

New QC, parameters, and automation for hematology analyzers

Anne Ford

As Mary Beth Johnson, Beckman Coulter marketing manager, rediscovered on a trip to Best Buy the other day, the breakneck pace at which today's technology evolves can sometimes leave consumers in the dust. When the salesman she spoke with there found out that her television was a whopping four years old, "he just looked at me like, 'Gosh, no one has *these* things anymore,'" she says. "He was telling me, 'Oh, this is so out of

date.' All I could say was, 'What?'" At Beckman Coulter, she says, "We don't want that to happen to our customers."

That's why the company is planning to make some of the functionality of its high-volume hematology analyzer, the recently introduced LH 780, available in the form of a software upgrade for customers who already own Beckman Coulter's LH 750 instrument. "We have about 2,000 LH 750s out there, which is a substantial number," Johnson says. "Of course there's

differentiation between the two systems. But some of the things, like the QC package, will be added back to the 750. So we're taking care of our current customers as well. That makes you feel really good."

Along with a score of other products from several different vendors, the LH 780 and LH 750 appear in this month's instrumentation survey, which focuses on hematology analyzers for high-volume laboratories. The five manufacturers represented offer an array

of new instruments and features that reflect Sysmex senior marketing manager Nilam Patel's statement: "We're always looking at what the market needs are and how we can take hematology to the next level."

One of the latest developments from Sysmex: the RET-He, or reticulocyte hemoglobin equivalent, parameter, which is being made available on the company's XE series of analyzers. "We're finding in the studies that we've done that RET-He is a more sensitive indicator of functional iron deficiency anemia, more so than some of the biochemical markers that are traditionally used," says Sysmex diagnostics market manager Barbara Connell. "We've got some folks who are beginning to use the parameter," Patel adds. "The nice thing about it is that this parameter is available to current customers with just an upgrade to the software." And with no additional sample draw required, "it's very convenient to get that parameter from the same lavender-top tube."

In the last several months, Sysmex customers have been able to access another new parameter as well—IPF, or immature platelet fraction. "We think this really has broad application," Connell says. "We feel that IPF may help in treating a patient that has thrombocytopenia." Without this parameter, she says, laboratories have to perform a reticulated platelet count, a flow cytometry procedure that many labs must send to a reference laboratory for completion. "If they do have a flow lab and they want to start using this procedure, they're looking at a more complicated procedure—something that typically needs a dedicated technologist. Whereas with IPF, it's available 24 hours a day, seven days a week, on their routine hematology analyzer," Connell says.

As readers of the 2005 CAP TODAY hematology instrumentation survey may recall, Sysmex has been working with Bio-Rad Laboratories to make the latter's Variant II Turbo hemoglobin system available on Sysmex's HST-N hematology automation line. Patel reports that her company plans to launch the product in the first quarter of 2007. "The purpose of this, again, is to give the advantage to labs to draw just that one single purple top and put it on the automation line," she says.

In addition to providing a software upgrade to owners of the LH 750, Beckman Coulter is also touting the features of its new LH 780, which this year's AACC attendees previewed and which the company

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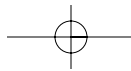
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Analyzers

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plans to begin shipping this month. "The LH 780 really focuses on two primary areas," Johnson says. "We're looking at enhanced functionality as well as advanced technology with research parameters." Regarding the latter, she says, "Our customers can use this information to gain further insight on changes at the cellular level for the different types of white blood cells as well as insight on the red blood cells and platelets. It's really cool."

Other features of the LH 780: a new RDW-SD parameter, shown to help differentiate anemias; a user-friendly interface; and the XM quality control package, which offers exponentially weighted moving average, or EWMA, of CBC, five-part differential, nucleated red blood cell count, and reticulocyte parameters. Extended QC rules for measuring total air imprecision and bias are also available. A companion instrument, the LH 785, adds Beckman Coulter's LH SlideMaker and SlideStainer to the LH 780.

The buzz at Bayer these days focuses on a forthcoming hematology automation solution that will feature Bayer's Advia 2120 and Advia AutoSlide hooked onto the company's Advia LabCell system. Ron Hebert, senior product manager worldwide for hematology, says, "We're also working on body fluids—the ability to have a complete body fluid panel on the Advia 2120, which would be the plural peritoneal and dialysate fluids." Hebert continues, "We're very unique in the fact that we offer true, practical automation, where we can truly automate all the manual procedures that a hematology laboratory does on a daily basis without the need for large track-based systems or reflexive testing or special stains. We're able to do it and get accurate results on the first pass."

In the future, Hebert says, the data that hematology analyzers provide will fuel automated diagnosis of patient samples. "Bayer has the ability to offer a 'neural net' of information," he says. "This has been shown to offer great potential as a practical tool for medical staff to offer an automated differential diagnosis, which can lead to earlier diagnosis and more effective treatment for patients. We look at that as true information technology."

CAP TODAY's survey of hematology analyzers for high-volume laboratories includes systems from the aforementioned manufacturers and from Abbott Hematology and Horiba ABX Diagnostics. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm it has the stated features and capabilities. □

Anne Ford is a writer in Chicago.

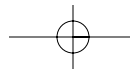
High-volume hematology analyzers

Part 1 of 12 See related article, page 12	Abbott Hematology Deborah Archer 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2005 No. units installed in U.S./outside U.S./list price	CELL-DYN Sapphire 2005/2005/— n/a/n/a/\$250,000
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 available but submitted for clearance Tests in development For research use only Tests unique to analyzer	Chartable Laboratory Flags standard menu (left) plus: MPV, RDW, retic %&#, IRF, NRBC %&#, CD61, CD3T %&#, CD4T %&#, CD8T %&#, 4/8 — band, IG, blast, variant lymph, nvWBC, rstRBC, IR, Plt clmp, ASYM, FP, CD61 agg., clot detected during aspiration, short sample none none body fluid assay, optical RBC morphology none CD61 for Plts, WVF, CD3/4, CD3/8 (immuno T-cell)
Differential method(s) used Linearity: Precision: Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation Interfering substances:	optical scatter & 3-color fluorescence 0.4–250.0 × 10 ³ μL / 0.0–7.50 × 10 ⁶ μL 7–24.8 g/dL (cyanide free)/11.0–2000.0 × 10 ³ μL 37.0–179 fL (MCV) ≤2.7%/≤1.5% ≤1.0%/≤4.0% ≤1.0% (MCV) neut% r=0.942 slope 0.947 y=0.446; lym% r=0.936 slope=0.943 y=2.811; mono% r=0.623 slope=1.057 y=0.851; eos% r=0.446 slope=1.024 y=0.288; baso% r=0.232 slope=0.257 y=0.350 Plt clumps, neut aggregates, Hb C crystals, lyse-resist. RBCs, cryoglob., cryofibr., frag. WBC, nRBC autoagg., cold agg., elevated WBC, giant Plts, hemolysis, sm WBC MCV: autoagg., cold agg., elevated WBC, giant Plt, hemolysis, hyperglycemic Plt satellitism, RBC frag, WBC frag, microcytic RBC auto & cold agg, cryoglob., cryofibrin., giant Plt, micro RBC, Plt clumps lipids>700 mg/dL, WBCs>250 × 10 ⁹ /L, bilirubin>33 mg/dL, Hb crystals see WBC
Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average 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 106/106 6 months verification open-closed single procedure/WBC, RBC, Hb, Plt, MPV per regulatory requirement/n/a 117 μL/117 mL/0.5 mL, 0.3 mL for 10.25 × 64 mm tubes yes (11.5–13 × 65–75 mm, 10.25 × 64 mm, 9 × 66 mm [Sarstedt Monovette]) no yes yes (flags only) n/a/\$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 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 user or vendor 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 yes yes user or vendor 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	ASTM 1394 numeric & flag results, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics & orders no n/a yes, Abbott Accelerator DM enhanced QC, data archiving, data collation from multiple instruments, remote viewing Accelera APS 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 Mfr. can perform diagnostics via modem	daily: 30 sec; weekly: 10 min; monthly: 5 min yes — yes/no no
Acquisition program based on cost-per-reportable result	yes
Distinguishing features	4 optical and 3 fluorescent detectors providing Multiple Scatterplot Analysis; 2-D optical platelets that avoid interferences; fluorescent analysis of reticulocytes, nRBCs, and 3-color monoclonal analysis on a routine hematology analyzer

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

Survey editor: Raymond D. Aller, MD



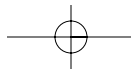


High-volume hematology analyzers

Part 2 of 12	Abbott Hematology Jeff Kolberg jeff.kolberg@abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com	Abbott Hematology Jeff Kolberg jeff.kolberg@abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com
See related article, page 12		
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2005 No. units installed in U.S./outside U.S./list price	CELL-DYN Ruby 2006/2006/n/a n/a/n/a/\$185,000	CELL-DYN 3700 1999/1999/— n/a/n/a/\$180,000 SL Model, \$140,000 CS Model
Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso	•Chartable •Laboratory •Flags standard menu (left) plus: MPV, RDW, RETIC #&#% #&#% for bands, IG, blast, var lymph —	standard menu (left) plus: RDW, MPV, retic #&#%, IRF 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 Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer	none none body fluid assay none atypical depolarization flag	none none none none IRF
Differential method(s) used Linearity: •WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%) Precision: •WBC count/RBC count •Hb/platelet •MCV or Hct Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation Interfering substances: •WBC •RBC •MCV or Hct •Platelet •Hb Interfering substances: differential	MAPSS (Multi-Angle Polarized Scatter Separation) 0.00–246 × 10 ³ /μL/0.00–7.16 × 10 ⁶ /μL 0.00–19.9 g/dL/0.00–1,903 × 10 ³ /μL 0.00–139 fL: (MCV) 2.4%/1.8% 1.4%/3.8% 0.8% (MCV) neu% r=0.983, slope=0.97, y=-1.98; lymph r=0.921, slope=0.95, y=0.94; mono r=0.711, slope=1.10, y=1.93; eos r=0.952, slope=1.04, y=0.01; baso r=0.146, slope=0.18, y=1.22 fragile WBC, neutrophil aggregates, lytic-resistant RBC, NRBC, Plt clumps, cryofibrinogen, cryoglobulin elevated WBC, increased numbers of giant Plt, auto agglutination, in vitro hemolysis MCV: elevated WBC, hyperglyc., in vitro hemolysis, increased No. of giant Pits WBC fragments, in vitro hemolysis, microcytic RBC, cryofibrinogen, cryoglobulins, Plt clumping, increased No. of giant Plt elevated WBC, increased plasma substances (triglycerides, bilirubin, in vivo hemolysis, lytic resistant RBC) fragile WBC, neutrophil aggregates, lytic-resistant RBC, NRBC, Plt clumps, cryofibrinogen, cryoglobulin, paraproteins	MAPSS (Multi-Angle Polarized Scatter Separation) 0–250/0–8 0–24/0–2,000 50–200 (MCV) ≤2.5%/≤1.5% ≤1.2%/≤5.0% ≤1.0% (MCV) neut #&#%: ≥0.95, n/a; lymph #&#%: ≥0.94, n/a; mono #&#%: ≥0.86, n/a; eos #&#%: ≥0.84, n/a; baso #&#%: ≥0.73, n/a NRBCs (WIC only), lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrino- gen, fragile WBCs increased No. giant Pits, autoagglutination, in vitro hemolysis MCV: elevated WBC count, increased No. giant Pits, hyperglycemia, in vitro hemolysis WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulin, Plt clumps, increased No. giant Pits increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs see WBC
Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average 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 up to 76 per hour/up to 76 per hour 6 months verification open or closed/WBC, RBC, Hgb, MCV, Plt per local regulatory requirements/n/a 150 μL/230 μL/1.2 mL yes (13 × 75 mm) no no no no >200/\$125,000	yes 90/90 6 months verification open & closed/WBC, RBC, Hb, MCV, Plt as per regulatory requirement/n/a 130 μL/355 μL/1.0 mL yes (13x75 mm) yes yes yes (flags only) n/a/\$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 •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 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 yes 10,000 results 10,000 results 10,000 results yes yes yes yes no yes user or vendor 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	LIS1/LIS2 CLSI numeric & flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders no n/a yes, Abbott Accelerator DM enhanced QC, data archiving, data collation from multiple instruments — Codabar, codes 39 & 128, interl. 2 of 5, ISBT yes	proprietary numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no n/a yes, proprietary enhanced QC, data archiving, data collation from multiple instruments Lab-InterLink (planned), MDS/AutoLab, Roche (planned), Labotix (planned) 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 Mfr. can perform diagnostics via modem	daily: 30 sec; weekly: 5 min; monthly: 10 min yes varies yes/no yes	daily: 30 sec; bi-weekly: 5 min; monthly: 10 min yes same day yes/no in development
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	touch-sensitive screen, all optical technology; onboard maintenance videos; lyse-resistant RBC mode	MAPSS cell-by-cell analysis provides a better diff.; retic with reportable IRF (immature retic. fraction); 60-species veterinary package

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High-volume hematology analyzers

Part 3 of 12	Abbott Hematology Jeff Kolberg jeff.kolberg@abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com	Bayer HealthCare Diagnostics Fred Stelling 511 Benedict Ave. Tarrytown, NY 10591 800-431-1970 www.bayerdiag.com
See related article, page 12		
Name of instrument	CELL-DYN 3200	Advia 120 Hematology System
First year installed in U.S./outside U.S./No. of units sold in 2005	1997/1997/—	1998/1998/—
No. units installed in U.S./outside U.S./list price	n/a/n/a/\$165,000	>750/3,400/\$169,000–\$189,000
Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, % neut, mono, lymph, eos, baso	•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
FDA-cleared tests but not clinically released	none	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
Tests not available but submitted for clearance	none	none
Tests in development	none	IRF, MPC, MPM
For research use only	atypical depolarization flag outside U.S.	CSF, eos
Tests unique to analyzer	3-D optical RBC analysis with advanced MCV measurement	CHCM, HDW, Chr, CHCMr, MPC, MPM; CSF: WBC, RBC, PMN, neut, lymph, mono
Differential method(s) used	MAPSS (Multi-Angle Polarized Scatter Sep.)	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) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%)	0.02–400/0–7.0; CSF WBC 0–5,000/μL; CSF RBC 0–1,500/μL 0–22.5/5–3,500 30–180 (MCV)
Precision:	•WBC count/RBC count •Hb/platelet •MCV or Hct	2.7%/1.2% 0.93%/2.93% 0.78% (MCV)
Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation	neut #&%: ≥0.95, n/a; lymph #&%: ≥0.94, n/a; mono #&%: ≥0.86, n/a; eos #&%: ≥0.84, n/a; baso #&%: ≥0.73, n/a	neut% r=0.997, y=1.02x–0.6; lymph% r=0.997, y=1.00x+0.8; mono% r=0.943, y=0.85x–0.3; eos% r=0.979, y=0.87x+0.2; baso% r=0.772, y=0.67x+0.0; luc% r=0.994, y=0.92x+0.6 incomplete RBC lysis (perox only)
Interfering substances:	•WBC •RBC •MCV or Hct •Platelet •Hb	NRBCs, lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrinogen, fragile WBCs elevated WBC count, increased No. giant Pits, autoagglutination, in vitro hemolysis MCV: elevated WBC count, hyperglycemia, in vitro hemolysis, increased No. giant Pits WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulins, Plt clumping, increased No. giant Pits elevated WBC count, incr. plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs see WBC
Interfering substances: differential		cold agglutinins, extreme sickle cell none none high WBC, lip., extremely high bili., interfere with cyanmethb. only, none with direct cellular Hb (CHCM) incomplete lysis of RBCs, complete myeloperox. deficiency
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	71/71	120/120
Recommended average frequency of calib.	6 months verification	6 months
•Modes calibrated/parameters calibrated	open & closed/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	150 μL/250 μL/1 mL (sample loader)	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	yes
Prepares microscopic slides automatically or flags	yes	yes
problems for slide prep		
If auto. slidemaker available, No. installed/list price	n/a/\$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 samples
Memory capacity—histo/cytograms—No. specimens	10,000 results	10,000 samples
•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 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 threshold	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	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	no	no
How labs get LOINC codes for reagent kits	n/a	online documentation
Optional data mgmt. or collation system	yes, proprietary	yes (CentralLink)
• Software features	enhanced QC, data archiving, data collation from multiple instruments	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	Lab-InterLink, MDS/Autolab, Roche (planned), Labotix	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
Mfr. can perform diagnostics via modem	in development	yes
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 Pits; uses only 3 reagents; 3-D MCV	unique laser technology provides cellular Hb for RBCs and retics; 2-D Plt analysis that eliminates interference from RBC fragments and exclusion of large Pits; dual WBC counts with a linearity of up to 400,000; CSF assay

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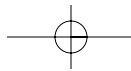


High-volume hematology analyzers

SURVEY
OF INSTRUMENTS

Part 4 of 12	Bayer HealthCare Diagnostics Fred Stelling 511 Benedict Ave. Tarrytown, NY 10591 800-431-1970 www.bayerdiag.com	Bayer HealthCare Diagnostics Fred Stelling 511 Benedict Ave. Tarrytown, NY 10591 800-431-1970 www.bayerdiag.com
See related article, page 12		
Name of instrument	Advia 70	Advia 2120 Hematology System
First year installed in U.S./outside U.S./No. of units sold in 2005	2001/2001/—	2004/2004/—
No. units installed in U.S./outside U.S./list price	100/400/\$89,000	>200/>900/\$225,000
Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso	•Chartable •Laboratory •Flags	standard menu (left) plus: RDW, MPV none diff., WBC, N, B, L, RBC, ABN, PL, Cl, Plt/RBC — — — MPC, MPM IRF, CSF, eos CHCM, HDW, Chr, CHCMr, cellular Hgb, MPC, MPM, CSF: WBC, RBC, PMN, MN, neut, lymph, mono
FDA-cleared tests but not clinically released	—	—
Tests not available but submitted for clearance	—	—
Tests in development	—	—
For research use only	Pct, PDW	—
Tests unique to analyzer	—	—
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) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%)	0.1–99/0.02–9.99 1.5–30/10–2,000 30–150 (MCV)	0.02–400; CSF WBC 0–5,000/0–7.0; CSF RBC 0–1,500 0–22.5/5–3,500 30–180 (MCV)
Precision: •WBC count/RBC count •Hb/platelet •MCV or Hct	2.0%/1.2% 1.0%/3–10% 1.0% (MCV)	2.7%/1.2% 0.93%/2.93% 0.78% (MCV)
Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation	neut% r=0.983, y=1.02x-3.3; lymph% r=0.983, y=0.96x+1.4; mono% r=0.797, y=1.02x+1.8; eos% r=0.963, y=0.91x+0.1; baso% r=0.322, y=0.30x+0.1	neut% r=0.997, y=1.02x-0.6; lymph% r=0.997, y=1.00x+0.8; mono% r=0.943, y=0.85x-0.3; eos% r=0.979, y=0.87x+0.2; baso% r=0.772, y=0.67x+0.0; luc% r=0.994, y=0.92x+0.6
Interfering substances:•WBC	incomplete RBC lysis cold agglutinins extremely high white blood cell count (Hct) RBC fragments lipemia, elevated WBC	incomplete RBC lysis (peroxidase only) cold agglutinins, extreme sickle cell none none extreme lipemia, high WBC, extreme high bili. interference w/ colorimetric Hb only, none with cellular Hb incomplete RBC lysis, complete myeloperox. deficiency
Interfering substances: differential	NRBCs, unlysed RBC, platelet clumps	
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	yes
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	Advia Autoslide, n/a/\$98,000
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 threshold	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 (Centralink)
• 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	—	LabCell (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
Mfr. 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 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 5 of 12	Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8438 www.beckmancoulter.com	Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8438 www.beckmancoulter.com
See related article, page 12		
Name of instrument	LH 1500 Hematology Automation Series	LH 780
First year installed in U.S./outside U.S./No. of units sold in 2005	2002/2003/14	2006/2007/—
No. units installed in U.S./outside U.S./list price	>40/10/varies	n/a/—/\$214,500
Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, % neut, mono, lymph, eos, baso	<ul style="list-style-type: none"> •Chartable •Laboratory •Flags 	<ul style="list-style-type: none"> •Laboratory •Flags
FDA-cleared tests but not clinically released	n/a	n/a
Tests not available but submitted for clearance	n/a	n/a
Tests in development	n/a	n/a
For research use only	MSCV, HLR %&#, PDW, PCT, WBC research population data (RPD)	RSF, MAF, MSCV, HLR %&#, RDWR-CV, RDWR-SD, PDW, PCT, WBC research population data (RPD)
Tests unique to analyzer	IVD: NRBC, body fluids; RUO: MSCV, WBC RPD	IVD: NRBC, body fluids, RDW-SD; RUO: MSCV, RSF, MAF, WBC RPD
Differential method(s) used	Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate & AccuFlex technologies	Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate & AccuFlex technologies
Linearity:	<ul style="list-style-type: none"> •WBC count (10⁹/L)/RBC count (10¹²/L) •Hemoglobin (g/dL)/platelet (10⁹/L) •MCV (fL) or Hct (%) 	<ul style="list-style-type: none"> •WBC count (10⁹/L)/RBC count (10¹²/L) •Hemoglobin (g/dL)/platelet (10⁹/L) •MCV (fL) or Hct (%)
Precision:	<ul style="list-style-type: none"> •WBC count/RBC count •Hb/platelet •MCV or Hct 	<ul style="list-style-type: none"> •WBC count/RBC count •Hb/platelet •MCV or Hct
Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation	lymph% = ±3.0%, n/a; neut% = ±3.0%, n/a; mono% = ±2.0%, n/a; eos% = ±1.0%, n/a; baso% = ±1.0%, n/a	lymph% = ±3.0%, n/a; neut% = ±3.0%, n/a; mono% = ±2.0%, n/a; eos% = ±1.0%, n/a; baso% = ±1.0%, n/a
Interfering substances: •WBC	unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps	unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps
•RBC	very high WBC, high conc. large Plt, autoagglutinins	very high WBC, high conc. large Plt, autoagglutinins
•MCV or Hct	very high WBC, high conc. large Plt, autoagglutinins	very high WBC, high conc. large Plt, autoagglutinins (MCV)
•Platelet	very small RBCs & WBC frags. may interfere	very small RBCs & WBC frags.
•Hb	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs
Interfering substances: differential	high triglycerides may affect lysing	high triglycerides may affect lysing
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	105 per analyzer on automation system/105 per analyzer on automation sys.	105/105
Recommended avg. frequency of calib.	as dictated by your lab procedures, local or national regulations	as dictated by your lab procedures, local or national regulations
•Modes calibrated/parameters calibrated	primary/RBC, WBC, Hb, MCV, Plt, MPV	primary/RBC, WBC, Hgb, MCV, Plt, MPV
Frequency of blood/latex controls	per CLIA, CAP, JCAHO, state or lab SOP/once per day	per CLIA, CAP, JCAHO, state or lab SOP/once per day
Min. specimen vol. open/closed/sample dead vol. closed	200 µL/300 µL, 550 µL with slidemaker/1.0 mL	200 µL/300 µL (550 µL with slidemaker)/1.0 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	yes
If auto. slidemaker available, No. installed/list price	>850 U.S./\$110,000	—/\$110,000
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes
Max. archived data accessible when system online	20,000 samples	20,000 results
Memory capacity—numeric results—No. specimens	20,000 samples	20,000 results
Memory capacity—histo/cytograms—No. specimens	5,000 samples	5,000 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	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 threshold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	RS-232	proprietary
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast
LOINC codes transmitted with results	no	no
How labs get LOINC codes for reagent kits	—	contact technical support
Optional data mgmt. or collation system	yes, Orchard Software Aqueduct, DL2000, Command Central	yes, DL2000, Command Central, Orchard Software Aqueduct
• Software features	enhanced QC, data archiving, data collection from multiple instruments, extensive decision rules, delta checking, patient results & graphics	enhanced QC, data archiving, data collection from multiple instruments, extensive decision rules, delta checking, patient results & graphics, centralized result management
Interface avail. or planned to auto. specimen-handling system	Beckman Coulter	Beckman Coulter
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5, NW7	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: automation system=5 min, analyzer=0; weekly: automation=10 min, analyzer=0; monthly: automation=15 min, analyzer=2 min	daily: 0; weekly: 0; monthly: 2 min
Onboard maintenance records	yes	yes
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	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; RUO: WBC research population data	extensive onboard user-defined decision support; extended linearity for WBC and Plt using AccuCount technology; enumeration of NRBCs with every differential; random access/automation ready; integrated slidemaker/slidestainer options; proservice; electronic IQAP; expanded QC module; RUO: WBC research population data

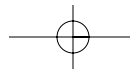
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High-volume hematology analyzers

Part 7 of 12	Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8438 www.beckmancoulter.com	Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8438 www.beckmancoulter.com
See related article, page 12		
Name of instrument	Coulter HmX	Coulter Ac•T 5diff Family; Ac•T 5diff AL
First year installed in U.S./outside U.S./No. of units sold in 2005	1999 HmX AL, 1999 HmX CP/133	2001/2000; 2003/2003; open vial-5, cap pierce-200, autoloader-122
No. units installed in U.S./outside U.S./list price	AL: 1,175/2,100/\$135,000; CP: 105/250/\$120,000	900/3,000/\$43,500 cap pierce model; \$38,500 open vial model; AL: 30/—; 300/750/\$54,500 autoloader model
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 #&%, graded RBC morph., IRF, MRV — comprehensive high/low, definitive & suspect messages none none none PCT, PDW none
		standard menu (left) plus: RDW, MPV atyp. lymph. # (ATL#), atyp. lymph % (ATL%), immature cells # (IMM#), immature cells % (IMM%), PCT, PDW complete operator selectable flagging none none none PCT, PDW, IMM, ATL none
Differential method(s) used	Coulter's 3-D VCS technology	A•V technology combining cytochemistry, focused flow impedance, and light absorbance principles of measurement
Linearity:	•WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%)	0–99.9/0–7.0 0–25/0–999 50–150 (MCV)
Precision:	•WBC count/RBC count •Hb/platelet •MCV or Hct	0.4–91.3/0.3–8.0*; AL: 0.4–120.0/0.3–8.0 0–22/10–1,000*; AL: 1.3–24.0/10.0–1,000 1.8–63.8 (Hct)* <2%/<2% <1%/<5% <1.0% (Hct); AL: <2.0% (Hct) not available in NCCLS H-20A format
Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation	lymph%= ±3.0%, n/a; mono%= ±2.0%, n/a; neut%= ±3.0%, n/a; eos%= ±1.0%, n/a; baso%= ±1.0%, n/a	
Interfering substances: •WBC	unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, large Plt	NRBCs, Plt clumps, large Plts, lyse-resistant RBCs
•RBC	very high WBC, high conc. of very large Plt, autoagglutinins	cold agglutinins, Plt clumps, WBC overlinearity
•MCV or Hct	MCV & Hct: very high WBC, high conc. of large Plt, autoagglutinins	Hct: lipemic samples, high WBC, cold aggluts
•Platelet	very small RBCs & WBC frags. may cause no fit	RBC and WBC fragments
•Hb	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs	elevated WBC, lipemia
Interfering substances: differential	high triglycerides may affect lysing	lyse-resistant RBCs, NRBCs, lipemia
Age- and sex-specific reference ranges	gender-specific printout	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	75/75	60/60; 80/80
Recommended average frequency of calib.	timing not specified	not specified by time
•Modes calibrated/parameters calibrated	primary/RBC, WBC, Hb, MCV, Plt, MPV	open or closed/RBC, WBC, Hb, Hct, Plt
Frequency of blood/latex controls	not specified/once per day	not specified/none
Min. specimen vol. open/closed/sample dead vol. closed	125 µL/185 µL/50 µL predilute/0.5 mL	30 µL for CBC/30 µL/varies by tube size; 53 µL for CBC-diff/53 µL for CBC-diff./varies by tube size
Tube sampling supported	yes (multiple sizes & styles)	yes (multiple sizes)
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	n/a
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	no
Max. archived data accessible when system online	5,000 samples	10,000 samples
Memory capacity—numeric results—No. specimens	5,000 samples	10,000 samples
Memory capacity—histo/cytograms—No. specimens	5,000 samples	10,000 samples
•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, through a selective batch process	yes, through user-defined criteria
Scattergram display: cell-specific color	4 colors/cell types	no
Histogram display: color with threshold	colors without thresholds	yes
Choice of desired specimen &/or result info. displayed	no	yes
LIS interface formats supported	RS-232, proprietary	proprietary; proprietary ASTM
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric & flag results, histograms & diff. plots, 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, DL2000, Orchard Software Aqueduct	yes, DL2000, Command Central, Orchard Software Aqueduct
• Software features	enhanced QC, data archiving, common database, delta checking, patient results & graphics	enhanced QC, data archiving, common database, optional data mgmt., extensive decision rules, delta checking, patient results & graphics available, centralized management of all instruments
Interface avail. or planned to auto. specimen-handling system	Beckman Coulter	no
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5, NW7	Codabar, codes 39 & 128, interl. 2 of 5, EAN 8 & 13
Accommodates bar-code placement per NCCLS standard Auto2A	no	yes
Time required for maintenance by lab personnel	none	none
Onboard maintenance records	no	yes
Time from communication of problem to engineer on site	—	—
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mfr. can perform diagnostics via modem	no	no
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	VCS technology; lowest review rate in class; no routine daily maintenance; triplicate counting; aperture burn circuit; sweepflow; SmartStart system; autoloader and single sample models	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 * linearity stated for Ac•T 5diff CP

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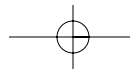


High-volume hematology analyzers

Part 8 of 12	Horiba ABX Diagnostics Inc. Jim Knowles jknowles@us.abx.fr 34 Bunsen Irvine, CA 92618 888-903-5001 ext. 553 www.abx.com	Horiba ABX Diagnostics Inc. Jim Knowles jknowles@us.abx.fr 34 Bunsen Irvine, CA 92618 888-903-5001 ext. 553 www.abx.com
See related article, page 12		
Name of instrument	Pentra 60C+ Hematology Analyzer	Pentra XL 80
First year installed in U.S./outside U.S./No. of units sold in 2005	2000/2000/52	2004/2003/33
No. units installed in U.S./outside U.S./list price	330/616/\$49,500	69/126/\$90,000
Test menu:	•Chartable standard menu (left) plus: RDW, MPV atyp. lymph, atyp. lymph %, LIC, LIC % •Laboratory operator selectable flagging •Flags	standard menu (left) plus: automatic dilution of overrange results (WBC x 3, RBC/hgb/Pit x 2), RDW, MPV atyp. lymph, atyp. lymph%, LIC, LIC% operator selectable flagging
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso		
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	—
For research use only	none	none
Tests unique to analyzer	none	automatic dilution protocol
Differential method(s) used	DHSS technology combining cytochemistry, focused flow impedance, & light absorbance principles of measurement	DHSS technology combining cytochemistry, focused flow impedance & light absorbance
Linearity:	•WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) 0-120/0-8 •Hemoglobin (g/dL)/platelet (10 ⁹ /L) 0.7-24/0-1,900 •MCV (fL) or Hct (%) 0.7-67% (Hct)	0-120/0-8 0-24/0-1,900 (>2 g/dL Hb) 0-67% (Hct)/0-2,800 (<2 g/dL Hb)
Precision:	•WBC count/RBC count <2%/<2% •Hb/platelet <1%/<5% •MCV or Hct <2% (Hct)	<2%/<2% <1%/<5% <2% (Hct)
Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation	neut% r=0.99, n/a; lymph% r=0.98, n/a; mono% r=0.96, n/a; eos% r=0.89, n/a; baso% r=0.54, n/a	neut% r=0.99, n/a; lymph% r=0.98, n/a; mono% r=0.96, n/a; eos% r=0.89, n/a; baso% r=0.54, n/a
Interfering substances:	•WBC NRBCs, Plt clumps, lyse-resistant RBCs •RBC cold agglutinins •MCV or Hct Hct: extreme leukocytosis •Platelet microcytes, Plt clumps •Hb extreme lipemia/leukocytosis	NRBCs, Plt clumps, lyse-resistant RBCs cold agglutinins Hct: extreme leukocytosis microcytes, Plt clumps extreme lipemia, leukocytosis
Interfering substances: differential	NRBC, 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	60/60	80/80
Recommended average frequency of calib.	6 months	6 months
•Modes calibrated/parameters calibrated	closed-open/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 µL for CBC & 53 µL for CBC + diff/30 µL for CBC & 53 µL for CBC + diff/—	30 µL for CBC/53 µL for CBC + diff/0.5 mL
Tube sampling supported	yes (multiple sizes)	yes (autoloader 13 x 75; closed tube 16 sizes + micro)
Veterinary capability	yes	yes
Microsample capability	yes	yes
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 backup drive	yes, with MultiLink Data Manager
Max. archived data accessible when system online	unlimited with backup drive	MultiLink Data Manager; 10,000 instrument only
Memory capacity—numeric results—No. specimens	10,000, unlimited with backup drive	MultiLink Data Manager; 10,000 instrument only
Memory capacity—histo/cytograms—No. specimens	10,000, unlimited with backup drive	MultiLink 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	yes
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	—
LIS interface formats supported	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, LIS to instrument—broadcast	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast
LOINC codes transmitted with results	yes	n/a
How labs get LOINC codes for reagent kits	—	n/a
Optional data mgmt. or collation system	yes	yes (MultiLink)
• Software features	enhanced QC, data archiving with Data Manager	enhanced QC, data archiving, data collation from multiple instruments
Interface avail. or planned to auto. specimen-handling system	no	yes
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	24 hrs	—
Onboard diagnostics/limited to software problems	yes/yes	no/yes
Mfr. can perform diagnostics via modem	yes, with Data Manager	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	reliable 5-part WBC diff. technology—MTBF over 200 days; small footprint; small sample size of 53 µL	compact 5-part differential instrument with autoloader and autodilution capability, autorerun feature, auto validation

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



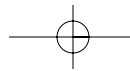


High-volume hematology analyzers

Part 9 of 12	Horiba ABX Diagnostics Inc. Jim Knowles jknowles@us.abx.fr 34 Bunsen Irvine, CA 92618 888-903-5001 ext. 553 www.abx.com	Sysmex America Inc. Nilam Patel 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
See related article, page 12		
Name of instrument	Pentra DX120	Sysmex XE-2100
First year installed in U.S./outside U.S./No. of units sold in 2005	2005/2004/6	2000/—/200
No. units installed in U.S./outside U.S./list price	14/70/\$196,000	1,050/3,700/\$225,000
Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso	•Chartable •Laboratory •Flags	standard menu (left) plus: NRBCs, reticulocytes, IRF, MRV LIC%&#, atyp lymphs %&#, IMG %&#, IML %&#, IMM %&#, RETL%, RETM%, RETH%, IMR%, MRU, MFI%, CRC%
FDA-cleared tests but not clinically released	double-diff matrix pending 510 (k)	standard menu (left) plus: NRBC %&#, retic %&#, RDW-SD, RDW-CV, IRF, Plt-O, HPC#, MPV, IG%, IG#
Tests not available but submitted for clearance	double-diff matrix pending 510 (k)	none
Tests in development	double-diff matrix pending 510 (k)	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
For research use only	—	RET-He, IPF
Tests unique to analyzer	—	none
Differential method(s) used	cytochemistry (chlorazol black E) and absorbance	fluorescent flow cytometry, RF/DC detecting method
Linearity:	•WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%)	0-440/0-8 0-25/0-5,000 0-75 (Hct)
Precision:	•WBC count/RBC count •Hb/platelet •MCV or Hct	<3%/<1.5% <1.0%/<4.0% <1.0% (Hct)
Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation	neut% r=0.99, n/a; lymph% r=0.98, n/a; mono% r=0.92, n/a; eos% r=0.97, n/a; baso% r=0.71, n/a	neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922
Interfering substances: •WBC •RBC	NRBCs, Plt clumps, lyse-resistant RBCs cold agglutinins	cold agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts, in vitro hemolysis
•MCV or Hct	Hct: extreme leukocytosis	Hct: cold agglutinins, leukocytosis (>100,000/μL), ABN red cell fragility, spherocytosis
•Platelet •Hb	microcytes, Plt clumps extreme lipemia, leukocytosis	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts lipemia, ABN proteins in blood plasma, severe leukocytosis (>100,000/μL)
Interfering substances: differential	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia	lyse-resistant RBCs
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	120/120	150/150
Recommended average frequency of calib. •Modes calibrated/parameters calibrated	6 months open, closed/WBC, RBC, Hb, Hct, Plt, MPV	twice per year by FSR open, closed, capillary/WBC, RBC, Hb, Hct, Plt
Frequency of blood/latex controls	per CLIA standards/none	per 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	yes	no
Microsample capability	yes, open mode	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes	yes with Alpha or HST upgrade
If auto. slidemaker available, No. installed/list price	—/—	>1,000/price depends on configuration
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes
Max. archived data accessible when system online	unlimited Data Manager; 10,000 instrument only	10,000 samples
Memory capacity—numeric results—No. specimens	unlimited Data Manager	10,000 samples
Memory capacity—histo/cytograms—No. specimens	unlimited Data Manager	10,000 samples
•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 or vendor
Some results can be transmitted to LIS while others held	—	yes
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	proprietary, ASTM 1394 & 1238, HL7, IEEE MIB	RS-232C/TCP IP
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; host query for patient demographics & orders
LOINC codes transmitted with results	n/a	yes
How labs get LOINC codes for reagent kits	n/a	contact vendor
Optional data mgmt. or collation system • Software features	yes (MultiLink) enhanced QC, data archiving, data collation from multiple instruments	yes, proprietary enhanced QC, data archiving, data collation from multiple instruments, online QC
Interface avail. or planned to auto. specimen-handling system	yes	Roche, Labotix, IDS, A&T
Bar-code symbologies read on tube	Codabar, codes 39 & 128, ASTM, interl. 2 of 5	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	weekly: 15 min	daily: 15 min walkaway with autoready
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	—	territory dependent
Onboard diagnostics/limited to software problems	no/yes	yes/no
Mfr. can perform diagnostics via modem	yes	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	high-throughput cell counter with integrated reticulocyte methodology and slidemaker/stainer; fluorescent NRBC counting, auto rerun and reflex testing, auto validation	enum. of NRBCs; throughput of 150 CBCs per hour; random access; discrete testing; HPC testing; online QC; remote diagnostics, IG enum., body fluid analysis; platelet linearity to 5 million, IPF, and RET He; hematocrit non-linear to 75%

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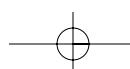


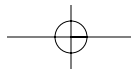


High-volume hematology analyzers

<p><i>Part 10 of 12</i></p> <p><i>See related article, page 12</i></p>	<p>Sysmex America Inc. Nilam Patel 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa</p>	<p>Sysmex America Inc. Nilam Patel 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa</p>
<p>Name of instrument</p> <p>First year installed in U.S./outside U.S./No. of units sold in 2005</p> <p>No. units installed in U.S./outside U.S./list price</p>	<p>Sysmex XE-2100L</p> <p>2001/—/20</p> <p>120/310/\$200,000</p>	<p>Sysmex XE-2100D</p> <p>2004/2004/12</p> <p>12/—/\$200,000</p>
<p>Test menu:</p> <p>All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso</p> <p>•Chartable</p> <p>•Laboratory</p> <p>•Flags</p> <p>FDA-cleared tests but not clinically released</p> <p>Tests not available but submitted for clearance</p> <p>Tests in development</p> <p>For research use only</p> <p>Tests unique to analyzer</p>	<p>standard menu (left) plus: MPV, RDW-SD, RDW-CV, NRBC %&#, HPC#, IG%, IG#</p> <p>none</p> <p>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</p> <p>none</p> <p>none</p> <p>none</p> <p>P-LCR, PCT, PDW</p> <p>HPC#, NRBC, IG%, IG#</p>	<p>standard menu (left) plus: RDW-SD, RDW-CV, IG%, IG#</p> <p>none</p> <p>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</p> <p>n/a</p> <p>n/a</p> <p>n/a</p> <p>P-LCR, PCT, PDW</p> <p>IG% & IG#</p>
<p>Differential method(s) used</p> <p>Linearity:</p> <p>•WBC count (10⁹/L)/RBC count (10¹²/L)</p> <p>•Hemoglobin (g/dL)/platelet (10⁹/L)</p> <p>•MCV (fL) or Hct (%)</p> <p>Precision:</p> <p>•WBC count/RBC count</p> <p>•Hb/platelet</p> <p>•MCV or Hct</p> <p>Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation</p> <p>Interfering substances:</p> <p>•WBC</p> <p>•RBC</p> <p>•MCV or Hct</p> <p>•Platelet</p> <p>•Hb</p> <p>Interfering substances: differential</p>	<p>fluorescent flow cytometry, RF/DC detecting method</p> <p>0-440/0-8</p> <p>0-25/0-5,000</p> <p>0-75 (Hct)</p> <p>≤3%/≤1.5%</p> <p>≤1.0%/≤4.0%</p> <p>≤1.0% (Hct)</p> <p>neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922</p> <p>cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs</p> <p>cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/μL)</p> <p>Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL)</p> <p>pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts</p> <p>lipemia, ABN proteins, leukocytosis (>100,000/μL)</p> <p>lyse-resistant RBCs</p>	<p>fluorescent flow cytometry</p> <p>0-440/0-8</p> <p>0-25/0-5,000</p> <p>0-75 (Hct)</p> <p>≤3%/≤1.5%</p> <p>≤1.0%/≤4.0%</p> <p>≤1.0% (Hct)</p> <p>neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922</p> <p>cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs</p> <p>cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/μL)</p> <p>Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL)</p> <p>pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts</p> <p>lipemia, ABN proteins, leukocytosis (>100,000/μL)</p> <p>lyse-resistant RBCs</p>
<p>Age- and sex-specific reference ranges</p> <p>Max. CBCs per hr/max. CBCs & diffs. per hr</p> <p>Recommended average frequency of calib.</p> <p>•Modes calibrated/parameters calibrated</p> <p>Frequency of blood/latex controls</p> <p>Min. specimen vol. open/closed/sample dead vol. closed</p> <p>Tube sampling supported</p> <p>Veterinary capability</p> <p>Microsample capability</p> <p>Prepares microscopic slides automatically or flags problems for slide prep</p> <p>If auto. slidemaker available, No. installed/list price</p>	<p>yes</p> <p>150/150</p> <p>twice per year by FSR</p> <p>open, closed, capillary/WBC, RBC, Hb, Hct, Plt</p> <p>per CLIA requirements/not required</p> <p>130 μL/200 μL/1 mL</p> <p>yes</p> <p>no</p> <p>yes</p> <p>yes with Alpha or HST upgrade</p> <p>>1,000/price depends on configuration</p>	<p>yes</p> <p>150/150</p> <p>twice per year by FSR</p> <p>open, closed, capillary/WBC, RBC, Hb, Hct, Plt</p> <p>per CLIA requirements/not required</p> <p>130 μL/200 μL/1 mL</p> <p>yes</p> <p>no</p> <p>yes</p> <p>yes, with Alpha or HST upgrade</p> <p>>1,000/—</p>
<p>Archives patient data for later comparison</p> <p>Patient-specific archiving</p> <p>Max. archived data accessible when system online</p> <p>Memory capacity—numeric results—No. specimens</p> <p>Memory capacity—histo/cytograms—No. specimens</p> <p>•Stored in conjunction with CBC data</p> <p>•Histo/cytogram images & CBC data printed as 1 report</p> <p>Saved results can be recalled and retransmitted</p> <p>Saved data can be sorted for reprocessing or report transmission</p> <p>Performs delta checks</p> <p>Tags and holds results for followup, confirm. testing, or rerun</p> <p>Parameters for flags for holding samples are defined by</p> <p>Some results can be transmitted to LIS while others held</p> <p>Scattergram display: cell-specific color</p> <p>Histogram display: color with threshold</p> <p>Choice of desired specimen &/or result info. displayed</p>	<p>yes</p> <p>yes</p> <p>10,000 samples</p> <p>10,000 samples</p> <p>10,000 samples</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p>	<p>yes</p> <p>yes</p> <p>10,000 samples</p> <p>10,000 samples</p> <p>10,000 samples</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p> <p>yes</p>
<p>LIS interface formats supported</p> <p>Information transferred on LIS interface</p> <p>LOINC codes transmitted with results</p> <p>How labs get LOINC codes for reagent kits</p> <p>Optional data mgmt. or collation system</p> <p>• Software features</p> <p>Interface avail. or planned to auto. specimen-handling system</p> <p>Bar-code symbologies read on tube</p> <p>Accommodates bar-code placement per NCCLS standard Auto2A</p>	<p>RS-232C/TCP IP</p> <p>numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders</p> <p>yes</p> <p>contact vendor</p> <p>yes, proprietary</p> <p>enhanced QC, data archiving, data collation from multiple instruments, online QC</p> <p>Roche, Labotix, A&T, IDS</p> <p>Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW7, EAN 8 & 13</p> <p>yes</p>	<p>RS-232C/TCP IP</p> <p>numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders</p> <p>yes</p> <p>contact vendor</p> <p>yes, proprietary</p> <p>enhanced QC, data archiving, data collation from multiple instruments, online QC</p> <p>Lab InterLink, MDS/AutoLab, Beckman Coulter, Roche, Labotix, A&T</p> <p>Codabar, codes 39 & 128, ASTM, interl. 2 of 5, ITF, NW7, EAN 8 & 13</p> <p>yes</p>
<p>Time required for maintenance by lab personnel</p> <p>Onboard maintenance records</p> <p>Time from communication of problem to engineer on site</p> <p>Onboard diagnostics/limited to software problems</p> <p>Mfr. can perform diagnostics via modem</p>	<p>daily: 15 min walkaway with autoready</p> <p>yes</p> <p>territory dependent</p> <p>yes/no</p> <p>yes</p>	<p>daily: 15 min walkaway with autoready</p> <p>yes</p> <p>contract and territory dependent</p> <p>yes/no</p> <p>yes</p>
<p>Acquisition program based on cost-per-reportable result</p>	<p>yes</p>	<p>yes</p>
<p>Distinguishing features</p>	<p>remote diagnostics; online QC; random access; HPC testing; 150 CBC per hour throughput; discrete testing; NRBC enumeration, IG enumeration, body fluid analysis</p>	<p>provides high throughput sample analysis; small footprint; configurable & scalable; platelet linearity—5 million, hematocrit extended to 75%</p>

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



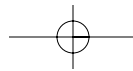


High-volume hematology analyzers

Part 11 of 12	Sysmex America Inc. Nilam Patel 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Inc. Margaret Triola 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
See related article, page 12		
Name of instrument	Sysmex XE-Alpha N/HST-N	Sysmex XT-2000i
First year installed in U.S./outside U.S./No. of units sold in 2005	2000/—/50	2002/—/150
No. units installed in U.S./outside U.S./list price	>1,000 worldwide/\$360,000–\$1,000,000	550/3,500/\$145,000
Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso	<ul style="list-style-type: none"> •Chartable •Laboratory •Flags 	<ul style="list-style-type: none"> standard menu (left) plus: RDW-SE, RDW-CV, IG%, IG#, NRBC%, NRBC#, retic%&#, IRG, Pit-O, HPC#, MPV none
FDA-cleared tests but not clinically released	standard menu (left) plus: retic %&#, IRF, Pit-O, MPV, RDW-SD, RDW-CV	standard menu (left) plus: retic %&#, IRF, Pit-O, MPV, RDW-SD, RDW-CV
Tests not available but submitted for clearance	none	none
Tests in development	Pit clumps, RBC agglut., turbidity, WBC ABN scattergram, RBC ABN distrib., Pit ABN distrib., RBC lyse resistance, blasts, left shift, atyp. lymph., ABN lymph./blast, ret. ABN scattergram	Pit clumps, Pit 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
For research use only	new release IPF & RET He	body fluids
Tests unique to analyzer	none	immature gran. %&#
Differential method(s) used	fluorescent flow cytometry, RF/DC detecting method	fluorescent flow cytometry
Linearity:	<ul style="list-style-type: none"> •WBC count (10⁹/L)/RBC count (10¹²/L) •Hemoglobin (g/dL)/platelet (10⁹/L) •MCV (fL) or Hct (%) 	<ul style="list-style-type: none"> 0–170/0–8 0–25/0–5,000 0–75 (Hct)
Precision:	<ul style="list-style-type: none"> •WBC count/RBC count •Hb/platelet •MCV or Hct 	<ul style="list-style-type: none"> 0–60 (Hct) ≤3.0%/≤1.5% ≤1.5%/≤4.0% ≤1.5% (Hct)
Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation	neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922	neut% r=0.95, y=0.95x+3.38; lymph% r=0.96, y=0.85x+1.67; mono% r=0.90, y=1.137x+1.89; eos% r=0.94, y=0.87x+0.04; baso% r=0.76, y=0.48x+0.24
Interfering substances:	<ul style="list-style-type: none"> •WBC •RBC •MCV or Hct •Platelet •Hb 	<ul style="list-style-type: none"> cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts, in vitro hemolysis Hct: cold agglut., leukocytosis (>100,000/μL), ABN red cell fragility, spherocytosis pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts lipemia, ABN proteins in blood plasma, severe leukocytosis (>100,000/μL) lyse-resistant RBCs
Interfering substances: differential		<ul style="list-style-type: none"> cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/μL) Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL) pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts lipemia, ABN proteins, leukocytosis (>100,000/μL) lyse-resistant RBCs
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	150/150 per analyzer on automation system	80/80
Recommended average frequency of calib.	twice per year by FSR	every 6 months by FSR
•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	85 μL/150 μL/1 mL
Tube sampling supported	yes	yes
Veterinary capability	no	yes, XT-V product
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes	no
If auto. slidemaker available, No. installed/list price	>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 samples
Memory capacity—histo/cytograms—No. specimens	10,000 samples	10,000 samples
•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 threshold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	RS-232C/TCP IP	RS-232/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	yes	yes
How labs get LOINC codes for reagent kits	contact vendor	contact vendor
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	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 with autoready	daily: 15 min walkaway with autoready
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	territory dependent	contract and territory dependent
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mfr. can perform diagnostics via modem	yes	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	multiple configurations available as are all distinguishing features of the XE-2100; platelet linearity—5 million; new parameters for platelet monitoring—IPF & retic Hb measurement & RET He	remote diagnostics; online QC; random access; fluorescent optical platelets; discrete testing; reagent monitoring; customized chartable report formats; XT-V unit for use in toxicology & research; body fluids now FDA approved

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





High-volume hematology analyzers

Part 12 of 12	Sysmex America Inc. Margaret Triola 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Inc. Margaret Triola 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
See related article, page 12		
Name of instrument	Sysmex XT-1800i	XS-1000i and XS-1000i AutoLoader (20 sample autoloader option)
First year installed in U.S./outside U.S./No. of units sold in 2005	2002/—/150	2005/2006/—
No. units installed in U.S./outside U.S./list price	550/3,500/\$125,000	released June 2006/200/\$85,000 (XS-1000i) \$95,000 (AutoLoader)
Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso	•Chartable •Laboratory •Flags	
FDA-cleared tests but not clinically released	standard menu (left) plus: MPV, RDW-SD, RDW-CV	standard menu (left) plus: MPV, RDW-SD, RDW-CV
Tests not available but submitted for clearance	none	none
Tests in development	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	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
For research use only	body fluids	none
Tests unique to analyzer	none	none
	immature gran. %&#	none
	IG%&#	n/a
	—	—
Differential method(s) used	fluorescent flow cytometry	fluorescent flow cytometry
Linearity:	•WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%)	0-440/0-8 0-25/0-5,000 0-60 (Hct)
Precision:	•WBC count/RBC count •Hb/platelet •MCV or Hct	0-400/0-8 0-25/0-5,000 0-60 (Hct)
Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation	neut% r=0.95, y=0.95x+3.38; lymph% r=0.96, y=0.85x+1.67; mono% r=0.90, y=11.37x+1.89; eos% r=0.94, y=0.87x+0.04; baso% r=0.76, y=0.48x+0.24	neut% r=0.96, y=0.9074x+3.8948; lymph% r=0.97, y=0.9017x+2.4817; mono% r=0.78, y=0.8626x+3.5938; eos% r=0.94, y=0.9076x+0.3651; baso% r=0.29, y=0.1538x+0.298
Interfering substances:	•WBC •RBC •MCV or Hct	cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs
	•Platelet •Hb	cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/μL)
Interfering substances: differential	cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL)	cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL)
	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts
	lipemia, ABN proteins, leukocytosis (>100,000/μL)	lipemia, ABN proteins, leukocytosis (>100,000/μL)
	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	60 per hr/60 per hr
Recommended average frequency of calib.	every 6 months by FSR	minimum annually
•Modes calibrated/parameters calibrated	open, closed, capillary/WBC, RBC, Hb, Hct, Plt	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	20 μL/20 μL/1.0 mL
Tube sampling supported	yes	yes (up to 85 mm height)
Veterinary capability	yes, XT-V product	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	no	yes
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	10,000 samples	10,000 specimens
Memory capacity—numeric results—No. specimens	10,000 samples	10,000 specimens
Memory capacity—histo/cytograms—No. specimens	10,000 samples	10,000 specimens
•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 threshold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	RS-232C/TCP-IP, ASTM	proprietary, ASTM 1394, 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	yes	yes
How labs get LOINC codes for reagent kits	contact vendor	contact vendor
Optional data mgmt. or collation system	yes, proprietary	yes, Molis WAM-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; SNCS diagnostics
Interface avail. or planned to auto. specimen-handling system	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, ASTM, interl. 2 of 5, 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 with autoready	daily: 3 min; weekly: none; monthly: 9 min
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; discrete testing; reagent monitoring; chartable report formats; XT-V for use in toxicology & research; unique specimen-gating SW is FDA Part II compliant; body fluids now FDA approved	common technology to other "X" series analyzers; small sample volume requirements for CBC + 5 part diff; SNCS remote diagnostics capability

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