Hematologyanalyzers—efficiency through automation

Anne Ford

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

Abbott, for example, "has focused its research and development efforts on providing automated instrument systems that maximize the efficiency of the analytical phase of the hematology workflow process," says James Schwartz, director of global public affairs and marketing communications. New from his company: the Cell-Dyn

Sapphire, which performs CBC analyses via Abbott's Multi-Angle Polarized Scatter Separation technology "plus three-color fluorescence," Schwartz says. He adds, "Industryleading first-pass CBC efficiency, even in the face of challenging pathologies, is our primary goal." The Sapphire also offers automated random-access monoclonal antibody analysis. In 2006, the company plans to introduce a sister instrument, the Cell-Dyn Ruby, aimed at mid-size laboratories; it will, Schwartz says, "streamline operations within the laboratory by offering reduced manual interventions in an easyto-use, Windows-based customizable operating software package." Already available is Abbott's Accelerator Decision Manager software, which "provides postanalytical connectivity and functionality across the entire laboratory in an open architecture."

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

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

Horiba ABX is anticipating the release of a double differential matrix with three immature cell line indexes—IMG, IMM, and IML—on its Pentra DX 120 analyzer. The Pentra DX 120 features more than 40 other parameters as well, such as reticulocyte analysis and NRBC enumeration, and can perform automated reruns or reflex testing in real time. Another new offering, the SPS Evolution, is "an integration slide maker/stainer available for both Pentra DX and DF systems," says Jim Knowles, U.S. hematology marketing manager.

Finally, Sysmex is celebrating the recent FDA clearance of two parameters, reticulocyte hemoglobin and immature platelet fraction, on its XE-2100 hematology analyzer. Body fluids on the analyzers in the XT series remain under investigation for FDA submission, says senior market manager Brian Verne. Also forthcoming, he says, is the result of his company's partnership with Bio-Rad Laboratories: the availability of Bio-Rad's Variant II Turbo hemoglobin testing system on the Sysmex HST-N hematology automation line. Expected to be available in 2006, "this initiative brings all testing of lavender-top sample tubes into the hematology laboratory," Verne says. "Some of the benefits are automated processing, elimination of sample splitting, and increases in operational efficiency with cost reductions."

Anne Ford is a writer in Chicago.

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RUMENTS 34	HI	gh-volume hematology	analyzers
Part 1 of 11		Abbott Diagnostics Hematology Business Unit 5440 Patrick Henry Dr. Santa Clara, CA 95054	Abbott Diagnostics Hematology Business Unit 5440 Patrick Henry Dr. Santa Clara, CA 95054
See related article, pa	ge 33	800-933-5535 www.abbottdiagnostics.com	800-933-5535 www.abbottdiagnostics.com
Name of instrument First year sold–install No. units installed in U	ed in U.S./outside U.S. J.S./outside U.S./list price	CELL-DYN 3200 1997/1997 >700/>1,500/\$165,000	CELL-DYN 3700 1999/1999 >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, Pit, %&# 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.,	band, IG, variant lymph, blast, PCT, PDW, NRBC #&% and retic so suspect populations, band, blast, variant lymph, IG, NRBC, RRBC
FDA-cleared tests but Tests not available bu	not clinically released t submitted for clearance	high/low interp. message, LRI, URI, LURI, WBC none none	URI, LURI, RBC morph., FWBC, high/low interp. message, WBC none none
Tests in development For research use only Tests unique to analyz		none atypical depolarization flag outside U.S. 3-D optical RBC analysis with advanced MCV measurement	none none IRF
Differential method(s) Linearity:	used •WBC count (10 ⁹ /L)/RBC count (10 ¹² /L)	MAPSS (Multi-Angle Polarized Scatter Sep.) 0-250/0-8	MAPSS (Multi-Angle Polarized Scatter Sep.) 0–250/0–8
	•Hemoglobin (g/dL)/platelet (109/L)	0–25/0–1,750	0-24/0-2,000
Precision:	•MCV (fL) or Hct (%) •WBC count/RBC count	34–172 (MCV) 2.7%/1.5%	50–200 (MCV) 2.5%/1.5%
	•Hb/platelet •MCV or Hct	1.0%/4.0% 1.0 % (MCV)	1.2%/5.0% 1.0% (MCV)
A		1.0 % (MCV)	1 .0% (MCV)
Accuracy of automate (per NCCLS H-20A), Interfering substances		neut #&%: 0 .95, n/a; lymph #&%: 0 .94, n/a; mono #&%: 0.8 6, n/a; eos #&%: 0 .84, n/a; baso #&%: 0.7 3, n/a NRBCs, lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrinogen,	neut #&%: 0.9 5, n/a; lymph #&%: 0.9 4, n/a; mono #&%: 0 .86, eos #&%: 0.84, n/a; baso #&%: 0 .73, n/a NRBCs (WIC only), lytic-resistant RBCs, PIt clumps, cryoglobulin and
	•RBC	fragile WBCs elevated WBC count, increased No. of giant Plts, autoagglutination, in vitro hemolysis	gen, fragile WBCs increased No. giant PIts, 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, hyperglycemi hemolysis
	•Platelet	WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulins, Plt clumping, increased No. giant Plts	WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulir 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 viv o her lyse-resistant RBCs
Interfering substances	s: differential	n/a	n/a
Age- and sex-specific	reference ranges	yes	yes
Max. CBCs per hr/max Recommended average	•	71/71 6 months verification	90/90 6 months
	/parameters calibrated	open & closed/WBC, RBC, Hb, MCV, Plt, MPV	open & closed/WBC, RBC, Hb, MCV, Pit
Frequency of blood/la	•	as per regulatory requirement/n/a	as per regulatory requirement/n/a
	en/closed/sample dead vol. closed	150 μL/250 μL/1 mL (sample loader)	130 µL/355 µL/1.0 mL
Tube sampling suppor Veterinary capability	rted	yes no	yes (13x75 mm) yes
Microsample capabilit	ty	yes	yes
	slides automatically or flags	yes	yes (flags only)
problems for slide p If auto. slidemaker av	rep ailable, No. installed/list price	n/a/\$125,000	n/a/\$125,000
Archives patient data	-	yes	yes
Patient-specific archive Max. archived data ac	ving ccessible when system online	yes 10,000 results	yes 10,000 results
	imeric results–No. specimens	10,000 results	10,000 results
	sto/cytograms–No. specimens	10,000 results	10,000 results
Stored in conjunct Histo/cytogram im	ages & CBC data printed as 1 report	yes yes	yes yes
	recalled and retransmitted	yes	yes
	ted for reprocessing or report transmission	yes	yes
Performs delta checks	s s for followup, confirm. testing, or rerun		no ves
	or holding samples are defined by	yes user or vendor	yes user or vendor
Some results can be t	ransmitted to LIS while others held	yes	yes
Scattergram display: o		yes ves	yes vec
Histogram display: co Choice of desired spe	cimen &/or result info. displayed	yes yes	yes yes
LIS interface formats Information transferre		proprietary numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	proprietary numeric and flag results, histograms and scatterplots, instrument patient demographics, orders, LIS to instrument—broadcast
LOINC codes transmit		по	по
How labs get LOINC co		n/a ves proprietary	N/a ves proprietary
Optional data mgmt. c • Software features	-	yes, proprietary enhanced QC, data archiving, data collation from multiple instruments	yes, proprietary enhanced QC, data archiving, data collation from multiple instru
Interface avail. or pla	nned to auto. specimen-handling system	Lab-InterLink, MDS/Autolab, Roche (planned), Labotix	Lab-InterLink (planned), MDS/AutoLab, Roche (planned), Labotix (pla
Bar-code symbologies Accommodates bar-co	s read on tube de placement per NCCLS standard Auto2A	Codabar, codes 39 & 128, interl. 2 of 5 yes	Codabar, codes 39 & 128, interl. 2 of 5 yes
-	ntenance by lab personnel	daily: 30 sec; weekly: 5 min; monthly: 10 min	daily: 30 sec; bi-weekly: 5 min; monthly: 10 min
Onboard maintenance Time from communica	records ation of problem to engineer on site	yes same day	yes same day
Onboard diagnostics/	imited to software problems	yes/no	yes/no
Mftr. can perform diag	gnostics via modem	in development	in development
Distinguishing feature		yes MAPSS cell-by-cell analysis provides a better diff.; focused flow	yes MAPSS cell-by-cell analysis provides a better diff.; retic with rep
2.comyaloning realure		2-D optical RBC and Plt analysis provides better separation between microcytic RBCs and large Plts; uses only 3 reagents; 3-D MCV	(immature retic. fraction); 60-species veterinary package

a ar	36 / CAP TODAY		Decem
JUNIT			
EV MENTS	FIL	gh-volume hematology a	analyzers
		Abbott Diagnostics Hematology Business Unit	Bayer HealthCare Diagnostics
Part 2 of 11		Deborah Archer 5440 Patrick Henry Dr.	Nancy Lavon 555 White Plains Rd.
		Santa Clara, CA 95054	Tarrytown, NY 10591
		800-933-5535	800-431-1970
See related article,	e, page 33	www.abbottdiagnostics.com	www.bayerdiag.com
Name of instrumer	nt stalled in U.S./outside U.S.	CELL-DYN Sapphire 2005/2005	Advia 120 Hematology System 1998/1998
-	in U.S./outside U.S./list price	n/a/n/a/\$250,000	800/3,500/\$169,000-\$189,000
Test menu:	•Chartable	standard menu (left) plus: MPV, RDW, retic %&#, IRF, NRBC %&#, CD61,</td><td>standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic</td></tr><tr><td>All instruments have</td><td>e: •Laboratory</td><td>CD3T %&#, CD4T %&#, CD8T %&#, 4/8 </td><td>CHCMr, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono; cellula %: hypo, hyper, macro, micro; calc. Hb, MPXI;</td></tr><tr><td>WBC, RBC, Hb, Hct, M</td><td>MCV,</td><td></td><td>%: blasts, PMN, MN; large Plt count; RBC frag. count; RBC ghost</td></tr><tr><td>MCH, MCHC, Pit, %&# n mono, lymph, eos, baso</td><td></td><td>band, IG, blast, variant lymph, nvWBC, rstRBC, IR, Plt clmp, ASYM, FP,</td><td>left shift, atyp. lymph, blasts, immature grans, myeloperox. defi</td></tr><tr><td></td><td></td><td>CD61 agg., clot detected during aspiration, short sample</td><td>aniso, micro, macro, Hb variation, hypo, hyper, NRBC, RBC frag. large Plt, Plt clumps</td></tr><tr><td></td><td>but not clinically released</td><td>none</td><td>none</td></tr><tr><td></td><td>e but submitted for clearance</td><td>none hadu fluid access, anticel RPC membelanu</td><td></td></tr><tr><td>Tests in developme For research use o</td><td></td><td>body fluid assay, optical RBC morphology none</td><td>IRF, MPC, MPM CSF, eos</td></tr><tr><td>Tests unique to an</td><td>-</td><td>CD61 for Plts, WVF, CD3/4, CD3/8 (immuno T-cell)</td><td>CSF, 80S CHCM, HDW, CHr, CHCMr, MPC, MPM; CSF: WBC, RBC, PMN, neut, I</td></tr><tr><td>Differential method</td><td>d(s) used</td><td>optical scatter & 3-color fluorescence</td><td>perox-peroxidase cytochem. staining with light scatter & absor</td></tr><tr><td>Lincority</td><td></td><td></td><td>baso-cytochem. stripping with 2-angle laser light scatter</td></tr><tr><td>Linearity:</td><td>•WBC count (10⁹/L)/RBC count (10¹²/L) •Hemoglobin (g/dL)/platelet (10⁹/L)</td><td>0.0–250.0 × 10³ μL/ 0.0–7.50 × 1 0⁶ μL 1.0–25.0 g/dL (cyanide free)/0.0–2000.0 × 10³ μL</td><td>0.02-400/0-7.0; CSF WBC 0-5,000/µL; CSF RBC 0-1,500/µL 0-22.5 /5-3,500</td></tr><tr><td></td><td>•MCV (fL) or Hct (%)</td><td>37.0–179 fL (MCV)</td><td>30–180 (MCV)</td></tr><tr><td>Precision:</td><td>•WBC count/RBC count</td><td>2.7%/1.5%</td><td>2.7%/1.2%</td></tr><tr><td></td><td>•Hb/platelet</td><td>1.0%/4.0%</td><td>0.93%/2.93%</td></tr><tr><td>Accuracy of autom</td><td> MCV or Hct nated diff. compared with manual diff. </td><td>1.0 % (MCV) neut% r=0.942 slope 0.947 y=0.446; lym% r=0.936 slope=0.943 y=2.811;</td><td>0.78% (MCV) neut% r=0.997, y=1.02x–0.6; lymph% r=0.997, y=1.00x+0.8; mo</td></tr><tr><td>-</td><td>DA), regression equation</td><td>mono% r=0.542 slope=1.057 y=0.440, rm % r=0.500 slope=0.545 y=2.011, mono% r=0.623 slope=1.057 y=0.851; eos% r=0.446 slope=1.024 y=0.288;</td><td>r=0.943, y=0.85x-0.3; eos% r=0.979, y=0.87x+0.2; baso% r=0.7</td></tr><tr><td></td><td></td><td>baso% r=0.232 slope=0.257 y=0.350</td><td>y=0.67x+0.0; luc% r=0.994, y=0.92x+0.6</td></tr><tr><td>Interfering substar</td><td>nces:•WBC</td><td>Plt clumps, neut aggregates, Hb C crystals, lyse-resist. RBCs, cryoglob., cryofibr., frag. WBC, nRBC</td><td>incomplete RBC lysis (perox only)</td></tr><tr><td></td><td>•RBC</td><td>autoagg., cold agg., elevated WBC, giant Plts, hemolysis, sm WBC</td><td>cold agglutinins, extreme sickle cell</td></tr><tr><td></td><td>•MCV or Hct</td><td>MCV: autoagg., cold agg., elevated WBC, giant Plt, hemolysis, hyperglycemic</td><td>none</td></tr><tr><td></td><td></td><td>Plt satellitism, RBC frag, WBC frag, microcytic RBC</td><td></td></tr><tr><td></td><td>•Platelet •Hb</td><td>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</td><td>none high WBC, lip., extremely high bili., interfere with cyanmethb. only</td></tr><tr><td>Interfering out store</td><td></td><td></td><td>direct cellular Hb (CHCM)</td></tr><tr><td>Interfering substar</td><td></td><td>see WBC</td><td>incomplete lysis of RBCs, complete myeloperox. deficiency</td></tr><tr><td></td><td>cific reference ranges 'max. CBCs & diffs. per hr</td><td>yes 106/106</td><td>yes 120/120</td></tr><tr><td></td><td>erage frequency of calib.</td><td>6 months verification</td><td>6 months</td></tr><tr><td></td><td>ited/parameters calibrated</td><td>open-closed single procedure/WBC, RBC, Hb, Plt, MPV</td><td>open, closed, autosampler/all measured parameters</td></tr><tr><td>Frequency of blood</td><td>d/latex controls . open/closed/sample dead vol. closed</td><td>per regulatory requirement/n/a 117 $\mu L/117$ mL/0.5 mL, 0.3 mL for 10.25 \times 64 mm tubes</td><td>once per shift/not required 157 µL/157 µL/<300 µL (tube size dependent)</td></tr><tr><td>Tube sampling sup</td><td></td><td>yes $(11.5-13 \times 65-75 \text{ mm}, 10.25 \times 64 \text{ mm}, 9 \times 66 \text{ mm} \text{ [Sarstedt Monovette]})$</td><td>yes (2, 3, 5, 7 mL—all sizes–open tube)</td></tr><tr><td>Veterinary capabili</td><td>ity</td><td>no</td><td>yes</td></tr><tr><td>Microsample capa Prenares microsco</td><td>ibility opic slides automatically or flags</td><td>yes yes (flags only)</td><td>yes ves</td></tr><tr><td>problems for slid</td><td>de prep</td><td></td><td>yes</td></tr><tr><td></td><td>r available, No. installed/list price</td><td>n/a/\$125,000</td><td>Advia S60, >100/\$35,000</td></tr><tr><td>Archives patient da Patient-specific ar</td><td>lata for later comparison</td><td>yes yes</td><td>yes no</td></tr><tr><td>•</td><td>a accessible when system online</td><td>yes 10,000 results</td><td>10,000 samples</td></tr><tr><td></td><td>–numeric results–No. specimens</td><td>10,000 results</td><td>10,000</td></tr><tr><td></td><td>-histo/cytograms-No. specimens</td><td>10,000 results</td><td>10,000</td></tr><tr><td>-</td><td>unction with CBC data</td><td>yes ves</td><td>yes ves</td></tr><tr><td></td><td>n images & CBC data printed as 1 report be recalled and retransmitted</td><td>yes yes</td><td>yes yes</td></tr><tr><td></td><td>sorted for reprocessing or report transmission</td><td>yes</td><td>yes</td></tr><tr><td>Performs delta che</td><td>ecks</td><td>yes</td><td>yes</td></tr><tr><td></td><td>sults for followup, confirm. testing, or rerun</td><td>yes user er vender</td><td>yes user er vorder</td></tr><tr><td></td><td>gs for holding samples are defined by be transmitted to LIS while others held</td><td>user or vendor yes</td><td>user or vendor yes</td></tr><tr><td></td><td>ay: cell-specific color</td><td>yes</td><td>yes</td></tr><tr><td>Histogram display:</td><td>color with threshhold</td><td>yes</td><td>yes</td></tr><tr><td>Choice of desired s</td><td>specimen &/or result info. displayed</td><td>yes</td><td>yes</td></tr><tr><td>LIS interface forma</td><td></td><td>ASTM 1394</td><td>proprietary (Spec 79)</td></tr><tr><td>Information transfe</td><td>erred on LIS interface</td><td>numeric & flag results, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics & orders</td><td>numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast;</td></tr><tr><td></td><td></td><td></td><td>host query for demographics & orders</td></tr><tr><td></td><td>mitted with results</td><td>no</td><td>no</td></tr></tbody></table>	

		nost 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, Abbott Accelerator DM	yes (CentraLink)
Software features	enhanced QC, data archiving, data collation from multiple instruments,	enhanced QC, data archiving, data collation from multiple instruments,
	remote viewing	auto-validation, integrated diff. pad, remote diagnostics, remote workstations
Interface avail. or planned to auto. specimen-handling system	Accelera APS	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: 10 min; monthly: 5 min	daily: 15 min; weekly: 15 min; monthly: 15 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	-	territory dependent
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	no	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	4 optical and 3 fluorescent detectors providing Multiple Scatterplot Analysis; 2-D optical platelets that avoids interferences; fluorescent analysis of reticulocytes, nRBCs, and 3-color monoclonal analysis on a routine hematology analyzer	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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137 OK SURVEY INSTRUMEN

High-volume hematology analyzers

| Part 3 of 11 | | |

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| Part 3 of 11 | | Bayer HealthCare Diagnostics | Bayer HealthCare Diagnostics

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| | | Nancy Lavon | Nancy Lavon

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| | | 555 White Plains Rd. | 555 White Plains Rd.

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| | | Tarrytown, NY 10591 | Tarrytown, NY 10591

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| | | 800-431-1970 | 800-431-1970

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| Can valated article na | 200 22 | |

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| See related article, pa | ige 33 | www.bayerdiag.com | www.bayerdiag.com

 |
| lame of instrument | | Advia 70 | Advia 2120 Hematology System

 |
| | ed in U.S./outside U.S. | 2001/2001 | 2004/2004

 |
| • | U.S./outside U.S./list price | 100/300/\$89,000 | >60/>70/\$225,000

 |
| | | 100/000/403,000 | 200/210/4223,000

 |
| est menu: | •Chartable | standard menu (left) plus: RDW, MPV | standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, CH</td></tr><tr><td>oot monu.</td><td></td><td></td><td>CHCMr, cellular Hgb, MCVr; CSF: WBC, RBC, PMN, MN, neu t, lymph, mono</td></tr><tr><td>All instruments have:</td><td>el oborotory</td><td>2020</td><td></td></tr><tr><td>BC, RBC, Hb, Hct, MCV,</td><td></td><td>none</td><td>% hypo, hyper, macro, micro; MPXI, % blast, PMN, MN, large Pit count, RBC</td></tr><tr><td>CH, MCHC, Plt, %&# neut,
ono, lymph, eos, baso</td><td></td><td></td><td>fragment count; RBC ghost count</td></tr><tr><td>nio, iyilipii, eos, baso</td><td>•Flags</td><td>diff., WBC, N, B, L, RBC, ABN, PL, CI, Plt/RBC</td><td>-</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td>not clinically released</td><td>-</td><td>none</td></tr><tr><td></td><td>it submitted for clearance</td><td>-</td><td>NRBC</td></tr><tr><td>ests in development</td><td></td><td>-</td><td>MPC, MPM</td></tr><tr><td>or research use only</td><td></td><td>Pct, PDW</td><td>IRF, CSF, eos</td></tr><tr><td>ests unique to analyz</td><td>zer</td><td>-</td><td>CHCM, HDW, CHr, CHCMr, cellular Hgb, MPC, MPM, CSF: WBC, RBC, PMN, M</td></tr><tr><td></td><td></td><td></td><td>neut, lymph, mono</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td>ifferential method(s)</td><td>used</td><td>optical & enhanced impedance</td><td>peroxidase WBC—peroxidase cytochem. staining w/ light scatter &</td></tr><tr><td></td><td></td><td></td><td>absorption; baso—cytochem. stripping w/ 2-angle laser light scatter</td></tr><tr><td>inearity:</td><td>•WBC count (109/L)/RBC count (1012/L)</td><td>0.1-99/0.02-9.99</td><td>0.02–400; CSF WBC 0–5,000/0–7.0; CSF RBC 0–1,500</td></tr><tr><td></td><td>. , ,</td><td>1.5–30/10–2,000</td><td>0-22.5/5-3,500</td></tr><tr><td></td><td></td><td>30–150 (MCV)</td><td>30–180 (MCV)</td></tr><tr><td>recision:</td><td>•WBC count/RBC count</td><td>2.0%/1.2%</td><td>2.7%/1.2%</td></tr><tr><td>00101011</td><td></td><td>2.0%/1.2%
1.0%/3–10%</td><td>0.93%/2.93%</td></tr><tr><td></td><td>•</td><td></td><td></td></tr><tr><td></td><td>•MCV or Hct</td><td>1.0% (MCV)</td><td>0.78% (MCV)</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td>-</td><td>ed diff. compared with manual diff.</td><td>neut% r=0.983, y=1.02x-3.3; lymph% r=0.983, y=0.96x+1.4; mono% r=0.797,</td><td>neut% r=0.997, y=1.02x-0.6; lymph% r=0.997, y=1.00x+0.8; mono%</td></tr><tr><td>(per NCCLS H-20A),</td><td>regression equation</td><td>y=1.02x+1.8; eos% r=0.963, y=0.91x+0.1; baso% r=0.322, y=0.30x+0.1</td><td>r=0.943, y=0.85x-0.3; eos% r=0.979, y=0.87x+0.2; baso% r=0.772,</td></tr><tr><td></td><td></td><td></td><td>y=0.67x+0.0; luc% r=0.994, y=0.92x+0.6</td></tr><tr><td>nterfering substances</td><td>s:•WBC</td><td>incomplete RBC lysis</td><td>incomplete RBC lysis (peroxidase only)</td></tr><tr><td>J J</td><td>•RBC</td><td>cold agglutinins</td><td>cold agglutinins, extreme sickle cell</td></tr><tr><td></td><td>•MCV or Hct</td><td>extremely high white blood cell count (Hct)</td><td>none</td></tr><tr><td></td><td>•Platelet</td><td>RBC fragments</td><td>none</td></tr><tr><td></td><td></td><td>•</td><td></td></tr><tr><td></td><td>•Hb</td><td>lipemia, elevated WBC</td><td>extreme lipemia, high WBC, extreme high bili. interference w/ colorimetric</td></tr><tr><td></td><td></td><td></td><td>Hb only, none with cellular Hb</td></tr><tr><td>iterfering substances</td><td>s: differential</td><td>NRBCs, unlysed RBC, platelet clumps</td><td>inclomplete RBC lysis, complete myeloperox. deficiency</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td>ge- and sex-specific</td><td>-</td><td>yes</td><td>yes</td></tr><tr><td></td><td>x. CBCs & diffs. per hr</td><td>70/70</td><td>120/120</td></tr><tr><td>lecommended avg. fr</td><td>requency of calib.</td><td>every 6 months per governmental requirements</td><td>6 months</td></tr><tr><td> Modes calibrated. </td><td>/parameters calibrated</td><td>open & closed/all measured parameters</td><td>autosampler, closed, open/all measured parameters</td></tr><tr><td>requency of blood/la</td><td>tex controls</td><td>one level per shift/not required</td><td>once per shift/not required</td></tr><tr><td>Min. specimen vol. op</td><td>en/closed/sample dead vol. closed</td><td>90 μL/180 μL/120 μL</td><td>175 μL/175 μL/<300 (tube size dependent)</td></tr><tr><td>ube sampling suppor</td><td></td><td>yes (12x75)</td><td>yes (2, 3, 5, 7 mL—all sizes open)</td></tr><tr><td>dbc sampling support</td><td></td><td>no</td><td></td></tr><tr><td></td><td>h,</td><td></td><td>yes</td></tr><tr><td>Aicrosample capabilit</td><td></td><td>yes</td><td>yes
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numeric & flag results, instrument to LIS; patient demographics, orders,
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online documentation
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Codabar, code 39, interl. 2 of 5
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online documentation
in development

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FUNENTS	Hi	gh-volume hematology a	analyzers
Part 4 of 11	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.cd 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com
See related article,			
-	t alled in U.S./outside U.S. n U.S./outside U.S./list price	LH 1500 Hematology Automation Series 2002/2003 >30/5/varies	Coulter LH 700 Series 2001 >1,600/>1,500/LH 750: \$195,000; LH 755: \$367,500
Test menu:	•Chartable	standard menu (left) plus: RDW, MPV, retic %&#, IRF, graded RBC morph, NRBC %&#, TNC & RBC on CSF, synovial and serous fluids</td><td>standard menu (left) plus: RDW, MPV, retic #&%, IRF, MPV, graded R</td></tr><tr><td>All instruments have WBC, RBC, Hb, Hct, N</td><td>ncv, •Laboratory</td><td>_ / / / /</td><td>NRBC %&#, TNC & RBC on CSF, synovial and serous fluids</td></tr><tr><td>MCH, MCHC, Pit, %&# n mono, lymph, eos, baso</td><td>•Flags</td><td>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</td><td>user-definable age-, gender-, &/or location-based ref. intervals; acti limits; user-def. RBC morph.; gradient msgs. (=+, ++, +++); user-se sensitivity for diff. abnormal population suspect messages</td></tr><tr><td>Tests not available</td><td>but submitted for clearance</td><td>none</td><td> none</td></tr><tr><td>Tests in developme For research use or</td><td></td><td>n/a PCT, PDW, high light scatter retics, mean sphered cell volume (MSCV)</td><td>none PCT, PDW, high light scatter retics, mean sphered cell volume</td></tr><tr><td>Tests unique to ana</td><td>-</td><td>NRBC, MSCV, body fluids</td><td>NRBC, mean sphered cell volume, body fluid analysis</td></tr><tr><td>Differential method</td><td>(s) used •WBC count (10⁹/L)/RBC count (10¹²/L)</td><td>Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate & Accuflex technologies</td><td>Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, & Accuflex technologies 0–400/0–8.0</td></tr><tr><td>Linearity:</td><td>•Hemoglobin (g/dL)/platelet (109/L)</td><td>0–25/0–3,000</td><td>0–25/0–3,000</td></tr><tr><td>Precision:</td><td> MCV (fL) or Hct (%) WBC count/RBC count </td><td>50–200 (MCV) <1.7%/<0.8%</td><td>50–200 (MCV) <1.7%/<0.8%</td></tr><tr><td></td><td>•Hb/platelet •MCV or Hct</td><td><0.8%/<3.3% <0.8% (MCV)</td><td><0.8%/<3.3% <0.8% (MCV)</td></tr><tr><td>Accuracy of automs</td><td>ated diff. compared with manual diff.</td><td>lymph% = ±3.0%, n/a; neut% = ±3.0%, n/a; mono% = ±2.0%, n/a;</td><td>lymph% = $\pm 3.0\%$, n/a; neut% = $\pm 3.0\%$, n/a; mono% = $\pm 2.0\%$, n/a</td></tr><tr><td>(per NCCLS H-20A</td><td>A), regression equation</td><td>eos% = ±1.0%, n/a; baso% = ±1.0%, n/a</td><td>eos% = ±1.0%, n/a; baso% = ±1.0%, n/a</td></tr><tr><td>Interfering substan</td><td>•RBC</td><td>unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps very high WBC, high conc. large Plt, autoagglutinins</td><td>unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unly >35 fL, giant Plt, Plt clumps very high WBC, high conc. large Plt, a utoagglutinins</td></tr><tr><td></td><td>•MCV or Hct •Platelet</td><td>very high WBC, high conc. large Plt, autoagglutinins very small RBCs & WBC frags. may interfere</td><td>MCV & Hct: very high WBC, high conc. large Plt, autoagglutinins very small RBCs & WBC frags. may interfere</td></tr><tr><td>Interfering substan</td><td>•Hb ces: differential</td><td>very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing</td><td>very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing</td></tr><tr><td>Age- and sex-speci</td><td>fic reference ranges</td><td>yes</td><td>yes</td></tr><tr><td></td><td>nax. CBCs & diffs. per hr</td><td>105 per analyzer on automation system/105 per analyzer on automation sys. twice per year on each analyzer</td><td>105/105 twice per year</td></tr><tr><td> Modes calibrate </td><td>ed/parameters calibrated</td><td>primary/RBC, WBC, Hb, MCV, Plt, MPV</td><td>primary/RBC, WBC, Hb, MCV, Plt, MPV</td></tr><tr><td>Frequency of blood, Min. specimen vol.</td><td>/latex controls open/closed/sample dead vol. closed</td><td>per CLIA, CAP, JCAHO, state or lab SOP/once per day 200 µL/300 µL, 550 µL with slidemaker/1.0 mL</td><td>per CLIA, CAP, JCAHO, state or lab SOP/once per day 200 µL/300 µL, 550 µL with slidemaker/1.0 mL</td></tr><tr><td>Tube sampling sup Veterinary capabilit</td><td></td><td>yes no</td><td>yes (multiple sizes & styles) no</td></tr><tr><td>Microsample capab</td><td>ility</td><td>yes</td><td>yes</td></tr><tr><td>problems for slide</td><td>oic slides automatically or flags e prep available, No. installed/list price</td><td>yes >400 U.S./\$110,000</td><td>yes, both >400 U.S./\$110,000</td></tr><tr><td>Archives patient da</td><td>ta for later comparison</td><td>yes</td><td>yes</td></tr><tr><td>Patient-specific arc</td><td>hiving</td><td>yes</td><td>yes</td></tr><tr><td>Memory capacity—</td><td>accessible when system online -numeric results–No. specimens</td><td>20,000 samples 20,000</td><td>20,000 samples 20,000</td></tr><tr><td></td><td>-histo/cytograms–No. specimens nction with CBC data</td><td>5,000 yes</td><td>5,000 yes</td></tr><tr><td>•Histo/cytogram</td><td>images & CBC data printed as 1 report be recalled and retransmitted</td><td>yes</td><td>yes</td></tr><tr><td>Saved data can be s</td><td>orted for reprocessing or report transmission</td><td></td><td>yes yes</td></tr><tr><td>Performs delta cheo Tags and holds res</td><td>cks ults for followup, confirm. testing, or rerun</td><td>yes yes</td><td>yes yes</td></tr><tr><td>Parameters for flag</td><td>s for holding samples are defined by e transmitted to LIS while others held</td><td>user or vendor</td><td>user or vendor</td></tr><tr><td>Scattergram display</td><td>y: cell-specific color</td><td>yes yes</td><td>yes yes</td></tr><tr><td></td><td>color with threshhold pecimen &/or result info. displayed</td><td>yes yes</td><td>yes yes</td></tr><tr><td>LIS interface formation transfe</td><td>ts supported rred on LIS interface</td><td>RS-232 numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast</td><td>RS-232, proprietary numeric & flag results, histograms & scatterplots, instrument to LIS demographics, orders, LIS to instrument—broadcast</td></tr><tr><td>LOINC codes transn</td><td></td><td>no</td><td>no</td></tr><tr><td></td><td>codes for reagent kits t. or collation system</td><td> yes, Orchard Software Aqueduct</td><td>technical support yes, DL 2000, Command Central, Orchard Software Aqueduct</td></tr><tr><td>Software featur</td><td>es</td><td>enhanced QC, data archiving, data colleciton from multiple instruments, extensive decision rules, delta checking, patient results & graphics</td><td>enhanced QC, data archiving, common database, extensive decision delta checking, patient results & graphics, centralized managemen instruments</td></tr><tr><td>Bar-code symbolog</td><td>lanned to auto. specimen-handling system ies read on tube -code placement per NCCLS standard Auto2A</td><td>Codabar, codes 39 & 128, interl. 2 of 5, NW7</td><td>Beckman Coulter Codabar, codes 39 & 128, interl. 2 of 5, NW7 yes</td></tr><tr><td>Time required for m</td><td>naintenance by lab personnel</td><td>daily: automation system= 5 min, analyzer=0; weekly: automation=10 min, analyzer=0; monthly: automation=15 min, analyzer=2 min</td><td>daily: 0; weekly: 0; monthly: 2 min</td></tr><tr><td>Onboard maintenan</td><td></td><td>yes</td><td>yes</td></tr><tr><td>Onboard diagnostic</td><td>ication of problem to engineer on site s/limited to software problems liagnostics via modem</td><td>yes/no yes</td><td> yes/no yes</td></tr><tr><td>Acquisition program</td><td>n based on cost-per-reportable result</td><td>yes</td><td>yes</td></tr><tr><td>Distinguishing featu</td><td>ures</td><td>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</td><td>extensive decision support; enumeration of NRBCs with every dif random access; automation ready; extended linearity for WBC an using AccuCount Technology; integrated slidemaker/staining opt</td></tr></tbody></table>	

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Distinguishing features extensive decision support, extended linearity for WBC & Plt, lowest review VCS technology; lowest review rate in class; no routine daily material statements of the statement of the stat	Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Mftr. can perform diagnostics via modem	yes	no
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High-volume hematology analyzers

ecember 2005			CAP TODAY / 41
	Hiah-	volume hematology and	CAP TODAY / 41
art 6 of 11		Beckman Coulter Inc. Martha M. Diaz/Cellular Analysis Marketing mmdiaz@beckman.com	JIM Knowles Jknowles@us.abx.fr
		200 S. Kraemer Blvd. Brea, CA 92822-8000	34 Bunsen Irvine, CA 92618
ee related article, p	age 33	714-993-8847 www.beckmancoulter.com	888-903-5001 ext. 553 www.abx.com
ame of instrument		Coulter Ac+T 5diff Family; Ac+T 5diff AL	Pentra 60C+ Hematology Analyzer
rst year sold–instal	led in U.S./outside U.S.	2001/2000; 2003/2003	2000/2000
o. units installed in	U.S./outside U.S./list price	1,200/2,750/\$43,500 cap pierce model; \$38,500 open vial model; AL: 30/—; \$54,500 autoloader	325/440/\$49,500
est menu:	•Chartable	standard menu (left) plus: RDW, MPV	standard menu (left) plus: RDW, MPV
All instruments have: BC, RBC, Hb, Hct, MC	v •Laboratorv	atyp. lymph. # (ATL#), atyp. lymph % (ATL%), immature cells # (IMM#),	atyp. lymph, atyp. lymph %, LIC, LIC %
CH, MCHC, Plt, %&# neu ono, lymph, eos, baso		immature cells % (IMM%), PCT, PDW complete operator selectable flagging	operator selectable flagging
	Ū.		
ests not available bi	t not clinically released ut submitted for clearance	none	none none
ests in development or research use only		none PCT, PDW, IMM, ATL	none none
ests unique to analy	zer	none	none
ifferential method(s) used	A°V technology combining cytochemistry, focused flow impedance, and light	DHSS technology combining cytochemistry, focused flow impedance, & light
nearity:		absorbance prinicples of measurement 0.4–91.3/0.3–8.0*; AL: 0.4–120.0/0.3–8.0	absorbance principles of measurement 0–120/0–8
	 Hemoglobin (g/dL)/platelet (10⁹/L) MCV (fL) or Hct (%) 	0-22/10-1,000*; AL: 1.3-24.0/10.0-1,000 1.8-63.8 (Hct)*	0.7–24/0–1,900 0.7–67% (Hct)
recision:	•WBC count/RBC count •Hb/platelet	<2%/<2% <1%/<5%	<2%/<2% <1%/<5%
	•MCV or Hct	<1%/<5% <1.0% (Hct); AL: <2.0% (Hct)	<1%/<3% <2% (Hct)
	ed diff. compared with manual diff.	not available in NCCLS H-20A format	neut% r=0.99, n/a; lymph% r=0.98, n/a; mono% r=0.96, n/a; eos% r=0.89,
(per NCCLS H-20A), terfering substance	regression equation s:•WBC	NRBCs, Plt clumps, large Plts, lyse-resistant RBCs	n/a; baso% r=0.54, n/a 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
terfering substance	•Hb s: differential	elevated WBC, lipemia lyse-resistant RBCs, NRBCs, lipemia	extreme lipemia/leukocytosis NRBC, lyse-resistant RBCs, extreme hyperbilirubinemia
ge- and sex-specifi	c reference ranges	yes	yes
•	x. CBCs & diffs. per hr ge frequency of calib.	60/60; 80/80 not specified by time	60/60 6 months
 Modes calibrated 	/parameters calibrated	open or closed/RBC, WBC, Hb, Hct, Plt	closed-open/WBC, RBC, Hb, Hct, Pit, MPV
equency of blood/la in. specimen vol. op	atex controls pen/closed/sample dead vol. closed	not specified/none 30 μL for CBC/30 μL/varies by tube size;	per CLIA standards/none 53 µL/53 µL/0.5 mL
ube sampling suppo	rted	53 µL for CBC-diff/53 µL for CBC-diff./varies by tube size yes (multiple sizes)	yes (multiple sizes)
eterinary capability icrosample capabili		no yes	yes yes
repares microscopio	slides automatically or flags	no	no
problems for slide auto. slidemaker av	prep /ailable, No. installed/list price	n/a	_
rchives patient data	for later comparison	yes	yes
atient-specific archi	-	no 10,000 samples	yes, with Hemalink Data Manager unlimited with Hemalink Data Manager
emory capacity—n	umeric results–No. specimens	10,000	10,000, unlimited with Hemalink Data Manager
emory capacity—h •Stored in conjunc	isto/cytograms–No. specimens tion with CBC data	10,000 yes	10,000, unlimited with Hemalink Data Manager yes
	nages & CBC data printed as 1 report recalled and retransmitted	yes yes	yes yes
	ted for reprocessing or report transmission	yes	yes
ags and holds result	ts for followup, confirm. testing, or rerun	no yes	yes yes
-	for holding samples are defined by transmitted to LIS while others held	user or vendor yes, through user-defined criteria	user yes
cattergram display:		no	yes
	cimen &/or result info. displayed	yes yes	yes yes
S interface formats		proprietary; proprietary ASTM	ASTM 1394 & 1238, HL7, IEEE MIB
formation transferr	ed 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
DINC codes transmit	tted with results codes for reagent kits	no	yes —
ptional data mgmt.	or collation system	technical support yes, DL 2000, Command Central, Orchard Software Aqueduct	yes
 Software features 	3	enhanced QC, data archiving, common database, optional data mgmt., extensive decision rules, delta checking, patient results & graphics available,	enhanced QC, data archiving with Hemalink Data Manager
terface avail, or pla	nned to auto. specimen-handling system	centralized management of all instruments	no
ar-code symbologie	s read on tube	Codabar, codes 39 & 128, interl. 2 of 5, EAN 8 & 13	Codabar, codes 39 & 128, ASTM, interl. 2 of 5
	ode placement per NCCLS standard Auto2A		yes
me required for ma nboard maintenance	intenance by lab personnel e records	none yes	weekly: 15 min yes
me from communic	ation of problem to engineer on site 'limited to software problems	yes/no	24 hrs yes/yes
	gnostics via modem	no	yes, with Hemalink Data Manager
cquisition program	based on cost-per-reportable result	yes	yes
	25	quant. 5-part WBC diff.; aspirates only 30 µL of sample; requires small space	reliable 5-part WBC diff. technology—MTBF over 200 days; small footprint;
istinguishing featur	53	quant. o part mbo ani, aspirates only oo pe of sample, requires sinan space	fondble e part fibe ann teeningig infor bee auje, entan foetprint,

1MF			
EV MENTS	Hi	gh-volume hematology	analvzers
		<u> </u>	
		Horiba ABX Diagnostics Inc.	Horiba ABX Diagnostics Inc.
Part 7 of 11		Jim Knowles jknowles@us.abx.fr	Jim Knowles jknowles@us.abx.fr
		34 Bunsen	34 Bunsen
		Irvine, CA 92618 888-903-5001 ext. 553 www.abx.com	Irvine, CA 92618 888-903-5001 ext, 553 www.abx.com
See related article,	e, page 33	000-903-9001 ext. 993 www.abx.com	000-903-9001 ext. 993 www.abx.com
Name of instrumen	nt	Pentra 120 Retic Hematology Analyzer	Pentra 80
	stalled in U.S./outside U.S.	1999/1997	2003/2002
	in U.S./outside U.S./list price	96/700/\$170,000	114/330/\$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, I		LIC#, LIC%, atyp lymph #&%, CRC%, RETL%, RETM%, RETH%, IMR%, MRV,	atyp. lymph, atyp. lymph%, LIC, LIC%
MCH, MCHC, Plt, %&# i mono, lymph, eos, baso	•	MFI%	
110110, 1 y 111p11, 003, bu30	• Flags	operator selectable flagging	operator selectable flagging
FDA-cleared tests	but not clinically released	none	none
	e but submitted for clearance	none	none
Tests in developme		none	none
For research use o		none	none
Tests unique to ana	-	-	none
Differential method	d(s)	cytochemistry, focused flow impedance, light absorbance	DHSS technology combining cytochemistry, focused flow impedance
Differential method		cytochemistry, rocused now impedance, nynt absorbance	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 autom	nated diff. compared with manual diff.	neut% r=0.99, n/a; lymph% r=0.99, n/a; mono% r=0.92, n/a; eos% r=0.97,	neut% r=0.99, n/a; lymph% r=0.99, n/a; mono% r=0.36, n/a; eos%
(per NCCLS H-20/	DA), regression equation	n/a; baso% r=0.71, n/a	
Interfering substan	nces:•WBC	NRBCs, Plt clumps, lyse-resistant RBCs	NRBCs, Plt clumps, lyse-resistant RBCs
	- 000		
	•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 substan	nces: differential	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinem ia
	cific reference ranges max. CBCs & diffs. per hr	yes 120/120	yes 80/80
	max. GBCS & diffs. per fir erage frequency of calib.	6 months	80/80 6 months
	erage frequency of callb. ited/parameters calibrated	closed, open/WBC, RBC, Hb, Hct, Plt	o months closed rack/WBC, RBC, Hb, Hct, Pit, MPV
Frequency of blood	•	per CLIA standards/not required	per CLIA standards/none
	. open/closed/sample dead vol. closed	130 μ L/200 μ L/1 mL	53 µL/53 µL/0.5 mL
Tube sampling sup	• •	yes	yes
Veterinary capabili		yes	no
Microsample capal	-	yes	yes
	opic slides automatically or flags	yes	no
problems for slid If auto. slidemaker	de prep r available, No. installed/list price	/\$40,000	n/a
	· ·		
Archives patient da Patient-specific arc	ata for later comparison	yes ves	yes yes, with Hemalink Data Manager
•	a accessible when system online	yes 90,000, unlimited with Hemalink Data Manager	unlimited with Hemalink Data Manager
	–numeric results–No. specimens	90,000, unlimited with Hemalink Data Manager	10,000
	histo/cytograms-No. specimens	90,000, unlimited with Hemalink Data Manager	10,000
	Inction with CBC data	yes	yes
	n images & CBC data printed as 1 report	yes	yes
	be recalled and retransmitted	yes	yes
	sorted for reprocessing or report transmission	•	yes
Performs delta che		yes	yes
Tags and holds res	sults for followup, confirm. testing, or rerun		yes
Parameters for flag	gs for holding samples are defined by	user	user
	be transmitted to LIS while others held	yes (operator programmable)	yes
	ay: cell-specific color	no	yes
	: color with threshhold	yes	yes
Choice of desired s	specimen &/or result info. displayed	yes	—
LIS interface forma	ats supported	proprietary, ASTM 1394 & 1238, HL7, IEEE MIB	proprietary, ASTM 1 394 & 1238, HL7, IEEE MIB
	erred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS;	numeric & flag results, histograms & scatterplots, instrument to LIS;
		patient demographics, orders, LIS to instrument— broadcast;	patient demographics, orders, LIS to instrument— broadcast
		host query for demographics & orders	

	nost query for demographics & orders	
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	enhanced QC, data archiving, data collation from multiple instruments
	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

a a	44 / CAP TODAY		Decemi
UNI			
EX MENTS	HI	gh-volume hematology	analyzers
		Horiba ABX Diagnostics Inc.	Horiba ABX Diagnostics Inc.
Part 8 of 11		Jim Knowles jknowles@us.abx.fr 34 Bunsen	Jim Knowles jknowles@us.abx.fr 34 Bunsen
		Irvine, CA 92618	Irvine, CA 92618
		888-903-5001 ext. 553	888-903-5001 ext. 553
See related article,	, page 33	www.abx.com	www.abx.com
Name of instrumen	nt talled in U.S./outside U.S.	Pentra XL 80 2004/2003	Pentra DX120 2005/2004
	in U.S./outside U.S./list price	32/90/\$90,000	5/50/\$196,000
Test menu:	•Chartable	standard menu (left) plus: automatic dilution of overrange results (WBC x 3,	standard menu (left) plus: NRBCs, reticulocytes, IRF, MRV
All 1		RBC/hgb/Plt x 2), RDW, MPV	
All instruments have WBC, RBC, Hb, Hct, M	MCV	atyp. lymph, atyp. lymph%, LIC, LIC%	LIC%&#, atyp lymphs %&#, IMG %&#, IML %&#, IMM %&#, RETL% RETH%, IMR%, MRU, MFI%, CRC%</td></tr><tr><td>MCH, MCHC, Plt, %&# r mono, lymph, eos, baso</td><td>^{neut,} •Flags</td><td>operator selectable flagging</td><td>—</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td>but not clinically released but submitted for clearance</td><td>none none</td><td>double-diff matrix pending 510 (k) double-diff matrix pending 510 (k)</td></tr><tr><td>Tests in developme</td><td></td><td></td><td>double-diff matrix pending 510 (k)</td></tr><tr><td>For research use or</td><td>nly</td><td>none</td><td>_</td></tr><tr><td>Tests unique to ana</td><td>alyzer</td><td>automatic dilution protocol</td><td>-</td></tr><tr><td>Differential method</td><td>d(s) used</td><td>DHSS technology combining cytochemistry, focused flow impedance & light absorbance</td><td>cytochemistry (chlorazolic black) and absorbance</td></tr><tr><td>Linearity:</td><td>•WBC count (10⁹/L)/RBC count (10¹²/L)</td><td>0–120/0–8</td><td>0–150/0.5–8.1</td></tr><tr><td>-</td><td>•Hemoglobin (g/dL)/platelet (109/L)</td><td>0–24/0–1,900 (>2 g/dL Hb)</td><td>2–25/0–2,000</td></tr><tr><td></td><td>•MCV (fL) or Hct (%)</td><td>0–67% (Hct)/0–2,800 (<2 g/dL Hb)</td><td>0–80 (Hct)</td></tr><tr><td>Precision:</td><td> WBC count/RBC count Hb/platelet </td><td><2%/<2% <1%/<5%</td><td><2%/<2% <1%/<5%</td></tr><tr><td></td><td>•MCV or Hct</td><td><1%/<3% <2% (Hct)</td><td><1%/<5% <2% (Hct)</td></tr><tr><td>Accuracy of autom</td><td>nated diff. compared with manual diff.</td><td>neut%r=0.99, n/a; lymph% r=0.98, n/a; mono% r=0.96, n/a; eos% r=0.89,</td><td>neut%r=0.99, n/a; lymph% r=0.98, n/a; mono% r=0.92, n/a; eo</td></tr><tr><td>-</td><td>A), regression equation</td><td>n/a; baso% r=0.54, n/a</td><td>n/a; baso% r=0.71, n/a</td></tr><tr><td>Interfering substan</td><td>nces:•WBC</td><td>NRBCs, Plt clumps, lyse-resistant RBCs</td><td>NRBCs, Plt clumps, lyse-resistant RBCs</td></tr><tr><td></td><td>•RBC</td><td>cold agglutinins</td><td>cold agglutinins</td></tr><tr><td></td><td>•MCV or Hct</td><td>Hct: extreme leukocytosis</td><td>Hct: extreme leukocytosis</td></tr><tr><td></td><td>•Platelet</td><td>microcytes, Plt clumps</td><td>microcytes, Plt clumps</td></tr><tr><td>Interfering substan</td><td>•Hb nces: differential</td><td>extreme lipemia, leukocytosis NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia</td><td>extreme lipemia, leukocytosis NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia</td></tr><tr><td>Age- and sex-spec</td><td>ific reference ranges</td><td>yes</td><td>yes</td></tr><tr><td></td><td>max. CBCs & diffs. per hr</td><td>80/80</td><td>120/120</td></tr><tr><td></td><td>erage frequency of calib.</td><td>6 months</td><td>6 months</td></tr><tr><td></td><td>ted/parameters calibrated</td><td>open, closed/WBC, RBC, Hb, Hct, Pit, MPV</td><td>open, closed/WBC, RBC, Hb, Hct, Pit, MPV</td></tr><tr><td>Frequency of blood Min. specimen vol.</td><td>. open/closed/sample dead vol. closed</td><td>per CLIA standards/none 30 for CBC/53 for CBC & diff/0.5 mL</td><td>per CLIA standards/none 130 µL/200 µL/1 mL</td></tr><tr><td>Tube sampling sup</td><td></td><td>yes (autoloader 13 x 75; closed tube 16 sizes + micro)</td><td>yes</td></tr><tr><td>Veterinary capabili</td><td></td><td>yes</td><td>no</td></tr><tr><td>Microsample capat</td><td>-</td><td>yes ves</td><td></td></tr><tr><td>problems for slid</td><td>• •</td><td>yes</td><td>yes</td></tr><tr><td>lf auto. slidemaker</td><td>r available, No. installed/list price</td><td>_/_</td><td>_/_</td></tr><tr><td>-</td><td>ata for later comparison</td><td>yes vos with Homalink Data Managor</td><td>yes ves</td></tr><tr><td>Patient-specific arc</td><td>chiving a accessible when system online</td><td>yes, with Hemalink Data Manager unlimited with Hemalink Data Manager; 10,000 instrument only</td><td>yes unlimited Data Manager; 10,000 instrument only</td></tr><tr><td></td><td>-numeric results-No. specimens</td><td>unlimited with Hemalink Data Manager; 10,000 instrument only</td><td>unlimited Data Manager</td></tr><tr><td></td><td>-histo/cytograms-No. specimens</td><td>unlimited with Hemalink Data Manager</td><td>unlimited Data Manager</td></tr><tr><td> Stored in conjunct </td><td>nction with CBC data</td><td>yes</td><td>yes</td></tr><tr><td></td><td>n images & CBC data printed as 1 report</td><td>yes</td><td>yes</td></tr><tr><td></td><td>be recalled and retransmitted</td><td>yes</td><td>yes voe</td></tr><tr><td>Performs delta che</td><td>sorted for reprocessing or report transmission acks</td><td>yes yes</td><td>yes yes</td></tr><tr><td></td><td>sults for followup, confirm. testing, or rerun</td><td>yes</td><td>yes</td></tr><tr><td></td><td>gs for holding samples are defined by</td><td>user</td><td>user</td></tr><tr><td>Some results can b</td><td>be transmitted to LIS while others held</td><td>yes</td><td>-</td></tr><tr><td></td><td>ay: cell-specific color</td><td>yes</td><td>yes</td></tr><tr><td></td><td>color with threshhold specimen &/or result info. displayed</td><td>yes</td><td>yes yes</td></tr><tr><td>LIS interface forma</td><td></td><td>proprietary, ASTM 1394 & 1238, HL7, IEEE MIB</td><td>proprietary, ASTM 1394 & 1238, HL7, IEEE MIB</td></tr><tr><td></td><td>erred on LIS interface</td><td>numeric & flag results, histograms & scatterplots, instrument to LIS;</td><td>numeric & flag results, histograms & scatterplots, instrument to LIS;</td></tr><tr><td></td><td></td><td>patient demographics, orders, LIS to instrument— broadcast</td><td>patient demographics, orders, LIS to instrument- broadcast</td></tr><tr><td></td><td></td><td>n/a</td><td>n/a</td></tr><tr><td>LOINC codes transr</td><td></td><td></td><td></td></tr></tbody></table>

How labs get LOINC codes for reagent kits Optional data mgmt. or collation system	n/a yes (Medicus, Hemalink)	n/a 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
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	- <u> </u>	—
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 autodilution capability, autorerun feature, auto validation	high-throughput cell counter with integrated reticulocyte methodology and slidemaker/stainer; fluorescent NRBC counting, auto rerun and reflex testing, auto validation

	5		CAP TODAY / 45
	High	volumo homotology ono	CAP TODAY / 45
	підп-	volume hematology ana	iyzers
		Sysmex America Inc.	Sysmex America Inc.
Part 9 of 11		Peggy Barranco	Peggy Barranco
		1 Nelson C. White Pkwy. Mundalain II. 60060	i neison G. winte Pkwy.
		Mundelein, IL 60060 800-379-7639	Mundelein, IL 60060 800-379-7639
See related article,	page 33	www.sysmex.com/usa	www.sysmex.com/usa
lame of instrument	t	Sysmex XE-2100	Sysmex XE-2100L
-	alled in U.S./outside U.S.	2000	2001
lo. units installed in	in U.S./outside U.S./list price	850/3,500/\$225,000	100/300/\$200,000
'est menu:	•Chartable	standard menu (left) plus: NRBC %&#, retic %&#*, RDW-SD, RDW-CV, IRF,</td><td>standard menu (left) plus: MPV, RDW-SD, RDW-CV, NRBC %&#, HPC#,</td></tr><tr><td>All instruments have:</td><td></td><td>Pit-O, HPC#, MPV, IG%, IG#</td><td>IG%, IG#</td></tr><tr><td>VBC, RBC, Hb, Hct, M ICH, MCHC, Plt, %&# n</td><td></td><td>none</td><td>none</td></tr><tr><td>nono, lymph, eos, baso</td><td></td><td>Plt clumps, RBC agglut, turbidity, WBC ABN scattergram, RBC ABN distrib.,</td><td>Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast, left shift,</td></tr><tr><td></td><td>. 1090</td><td>Pit ABN distrib., RBC lyse resistance, blasts, left shift, atyp. lymph., ABN</td><td>atyp. lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse resist-</td></tr><tr><td></td><td></td><td>lymph./blast., ret. ABN scattergram</td><td>ance, RBC agglut., turbidity</td></tr><tr><td>FDA-cleared tests b</td><td>out not clinically released</td><td>none</td><td>none</td></tr><tr><td>ests not available</td><td>but submitted for clearance</td><td>none</td><td>none</td></tr><tr><td>Tests in developme</td><td></td><td>RET-He, IPF</td><td>none</td></tr><tr><td>For research use on</td><td>•</td><td>P-LCR, PCT, PDW</td><td>P-LCR, PCT, PDW</td></tr><tr><td>lests unique to ana</td><td>alyzer</td><td>NRBC, HPC#, IG%, IG#, RET He, IPF</td><td>HPC#, NRBC, IG%, IG#</td></tr><tr><td>Differential method</td><td>(s) used</td><td>fluorescent flow cytometry, RF/DC detecting method</td><td>fluorescent flow cytometry, RF/DC detecting method</td></tr><tr><td>inearity:</td><td>•WBC count (10⁹/L)/RBC count (10¹²/L)</td><td>0–170/0–8</td><td>0–170/0–8</td></tr><tr><td></td><td>•Hemoglobin (g/dL)/platelet (10⁹/L)</td><td>0-25/0-5,000</td><td>0-25/0-5,000</td></tr><tr><td></td><td>•MCV (fL) or Hct (%)</td><td>0–60 (Hct)</td><td>0–60 (Hct)</td></tr><tr><td>Precision:</td><td>•WBC count/RBC count</td><td><3%/<1.5%</td><td>3%/1.5%</td></tr><tr><td></td><td>•Hb/platelet</td><td><1.0%/<4.0%</td><td>1.0%/4.0%</td></tr><tr><td></td><td>•MCV or Hct</td><td><1.0% (Hct)</td><td>1 .0% (Hct)</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td>-</td><td>ated diff. compared with manual diff.</td><td>neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79,</td><td>neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79,</td></tr><tr><td>(per NCCLS H-20A</td><td>A), regression equation</td><td>y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01;</td><td>y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01;</td></tr><tr><td>uterfering enheter</td><td></td><td>NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922</td><td>NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922</td></tr><tr><td>Interfering substand</td><td></td><td>cold agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs</td><td>cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs</td></tr><tr><td></td><td>•RBC</td><td>cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts, in vitro hemolysis</td><td>cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/µL)</td></tr><tr><td></td><td>•MCV or Hct</td><td>nemolysis Hct: cold agglutinins, leukocytosis (>100,000/µL), ABN red cell fragility,</td><td>Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis</td></tr><tr><td></td><td></td><td>spherocytosis</td><td>(>100,000/μL)</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td></td><td>•Platelet</td><td>pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts</td><td>pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts</td></tr><tr><td></td><td>•Hb</td><td>lipemia, ABN proteins in blood plasma, severe leukocytosis (>100,000/µL)</td><td>lipemia, ABN proteins, leukocytosis (>100,000/µL)</td></tr><tr><td>nterfering substand</td><td>ces: differential</td><td>lyse-resistant RBCs</td><td>lyse-resistant RBCs</td></tr><tr><td>Age- and sex-speci</td><td>ific reference ranges</td><td>yes</td><td>yes</td></tr><tr><td></td><td>nax. CBCs & diffs. per hr</td><td>150/150</td><td>150/150</td></tr><tr><td></td><td>rage frequency of calib.</td><td>twice per year by FSR</td><td>twice per year by FSR</td></tr><tr><td></td><td>ed/parameters calibrated</td><td>open, closed, capillary/WBC, RBC, Hb, Hct, Plt</td><td>open, closed, capillary/WBC, RBC, Hb, Hct, Plt</td></tr><tr><td>Frequency of blood</td><td></td><td>per CLIA requirements/not required</td><td>per CLIA requirements/not required</td></tr><tr><td>Min. specimen vol. Tube sampling supp</td><td>open/closed/sample dead vol. closed</td><td>130 μL/200 μL/1 mL ves</td><td>130 μL/200 μL/1 mL ves</td></tr><tr><td>lube sampling supp /eterinary capabilit</td><td></td><td>yes no</td><td>yes no</td></tr><tr><td>Microsample capabilit</td><td></td><td>yes</td><td>yes</td></tr><tr><td></td><td>pic slides automatically or flags</td><td>yes with Alpha or HST upgrade</td><td>yes with Alpha or HST upgrade</td></tr><tr><td>problems for slide</td><td>e prep</td><td></td><td>· · · · · · · · · · · · · · · · · · ·</td></tr><tr><td>f auto. slidemaker</td><td>available, No. installed/list price</td><td>>1,000</td><td>>1,000</td></tr><tr><td>rchives patient da</td><td>ita for later comparison</td><td>yes</td><td>yes</td></tr><tr><td>Patient-specific arc</td><td>chiving</td><td>yes</td><td>yes</td></tr><tr><td></td><td>accessible when system online</td><td>10,000 samples</td><td>10,000 samples</td></tr><tr><td></td><td>-numeric results-No. specimens</td><td>10,000 samples</td><td>10,000 samples</td></tr><tr><td>lemory capacity—</td><td>-histo/cytograms–No. specimens</td><td>10,000 samples</td><td>10,000 samples</td></tr><tr><td></td><td>nction with CBC data</td><td>yes</td><td>yes</td></tr><tr><td></td><td>images & CBC data printed as 1 report</td><td>yes</td><td>yes</td></tr><tr><td></td><td>be recalled and retransmitted</td><td>yes</td><td>yes</td></tr><tr><td></td><td>sorted for reprocessing or report transmission</td><td>yes</td><td>yes</td></tr><tr><td>Performs delta cheo</td><td></td><td>yes</td><td>yes</td></tr><tr><td></td><td>ults for followup, confirm. testing, or rerun</td><td>yes</td><td>yes</td></tr><tr><td></td><td>is for holding samples are defined by</td><td>user or vendor</td><td>user or vendor</td></tr><tr><td></td><td>e transmitted to LIS while others held</td><td>yes</td><td>yes</td></tr><tr><td></td><td>y: cell-specific color</td><td>yes</td><td>yes</td></tr><tr><td>• • •</td><td>color with threshhold pecimen &/or result info. displayed</td><td>yes yes</td><td>yes yes</td></tr><tr><td></td><td></td><td>,</td><td>,</td></tr><tr><td>LIS interface format</td><td>ts supported</td><td>RS-232C/TCP IP</td><td>RS-232C, TCP IP</td></tr><tr><td></td><td>erred on LIS interface</td><td>numeric & flag results, histograms & scatterplots, instrument to LIS;</td><td>numeric & flag results, histograms & scatterplots, instrument to LIS;</td></tr><tr><td></td><td></td><td>patient demographics, orders, LIS to instrument—broadcast; host query</td><td>patient demographics, orders, LIS to instrument—broadcast; host query</td></tr><tr><td></td><td></td><td>for patient demographics & orders</td><td>for patient demographics & orders</td></tr><tr><td>OINC codes transm</td><td>nitted with results</td><td>_</td><td>_</td></tr><tr><td>low labs get LOINC</td><td>C codes for reagent kits</td><td>n/a</td><td>n/a</td></tr><tr><td>-</td><td>t or collation system</td><td></td><td>ves proprietary</td></tr></tbody></table>	

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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 with autoready	daily: 15 min walkaway with autoready
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; HPC testing; online QC; remote diagnostics, IG enumeration, body fluid analysis; platelet linearity to 5 million, IPF, and RET He	remote diagnostics; online QC; random access; HPC testing; 150 CBC per hour throughput; discrete testing; NRBC enumeration, IG enumeration body fluid analysis

Part 10 of 11	Hig	gh-volume hematology a	analyzers
Part 10 of 11		, in the second s	anaryzers
Part 10 of 11		Sysmex America Inc.	Sysmex America Inc.
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		800-379-7639	800-379-7639
See related article, pag	ge 33	www.sysmex.com/usa	www.sysmex.com/usa
Name of instrument		Sysmex XE-2100D	Sysmex XE-Alpha N/HST-N
First year sold-installe	d in U.S./outside U.S.	2004/2004	2000
-	.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: RDW-SE, RDW-CV, IG%, IG#, NRBG%, N
All instruments have:			retic%&#, IRG, Plt-O, HPC#, MPV
WBC, RBC, Hb, Hct, MCV,		none	none
MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso</td><td></td><td></td><td></td></tr><tr><td>,,,</td><td>•Flags</td><td>Pit clumps, Pit ABN distribution, WBC ABN scattergram, blast, left shift, atyp. lymph., ABN lymph./blast, RBC ABN distribution, RBC lyse resistance,</td><td>Plt clumps, RBC agglut., turbidity, WBC ABN scattergram, RBC AB</td></tr><tr><td></td><td></td><td>RBC agglut., turbidity</td><td>Pit ABN distrib., RBC lyse resistance, blasts, left shift, atyp. lympl ABN lymph./blast, ret. ABN scattergram</td></tr><tr><td>FDA-cleared tests but</td><td>not clinically released</td><td>n/a</td><td>new release IPF & RET He</td></tr><tr><td></td><td>submitted for clearance</td><td>n/a</td><td>none</td></tr><tr><td>Tests in development</td><td></td><td>n/a</td><td>RET-He, IPF</td></tr><tr><td>For research use only</td><td></td><td>P-LCR, PCT, PDW</td><td>P-LCR, PCT, PDW</td></tr><tr><td>Tests unique to analyz</td><td>er</td><td>IG% & IG#</td><td>NRBC, HPC#, IG%, IG#</td></tr><tr><td>Differential method(s)</td><td>used</td><td>fluorescent flow cytometry</td><td>fluorescent flow cytometry, RF/DC detecting method</td></tr><tr><td>Linearity:</td><td>•WBC count (10⁹/L)/RBC count (10¹²/L)</td><td>0–170/0–8</td><td>0–170/0–8</td></tr><tr><td></td><td>•Hemoglobin (g/dL)/platelet (10⁹/L)</td><td>0-25/0-5,000</td><td>0-25/0-5,000</td></tr><tr><td>Precision:</td><td> MCV (fL) or Hct (%) WBC count/RBC count </td><td>0–60 (Hct) 3%/1,5%</td><td>0–60 (Hct) <3%/<1.5%</td></tr><tr><td>FIECISION.</td><td>•Hb/platelet</td><td>1.0%/4.0%</td><td><3%/<1.0% <1.0%/<4.0%</td></tr><tr><td></td><td>•MCV or Hct</td><td>1 .0% (Hct)</td><td><1.0% (Hct)</td></tr><tr><td>Accuracy of automater</td><td>d diff. compared with manual diff.</td><td>neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79,</td><td>neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono'</td></tr><tr><td>(per NCCLS H-20A), r</td><td>•</td><td>y=0.77x+1.88</math>; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01;</td><td>y=0.77x+1.88</math>; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x-</td></tr><tr><td>(For the second s</td><td></td><td>NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922</td><td>NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922</td></tr><tr><td>Interfering substances</td><td>:•WBC</td><td>cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs</td><td>cold agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RB</td></tr><tr><td></td><td>•RBC</td><td>cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/µL)</td><td>cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts</td></tr><tr><td></td><td></td><td></td><td>hemolysis</td></tr><tr><td></td><td>•MCV or Hct</td><td>Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/µL)</td><td>Hct: cold agglut., leukocytosis (>100,000/µL), ABN red cell fragilit spherocytosis</td></tr><tr><td></td><td>•Platelet</td><td>pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts</td><td>pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalo</td></tr><tr><td></td><td>•Hb</td><td>lipemia, ABN proteins, leukocytosis (>100,000/µL)</td><td>lipemia, ABN proteins in blood plasma, severe leukocytosis (>100</td></tr><tr><td>Interfering substances</td><td></td><td>lyse-resistant RBCs</td><td>lyse-resistant RBCs</td></tr><tr><td>Age- and sex-specific</td><td>reference ranges</td><td>yes</td><td>yes</td></tr><tr><td>Max. CBCs per hr/max</td><td>. CBCs & diffs. per hr</td><td>150/150</td><td>150/150 per analyzer on automation system</td></tr><tr><td>Recommended average</td><td></td><td>twice per year by FSR</td><td>twice per year by FSR</td></tr><tr><td></td><td>parameters calibrated</td><td>open, closed, capillary/WBC, RBC, Hb, Hct, Plt</td><td>open, closed, capillary/WBC, RBC, Hb, Hct, Plt</td></tr><tr><td>Frequency of blood/lat</td><td>ex controls en/closed/sample dead vol. closed</td><td>per CLIA requirements/not required 130 μL/200 μL/1 mL</td><td>per CLIA requirements/not required 130 μL/200 μL/1 mL</td></tr><tr><td>Tube sampling support</td><td>-</td><td>130 µL/200 µL/1 mL yes</td><td>130 µL/200 µL/1 mL yes</td></tr><tr><td>Veterinary capability</td><td></td><td>no</td><td>no</td></tr><tr><td>Microsample capability</td><td></td><td>yes</td><td>yes</td></tr><tr><td>Prepares microscopic problems for slide pr</td><td>slides automatically or flags</td><td>yes, with Alpha or HST upgrade</td><td>yes</td></tr><tr><td>•</td><td>ep ilable, No. installed/list price</td><td>>1,000/—</td><td>>1,000/\$250,000</td></tr><tr><td>Archives patient data f</td><td>or later comparison</td><td>yes</td><td>yes</td></tr><tr><td>Patient-specific archiv</td><td></td><td>yes</td><td>yes</td></tr><tr><td>Max. archived data acc</td><td>cessible when system online</td><td>10,000 samples</td><td>10,000 samples</td></tr><tr><td></td><td>meric results-No. specimens</td><td>10,000 samples</td><td>10,000</td></tr><tr><td></td><td>to/cytograms–No. specimens</td><td>10,000</td><td>10,000</td></tr><tr><td> Stored in conjuncti Histo/cytogram important </td><td></td><td>yes vec</td><td>yes ves</td></tr><tr><td></td><td>ages & CBC data printed as 1 report ecalled and retransmitted</td><td>yes yes</td><td>yes yes</td></tr><tr><td></td><td>ed for reprocessing or report transmission</td><td></td><td>yes</td></tr><tr><td>Performs delta checks</td><td></td><td>yes</td><td>yes</td></tr><tr><td></td><td>for followup, confirm. testing, or rerun</td><td>yes</td><td>yes</td></tr><tr><td>•</td><td>or holding samples are defined by</td><td>user or vendor</td><td>user or vendor</td></tr><tr><td></td><td>ansmitted to LIS while others held</td><td>yes</td><td>yes</td></tr><tr><td>Scattergram display: c</td><td></td><td>yes voc</td><td>yes</td></tr><tr><td>Histogram display: col</td><td>or with threshnold imen &/or result info. displayed</td><td>yes yes</td><td>yes yes</td></tr><tr><td>choice of desired spec</td><td></td><td></td><td></td></tr><tr><td>-</td><td>unnorted</td><td></td><td></td></tr><tr><td>LIS interface formats s</td><td></td><td>RS-232C, TCP IP numeric & flag results, histograms & scatterplots, instrument to LIS; patient</td><td>RS-232C, TCP IP numeric & flag results, histograms & scatterplots, instrument to l</td></tr><tr><td></td><td></td><td>numeric & flag results, histograms & scatterplots, instrument to LIS; patient</td><td>numeric & flag results, histograms & scatterplots, instrument to L</td></tr><tr><td>LIS interface formats s</td><td></td><td>,</td><td>RS-232C, TCP IP numeric & flag results, histograms & scatterplots, instrument to L demographics, orders, LIS to instrument—broadcast; host query t demographics & orders</td></tr></tbody></table>			

	demographics & orders	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,	enhanced QC, data archiving, data collation from multiple instruments,
	online QC	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 with autoready	daily: 15 min walkaway with autoready
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; platelet linearity—5 million	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

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EX HENTS	Πιξ	gh-volume hematology	analyzers
		Sysmex America Inc.	Sysmex America Inc.
Part 11 of 11		Peggy Barranco	Peggy Barranco
		1 Nelson C. White Pkwy. Mundelein, IL 60060	1 Nelson C. White Pkwy. Mundelein, IL 60060
		800-379-7639	800-379-7639
See related article,	e, page 33	www.sysmex.com/usa	www.sysmex.com/usa
Name of instrumer		Sysmex XT-2000i	Sysmex XT-1800i
	stalled in U.S./outside U.S. in U.S./outside U.S./list price	2002 400/3,500/\$145,000	2002 400/3,500/\$125,000
Test menu:	•Chartable	standard menu (left) plus: retic %&#, IRF, Plt-0, MPV, RDW-SD, RDW-CV	standard menu (left) plus: MPV, RDW-SD, RDW-CV
All instruments have WBC, RBC, Hb, Hct, I		none	none
MCH, MCHC, Pit, %&#</td><td></td><td></td><td>liole</td></tr><tr><td>mono, lymph, eos, basc</td><td>• • Flags</td><td>Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast imm. gran.,</td><td>Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast imm.</td></tr><tr><td></td><td></td><td>left shift, atyp lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse</td><td>left shift, atyp. lymph., ABN lymph./blasts, RBC ABN distribution, RE</td></tr><tr><td></td><td>hut not all significants and</td><td>resistance, RBC agglut., turbidity, ret ABN scattergram, NRBC</td><td>resistance, RBC agglut., turbidity, NRBC</td></tr><tr><td></td><td>but not clinically released e but submitted for clearance</td><td>none none</td><td>none none</td></tr><tr><td>Tests in developme</td><td></td><td>body fluids, immature gran. %&#</td><td>body fluids, immature gran. %&#</td></tr><tr><td>For research use o</td><td>only</td><td>IG%&#</td><td>IG%&#</td></tr><tr><td>Tests unique to an</td><td>alyzer</td><td>Pit-0</td><td>—</td></tr><tr><td>Differential method</td><td>.,</td><td>fluorescent flow cytometry</td><td>fluorescent flow cytometry</td></tr><tr><td>Linearity:</td><td>•WBC count (10⁹/L)/RBC count (10¹²/L)</td><td>0-310/0-8</td><td>0-310/0-8</td></tr><tr><td></td><td>Hemoglobin (g/dL)/platelet (10⁹/L) MCV (ft) or Het (%)</td><td>0-25/0-2,000</td><td>0-25/0-2,000</td></tr><tr><td>Precision:</td><td>•MCV (fL) or Hct (%) •WBC count/RBC count</td><td>0–60 (Hct) 3.0%/1.5%</td><td>0–60 (Hct) 3.0%/1.5%</td></tr><tr><td>1100131011.</td><td>•Hb/platelet</td><td>1.5%/4.0%</td><td>1.5%/4.0%</td></tr><tr><td></td><td>•MCV or Hct</td><td>1.5% (Hct)</td><td>1 .5% (Hct)</td></tr><tr><td>Accuracy of autom</td><td>nated diff. compared with manual diff.</td><td>neut% r=0.95, y=0.95x+3.38; lymph% r=0.96, y=0.85x+1.67; mono% r=0.90,</td><td>neut% r=0.95, y=0.95x+3.38; lymph% r=0.96, y=0.85x+1.67; mono% r=</td></tr><tr><td>-</td><td>)A), regression equation</td><td>y=11.37x+1.89; eos% r=0.94, y=0.87x+0.04; baso% r=0.76, y=0.48x+0.24</td><td>y=11.37x+1.89; eos% r=0.94, y=0.87x+0.04; baso% r=0.76, y=0.48x+0.</td></tr><tr><td>Interfering substan</td><td>nces:•WBC</td><td>cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs</td><td>cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs</td></tr><tr><td></td><td>•RBC</td><td>cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/µL)</td><td>cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,00</td></tr><tr><td></td><td>•MCV or Hct</td><td>Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis</td><td>Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis</td></tr><tr><td></td><td>-</td><td>(>100,000/μL)</td><td>(>100,000/µL)</td></tr><tr><td></td><td>•Platelet</td><td>pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts</td><td>pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalobla</td></tr><tr><td>Interfering substar</td><td>•Hb nces: differential</td><td>lipemia, ABN proteins, leukocytosis (>100,000/μL) lyse-resistant RBCs</td><td>lipemia, ABN proteins, leukocytosis (>100,000/µL) lyse-resistant RBCs</td></tr><tr><td>Age- and sex-spec</td><td>cific reference ranges</td><td>yes</td><td>yes</td></tr><tr><td>•</td><td>max. CBCs & diffs. per hr</td><td>80/80</td><td>80/80</td></tr><tr><td></td><td>erage frequency of calib.</td><td>every 6 months by FSR</td><td>every 6 months by FSR</td></tr><tr><td></td><td>ted/parameters calibrated</td><td>open, closed, capillary/WBC, RBC, Hb, Hct, Plt</td><td>open, closed, capillary/WBC, RBC, Hb, Hct, Plt</td></tr><tr><td>Frequency of blood</td><td>. open/closed/sample dead vol. closed</td><td>per CLIA requirements/not required 85 μL/150 μL/1 mL</td><td>per CLIA requirements/not required 85 μL/150 μL/1 mL</td></tr><tr><td>Tube sampling sup</td><td></td><td>yes</td><td>yes</td></tr><tr><td>Veterinary capabili</td><td></td><td>yes, XT-V product</td><td>yes, XT-V product</td></tr><tr><td>Microsample capa</td><td>-</td><td>yes</td><td>yes</td></tr><tr><td></td><td>opic slides automatically or flags</td><td>no</td><td>no</td></tr><tr><td>problems for slid If auto. slidemaker</td><td>de prep r available, No. installed/list price</td><td>-</td><td>_</td></tr><tr><td>Archives patient da</td><td>ata for later comparison</td><td>yes</td><td>yes</td></tr><tr><td>Patient-specific ar</td><td>rchiving</td><td>yes</td><td>yes</td></tr><tr><td></td><td>a accessible when system online</td><td>10,000 samples</td><td>10,000 samples</td></tr><tr><td></td><td>-numeric results-No. specimens</td><td>10,000 samples</td><td>10,000 samples</td></tr><tr><td></td><td>—histo/cytograms–No. specimens unction with CBC data</td><td>10,000 yes</td><td>10,000 yes</td></tr><tr><td></td><td>n images & CBC data printed as 1 report</td><td>yes</td><td>yes</td></tr><tr><td></td><td>be recalled and retransmitted</td><td>yes</td><td>yes</td></tr><tr><td>Saved data can be</td><td>sorted for reprocessing or report transmission</td><td></td><td>yes</td></tr><tr><td>Performs delta che</td><td></td><td>yes</td><td>yes</td></tr><tr><td></td><td>sults for followup, confirm. testing, or rerun</td><td>yes user er vender</td><td>yes user er vender</td></tr><tr><td></td><td>gs for holding samples are defined by be transmitted to LIS while others held</td><td>user or vendor</td><td>user or vendor</td></tr><tr><td></td><td>ay: cell-specific color</td><td>yes yes</td><td>yes yes</td></tr><tr><td></td><td>: color with threshhold</td><td>yes</td><td>yes</td></tr><tr><td>• • •</td><td>specimen &/or result info. displayed</td><td>yes</td><td>yes</td></tr><tr><td>LIS interface forma</td><td>ats supported</td><td>RS-232C, TCP IP, ASTM</td><td>RS-232C, TCP IP, ASTM</td></tr><tr><td></td><td>erred on LIS interface</td><td>numeric & flag results, histograms & scatterplots, instrument to LIS; patient</td><td>numeric & flag results, histograms & scatterplots, instrument to LIS</td></tr><tr><td></td><td></td><td>demographics, orders, LIS to instrument—broadcast; host query for patient</td><td>demographics, orders, LIS to instrument—broadcast; host query for</td></tr><tr><td></td><td></td><td>demographics & orders</td><td>demographics & orders</td></tr><tr><td></td><td>mitted with results</td><td></td><td></td></tr></tbody></table>			

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,	enhanced QC, data archiving, data collation from multiple instruments,
	online QC	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 with autoready	daily: 15 min walkaway with autoready
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; XT-V unit for use in toxicology & research	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