN lymph./blast, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity	Plt clumps, RBC agglut., turbidity, WBC ABN scattergram, RBC ABN distrib., Plt ABN distrib., RBC lyse resistance, blasts, left shift, atyp. lymph., ABN lymph./blast, ret. ABN scattergram
FDA-cleared tests but not clinically released	n/a	none
Tests not available but submitted for clearance	n/a	none
Tests in development	n/a	RET-He, IPF
For research use only	P-LCR, PCT, PDW	P-LCR, PCT, PDW
Tests unique to analyzer	IG% & IG#	NRBC, HPC#, IG%, IG#
Differential method(s) used	fluorescent flow cytometry	fluorescent flow cytometry, RF/DC detecting method
Linearity: •WBC count (10⁹/L)/RBC count (10¹²/L)	0–170/0–8	0–170/0–8
•Hemoglobin (g/dL)/platelet (10⁹/L)	0–25/0–5,000	0–25/0–5,000
•MCV (fL) or Hct (%)	0–60 (Hct)	0–60 (Hct)
Precision: •WBC count/RBC count	3%/1.5%	<3%/<1.5%
•Hb/platelet	1.0%/4.0%	<1.0%/<4.0%
•MCV or Hct	1 .0% (Hct)	<1.0% (Hct)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	neut% R=0.95, lymph% R=0.96, mono% R=0.79, eos% R=0.92, baso% R=0.82, IG% R=0.80	neut% R=0.95, lymph% R=0.95, mono% R=0.79, eos% R=0.92, baso% R=0.82, NRBC% R=0.96, IG% R=0.80
Interfering substances:•WBC	cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs	cold agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs
•RBC	cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/µL)	cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts, in vitro hemolysis
•MCV or Hct	Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/µL)	Hct: cold agglut., leukocytosis (>100,000/µL), ABN red cell fragility, spherocytosis
•Platelet	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts
•Hb	lipemia, ABN proteins, leukocytosis (>100,000/µL)	lipemia, ABN proteins in blood plasma, severe leukocytosis (>100,000/µL)
Interfering substances: differential	lyse-resistant RBCs	lyse-resistant RBCs
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	150/150	150/150 per analyzer on automation system
Recommended average frequency of calib.	twice per year	twice per year
•Modes calibrated/parameters calibrated	open, closed, capillary/WBC, RBC, Hb, Hct, Plt	open, closed, capillary/WBC, RBC, Hb, Hct, Plt
Frequency of blood/latex controls	per CLIA requirements/not required	per CLIA requirements/not required
Min. specimen vol. open/closed/sample dead vol. closed	130 µL/200 µL/1 mL	130 µL/200 µL/1 mL
Tube sampling supported	yes	yes
Veterinary capability	no	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes, with Alpha or HST upgrade	yes
If auto. slidemaker available, No. installed/list price	>1,000/—	>1,000/$250,000
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes
Max. archived data accessible when system online	10,000 samples	10,000 samples
Memory capacity—numeric results–No. specimens	10,000 samples	10,000
Memory capacity—histo/cytograms–No. specimens	10,000	10,000
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	yes	yes
Tags and holds results for followup, confirm. testing, or rerun	yes	yes
Parameters for flags for holding samples are defined by	user or vendor	user or vendor
Some results can be transmitted to LIS while others held	yes	yes
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	RS-232C, TCP IP	RS-232C, TCP IP
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders
LOINC codes transmitted with results	—	—
How labs get LOINC codes for reagent kits	n/a	n/a
Optional data mgmt. or collation system	yes, proprietary	yes, proprietary
• Software features	enhanced QC, data archiving, data collation from multiple instruments, online QC	enhanced QC, data archiving, data collation from multiple instruments, online QC
Interface avail. or planned to auto. specimen-handling system	Lab InterLink, MDS/AutoLab, Beckman Coulter, Roche, Labotix, A&T	Roche, Labotix, IDS, A&T
Bar-code symbologies read on tube	Codabar, codes 39 & 128, ASTM, interl. 2 of 5, ITF, NW7, EAN 8 & 13	Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW7, EAN 8 & 13
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	daily: 15 min walkaway	daily: 15 min walkaway
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	contract and territory dependent	territory dependent
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	yes	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	provides high throughput sample analysis; small footprint; configurable & scalable	multiple configurations available as are all distinguishing features of the XE-2100

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SURVEY OF INSTRUMENTS

High-volume hematology analyzers

	Sysmex America Inc. Peggy Barranco 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Inc. Peggy Barranco 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
Part 11 of 11 *See related article, page 22*		
Name of instrument	Sysmex XT-2000i	Sysmex XT-1800i
First year sold–installed in U.S./outside U.S.	2002	2002
No. units installed in U.S./outside U.S./list price	200/500/$145,000	150/500/$125,000
Test menu: •Chartable	standard menu (left) plus: retic %&#, IRF, Plt-O, MPV, RDW-SD, RDW-CV	standard menu (left) plus: MPV, RDW-SD, RDW-CV
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	none	none
•Flags	Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast imm. gran., left shift, atyp lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity, ret ABN scattergram, NRBC	Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast imm. gran., left shift, atyp. lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity, NRBC
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	none
For research use only	IG%&#	IG%&#
Tests unique to analyzer	Plt-O	—
Differential method(s) used	fluorescent flow cytometry	fluorescent flow cytometry
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0–310/0–8	0–310/0–8
•Hemoglobin (g/dL)/platelet (10^9/L)	0–25/0–2,000	0–25/0–2,000
•MCV (fL) or Hct (%)	0–60 (Hct)	0–60 (Hct)
Precision: •WBC count/RBC count	3.0%/1.5%	3.0%/1.5%
•Hb/platelet	1.5%/4.0%	1.5%/4.0%
•MCV or Hct	1 .5% (Hct)	1.5% (Hct)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	neut% R=0.95, lymph% R=0.96, mono% R=0.90, eos% R=0.94, baso% R=0.76	neut% R=0.95, lymph% R=0.96, mono% R=0.90, eos% R=0.94, baso% R=0.76
Interfering substances:•WBC	cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs	cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs
•RBC	cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/µL)	cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/µL)
•MCV or Hct	Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/µL)	Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/µL)
•Platelet	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts
•Hb	lipemia, ABN proteins, leukocytosis (>100,000/µL)	lipemia, ABN proteins, leukocytosis (>100,000/µL)
Interfering substances: differential	lyse-resistant RBCs	lyse-resistant RBCs
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	80/80	80/80
Recommended average frequency of calib.	every 6 months	every 6 months
•Modes calibrated/parameters calibrated	open, closed, capillary/WBC, RBC, Hb, Hct, Plt	open, closed, capillary/WBC, RBC, Hb, Hct, Plt
Frequency of blood/latex controls	per CLIA requirements/not required	per CLIA requirements/not required
Min. specimen vol. open/closed/sample dead vol. closed	85 µL/150 µL/1 mL	85 µL/150 µL/1 mL
Tube sampling supported	yes	yes
Veterinary capability	planned for 2005	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	no	no
If auto. slidemaker available, No. installed/list price	—	—
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes
Max. archived data accessible when system online	10,000 samples	10,000 samples
Memory capacity—numeric results–No. specimens	10,000 samples	10,000 samples
Memory capacity—histo/cytograms–No. specimens	10,000	10,000
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	yes	yes
Tags and holds results for followup, confirm. testing, or rerun	yes	yes
Parameters for flags for holding samples are defined by	user or vendor	user or vendor
Some results can be transmitted to LIS while others held	yes	yes
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	RS-232C, TCP IP, ASTM	RS-232C, TCP IP, ASTM
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders
LOINC codes transmitted with results	—	—
How labs get LOINC codes for reagent kits	n/a	n/a
Optional data mgmt. or collation system	yes, proprietary	yes, proprietary
• Software features	enhanced QC, data archiving, data collation from multiple instruments, online QC	enhanced QC, data archiving, data collation from multiple instruments, online QC
Interface avail. or planned to auto. specimen-handling system	n/a	n/a
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW7, EAN 8 & 13	Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW7, EAN 8 & 13
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	daily: 15 min walkaway	daily: 15 min walkaway
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	contract and territory dependent	contract and territory dependent
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	yes	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	remote diagnostics; online QC; random access; fluorescent optical platelets; discrete testing; reagent monitoring; customized chartable report formats	remote diagnostics; online QC; random access; discrete testing; reagent monitoring; chartable report formats

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