SURVEY OF INSTRUMENTS

Hematology analyzers

Aiming to ease lab labor, cost, TAT pressures

Anne Ford

The traditional military strategists' adage, "Know your enemy," is advice that laboratory equipment manufacturers have been following for a long time. The enemy being, in this case, the laboratory labor shortage trend, which Grant Howes, director of strategic marketing for Beckman Coulter's cellular analysis business group, describes as a "now familiar, but ever increasing" dynamic that will "only intensify." While knowing this particular enemy hasn't been enough to vanquish it entirely, manufacturers continue to introduce instruments designed to ease the labor shortage's effects on laboratories. Two of the vendors in this month's instrumentation survey, Beckman Coulter and Sysmex America, share their perspectives on this and other trends in the hematology analyzer marketplace.

Sysmex America, reports Ron Walczak, director of marketing communications and research, has just received FDA clearance for its XE-5000 hematology analyzer, which the company expected at CAP TODAY press time to be on the market by the end of the year and which will feature a body fluid specific mode. "This system will fit in very well with Sysmex's current hematology product portfolio, consisting of innovative fluorescent flow technology, high throughput, and highly reliable platforms," Walczak says. It's part of the company's strategy to "provide rapid, accurate clinical information to the clinician that requires little or no additional technical intervention. In other words, the lab wants correct results the first time so they can report them faster to the clinician." In addition, "high reliability, more clinically relevant information, and standardized testing platforms to meet the needs of laboratories of various volumes and quality results are all very important right now." And in the future? "Continued increased reliability and less hands-on instrument technology" will be key.

Beckman Coulter plans to launch a new hematology analyzer in 2008, which follows on the heels of the Coulter LH 780 hematology series, introduced in late 2006. Among that series' features: whole blood count linearity of 0–400,000 and platelet linearity of 0–3,000,000; automatically enumerated NRBCs; the ability to read even low-print-quality bar-code labels; an RDW-SD parameter; and the ability to obtain an exponentially weighted moving average of CBC, five-part differential, and NRBC, as well as reticulocyte parameters.

"When we look at the near-term future for hematology," Howes says, "workloads and pressures for shorter turnaround times will continue to increase, as will the pressure to lower costs. That's why Beckman Coulter's new products are being designed to provide the solutions labs can use to step up to this new level of challenges."

Finally, Howes' colleague Alan Burton, director of marketing for Beckman Coulter's cellular analysis business group, places great importance on the value of integrated platforms. "Many of our customers know the benefits of integrated platforms," he says, "and will be happy to know that the range of hematology, chemistry, immunoassay, molecular diagnostics, and flow cytometry platforms made by one manufacturer, as well as reagents, data management, and service, is a trend that promises to continue and grow—especially since this integration addresses so many of the productivity and cost control issues labs face."

CAP TODAY's survey of hematology analyzers includes systems not only from Beckman Coulter and Sysmex America but also from Abbott Hematology, Siemens Medical Solutions Diagnostics, and Horiba ABX Diagnostics. Vendors supplied the information listed on this and the following pages. Readers interested in a particular analyzer should confirm it has the stated features and capabilities. □

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Part 1 of 11		Abbott Hematology David Overcash 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com
Name of instrument		CELL-DYN Sapphire
First year installed in U.S./outside U.S./No. of units sold in 2006		2005/2005/618
No. units installed in U.S./outside U.S./list price		179/439/$250,000
Test menu:	•Chartable	standard menu (left) plus: MPV, RDW, retic %&#, IRF, NRBC %&#, CD61, CD3T %&#, CD4T %&#, CD8T %&#, 4/8
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso	•Laboratory	—
	•Flags	band, IG, blast, variant lymph, nvWBC, rstRBC, IR, Plt clmp, ASYM, FP, CD61 agg., clot detected during aspiration, short sample
FDA-cleared tests but not clinically released		none
Tests not available but submitted for clearance		none
Tests in development		body fluid assay, optical RBC morphology
For research use only		none
Tests unique to analyzer		CD61 for Plts, WVF, CD3/4, CD3/8 (immuno T-cell)
Differential method(s) used		optical scatter & 3-color fluorescence
Linearity:	•WBC count (10^9/L)/RBC count (10^{12}/L)	0.4–250.0 × 10^3 µL/ 0.22–7.50 × 10^6 µL
	•Hemoglobin (g/dL)/platelet (10^9/L)	1.0–24.8 g/dL (cyanide free)/11.0–2,000.0 × 10^3 µL
	•MCV (fL) or Hct (%)	37.0–179 fL (MCV)
Precision:	•WBC count/RBC count	≤2.7%/≤1.5%
	•Hb/platelet	≤1.0%/≤4.0%
	•MCV or Hct	≤1.0% (MCV)
Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation		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
Interfering substances:	•WBC	Plt clumps, neut aggregates, Hb C crystals, lyse-resist. RBCs, cryoglob., cryofibr., frag. WBC, nRBC
	•RBC	autoagg., cold agg., elevated WBC, giant Plts, hemolysis, sm WBC
	•MCV or Hct	MCV: autoagg., cold agg., elevated WBC, giant Plt, hemolysis, hyperglycemia
	•Platelet	auto & cold agg., cryoglob., cryofibrin., giant Plt, micro RBC, Plt clumps, RBC frag., WBC frag., Plt satellitism
	•Hb	lipids>700 mg/dL, WBCs>250 × 10^9/L, bilirubin>33 mg/dL, Hb crystals
Interfering substances: differential		see WBC
Age- and sex-specific reference ranges		yes
Max. CBCs per hr/max. CBCs & diffs. per hr		106/106
Recommended average frequency of calib.		6 months verification
•Modes calibrated/parameters calibrated		open-closed single procedure/WBC, RBC, Hb, Plt, MPV
Frequency of blood/latex controls		per regulatory requirement/n/a
Min. specimen vol. open/closed/sample dead vol. closed		117 µL/117 mL/0.5 mL, 0.3 mL for 10.25 × 64 mm tubes
Tube sampling supported		yes (11.5–13 × 65-75 mm, 10.25 × 64 mm, 8.5 × 66 mm [Sarstedt Monovette])
Veterinary capability		no
Microsample capability		yes
Prepares microscopic slides automatically or flags problems for slide prep		yes (flags only)
If auto. slidemaker available, No. installed/list price		n/a/$125,000
Archives patient data for later comparison		yes
Patient-specific archiving		yes
Max. archived data accessible when system online		10,000 results
Memory capacity—numeric results–No. specimens		10,000 results
Memory capacity—histo/cytograms–No. specimens		10,000 results
•Stored in conjunction with CBC data		yes
•Histo/cytogram images & CBC data printed as 1 report		yes
Saved results can be recalled and retransmitted		yes
Saved data can be sorted for reprocessing or report transmission		yes
Performs delta checks		yes
Tags and holds results for followup, confirm. testing, or rerun		yes
Parameters for flags for holding samples are defined by		user or vendor
Some results can be transmitted to LIS while others held		yes
Scattergram display: cell-specific color		yes
Histogram display: color with threshold		yes
Choice of desired specimen &/or result info. displayed		yes
LIS interface formats supported		ASTM 1394
Information transferred on LIS interface		numeric & flag results, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics & orders
LOINC codes transmitted with results		no
How labs get LOINC codes for reagent kits		n/a
Optional data mgmt. or collation system		yes, multiple
•Software features		enhanced QC, data archiving, data collation from multiple instruments, remote viewing
Interface avail. or planned to auto. specimen-handling system		Accelerator APS
Bar-code symbologies read on tube		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: 30 sec; weekly: 10 min; monthly: 5 min
Onboard maintenance records		yes
Time from communication of problem to engineer on site		—
Onboard diagnostics/limited to software problems		yes/no
Mftr. can perform diagnostics via modem		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

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