New applications, middleware, and more for hematology analyzers

Brendan Dabkowski

Sysmex WAM Management Reports module and, soon, the WAM Select. Abbott's updated Cell-Dyn Sapphire. The DxH Slidemaker Stainer from Beckman Coulter. Just some of what's new in hematology as 2011 comes to a close and the new year gets underway.

With core labs, data management, workflow, and more in mind, hematology laboratories know what they need and companies do, too. "The market is looking for solutions that impact the entire testing process to achieve efficiency, address technical labor shortages, and reduce manual differential reviews and total cost of testing," says Bill Bailey, marketing manager, hematology, Abbott Diagnostics.

To this end, says Bailey, Abbott continues to refine its Cell-Dyn Sapphire hematology analyzer and in November released an updated version of Sapphire, a system for challenging samples in high-volume laboratories. Still available, and featured with Sapphire in this month's hematology analyzers product guide, are Abbott's Cell-Dyn Ruby, to which the company added a new service pack with updated software and hardware; Cell-Dyn Emerald; and Cell-Dyn 3700. Improvements to the company's Cell-Dyn systems, along with updates to its AbbottLink remote diagnostics product, have further enhanced instrument reliability and customer satisfaction, Bailey adds.

Sysmex America will soon release the Work Area Manager (WAM) Select middleware solution for its X series automated hematology analyzers and SP-1000i slidemaker/stainer, says Sysmex's director of marketing, Alan Burton. WAM Select, which incorporates decision support software, provides an autovalidation interface to laboratory information systems and is designed for small to mid-size labs. Other products intended to enhance the company's hematology systems are the WAM Management Reports module, which provides key metrics such as turnaround times, test costs, result validation rates, and rules and result statistics; e-Supply software solution, which streamlines reagent ordering, manages customers' on-site inventory, and reduces costs and errors associated with expedited reagent shipping; and Sysmex Managed Calibration, an evidence-based calibration program that provides six-month calibration verification and as-needed calibration adjustments to X series analyzers.

New to the guide this year is CellaVision, which offers its DM96 and DM1200 digital cell morphology systems. Both systems, says vice president of sales and business development Ron Hagner, automatically locate cells on stained slides, and, using artificial neural networks, classify the white blood cells and red blood cell morphology for the operator to verify. In September, CellaVision received FDA 510(k) clearance for a body fluid application on the DM1200. Users of the application can classify nucleated cells into seven classes and share cell images and regions of interest with colleagues. The application also provides a digital scan of a sample area in 10× and 50× magnifications. Next year, says Hagner, the company will launch its Image Capture System for small labs that perform one to 15 differentials per day. The system will be a part of CellaNet, a networking solution that allows hospitals to share cell images with related labs, pathologists, and clinicians in any location.

Beckman Coulter launched last month its UniCel DxH Slidemaker Stainer analysis system, a complement to the company's DxH 800 hematology system, which automates slide making and staining, says director of hematology and hemostasis strategic marketing Ronald Hebert. Response to the DxH 800, introduced in December 2008, has been "overwhelming," says Hebert, who notes that the company has sold nearly 1,000 of the instruments. The company's HematoFlow cellular analysis solution with CytoDiff, a new product available only in Europe, combines hematology and flow cytometry with auto-gating software to characterize WBC populations.

Finally, though not yet in the product guide, the Bloodhound integrated hematology system has been getting some buzz since its debut in July at the American Association for Clinical Chemistry's annual meeting. The morphology-based analyzer consists of a digital image-based cell locator, classifier, and counter and is designed to automatically perform a CBC, five-part differential, and reticulocyte count using digital imaging. The system's viewing station, consisting of a large-screen iMac computer, allows users to manipulate images of blood cells, such as organizing cells into rows, for the purpose of studying, interpreting, or classifying the cells. "You can zoom them up; you can reclassify things; you can make interpretations a little more efficiently because you can put the cells side by side," says James Linder, MD, chief medical officer, Constitution Medical, which is developing the Bloodhound system. The company will conduct clinical trials early next year and plans to submit the results to the FDA shortly thereafter.

CAP TODAY's hematology analyzers product guide includes systems from the aforementioned companies and from Horiba Medical and Siemens Healthcare Diagnostics. Companies supplied the information listed. Readers interested in a particular system should confirm that it has the stated features and capabilities.

Brendan Dabkowski is CAP TODAY *associate editor.*

Part 1 of 10	**Abbott Hematology** **Rick Gooch** rick.gooch@abbott.com **5440 Patrick Henry Drive** **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 2010	**2005/2005/—**
No. units installed in U.S./Outside U.S./List price	**>175/>750/$250,000**
Test menu: • Chartable *(standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso)*:	**standard menu (left) plus: MPV, RDW, retic %&#, IRF, NRBC %&#, CD61, CD3T %&#, CD4T %&#, CD8T %&#, 4/8**
• Laboratory	**—**
• Flags	**band, IG, blast, variant lymph, nvWBC, rstRBC, IR, PLT clmp, ASYM, FP, CD61 agglutination, clot detected during aspiration, short sample**
FDA-cleared tests not clinically released	**—**
Tests not available but submitted for 510(k) clearance	**—**
Tests in development	**—**
Tests for research use only	**—**
Tests unique to analyzer	**CD61 for PLTs, CD3/4, CD3/8 (immuno T-cell)**
Differential method(s) used	**MAPSS (Multi-Angle Polarized Scatter Separation) and three-color fluorescence**
Linearity: • WBC count/RBC count	**0.4–250.0 × 10^3 µL/ 0.22–7.50 × 10^6 µL**
• Hemoglobin/platelet	**1.0–24.8 g/dL/11.0–2,000.0 × 10^3 µL**
• MCV (fL) or Hct (%)	**37.0–179 fL (MCV)**
Precision: • WBC count/RBC count	**≤2.7 percent/≤1.5 percent**
• Hemoglobin/platelet	**≤1.0 percent/≤4.0 percent**
• MCV or Hct	**≤1.0 percent (MCV)**
Accuracy of automated differential compared with manual differential (per CLSI H-20A)	**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, neutrophil aggregates, HbC crystals, lyse-resistant RBCs, cryoglobulin, cryofibrinogen, fragmented WBC, NRBC**
• RBC	**autoagglutination, cold agglutinins, elevated WBC, giant PLTs, hemolysis, small WBC**
• MCV or Hct	**autoagglutination, cold agglutinins, elevated WBC, giant PLT, hemolysis, hyperglycemia**
• Platelet	**auto and cold agglutination, cryoglobulin, cryofibrinogen, giant PLT, micro RBC, PLT clumps, RBC fragments, WBC fragments, PLT satellitism**
• Hemoglobin	**lipids >700 mg/dL, WBCs >250 × 10^9/L, bilirubin >33 mg/dL, HbC crystals**
Interfering substances: differential	**see WBC**
Maximum CBCs per hour/Maximum CBCs and differentials per hour	**105/105**
Minimum specimen volume open/Closed/Sample dead volume closed	**120 µL/120 µL/0.5 mL, 0.3 mL for 10.25 × 64 mm tubes**
Microsample capability	**yes**
Prepares microscope slides automatically or flags problems for slide prep	**no**
No. of automatic slidemakers available/List price	**—/$125,000**
Archives patient data/Previous patient results included with recent results	**yes/yes**
Maximum archived data accessible when system online	**10,000 results**
No. specimens for which numeric results saved in memory at once	**10,000 results**
No. specimens for which histo/cytogram results saved in memory at once	**10,000 results**
Performs delta checks	**yes**
Tags and holds results for followup, confirmatory testing, or rerun	**yes**
Parameters for flags for holding samples defined by user or vendor	**user or vendor**
Scattergram display: cell-specific color	**yes**
Histogram display: color with thresholds	**yes**
User interface can display choice of specimen/result information	**yes**
LIS interface formats supported	**ASTM 1394**
Information transferred on LIS interface	**numeric and flag results, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders**
LOINC codes transmitted with all results	**no**
Interface available or planned to automated specimen-handling system	**none**
Bar-code symbologies read on specimen tube	**Codabar, codes 39 and 128, Interleaved 2 of 5**
Accommodates bar-code placement per CLSI standard Auto2A	**yes**
Time required for maintenance by lab personnel	**daily: 30 seconds; weekly: 10 minutes; monthly: 5 minutes**
Onboard diagnostics for troubleshooting/Limited to software problems	**yes/no**
Manufacturer can perform diagnostics via modem	**yes**
Distinguishing features (supplied by company)	**four optical and three fluorescent detectors provide multiple scatterplot analysis; 2-D optical platelets prevent interferences; fluorescent analysis of reticulocytes, NRBCs, and three-color monoclonal analysis on routine hematology analyzer; OpenFlow MAb test selections**
Note: a dash in lieu of an answer means company did not answer question or question is not applicable	**please see the CELL-DYN Sapphire operator's manual for product labeling, including warnings, limitations, and precautions*

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

Survey editor: Raymond D. Aller, MD

Hematology analyzers

Part 2 of 10	**Abbott Hematology** **Rick Gooch** rick.gooch@abbott.com **5440 Patrick Henry Drive** **Santa Clara, CA 95054** **800-933-5535** www.abbottdiagnostics.com	**Abbott Hematology** **Karen Busch** karen.busch@abbott.com **5440 Patrick Henry Drive** **Santa Clara, CA 95054** **800-933-5535** www.abbottdiagnostics.com	**Abbott Hematology** **Rick Gooch** rick.gooch@abbott.com **5440 Patrick Henry Drive** **Santa Clara, CA 95054** **800-933-5535** www.abbottdiagnostics.com
Name of instrument	**CELL-DYN Ruby***	**CELL-DYN Emerald***	**CELL-DYN 3700***
First year installed in U.S./Outside U.S./No. of units sold in 2010	**2006/2006/—**	**2009/2008/0**	**1999/1999/—**
No. units installed in U.S./Outside U.S./List price	**>450/>1,500/$185,000**	**>950/>1,600/$30,000**	**>200/>1,500/$180,000 SL Model, $140,000 CS model**
Test menu: • Chartable *(standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso)*:	standard menu (left) plus: MPV, RDW, retic #& percent	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, lymph percent&#, gran percent&#, mid percent&#, RDW, MPV	standard menu (left) plus: RDW, MPV, retic #&%, IRF
• Laboratory	—	—	—
• Flags	NRBC, FWBC, NWBC, RRBC, band, IG, blast, variant lymph, RBC morph., DFLT, MCHC, LRI, URI, LURI, ATYPDEP, high/low interp. message, WBC	dispersional data alerts, suspect measurand flags and count invalidation flags	suspect populations, band, blast, variant lymph, IG, NRBC, RRBC, NWBC, LRI, URI, LURI, RBC morphology, FWBC, high/low interpretation message, WBC
FDA-cleared tests not clinically released	—	—	—
Tests not available but submitted for 510(k) clearance	—	—	—
Tests in development	—	—	—
Tests for research use only	—	—	—
Tests unique to analyzer	atypical depolarization flag	none	IRF, veterinary capabilities**
Differential method(s) used	MAPSS (Multi-Angle Polarized Scatter Separation)	impedance counting	MAPSS (Multi-Angle Polarized Scatter Separation)
Linearity: • WBC count/RBC count	$0.02–246 \times 10^3$/µL/$0.00–7.50 \times 10^6$/µL	0.4–96.1 K/µL/0.22–7.61 M/µL	0–250 K/µL/0–8 M/µL
• Hemoglobin/platelet	$0.00–25.0$ g/dL/$0.00–3,000 \times 10^3$/µL	3.3–24.6 g/dL/9–1,375 K/uL	0–24 g/dL/0–2,000 K/µL
• MCV (fL) or Hct (%)	58–139 fL: (MCV)	5.3–75.6 percent (Hct)/48.8–115 fL (MCV)	50–200 fL (MCV)
Precision: • WBC count/RBC count	2.4 percent/1.8 percent	3.5 percent (95 percent confidence limit)/2.0 percent (95 percent confidence limit)	≤2.5 percent/≤1.5 percent
• Hemoglobin/platelet	1.4 percent/3.8 percent	2.1 percent (95 percent confidence limit)/6.1 percent (95 percent confidence limit)	≤1.2 percent/≤5.0 percent
• MCV or Hct	0.8 percent (MCV)	1.7 percent Hct (95 percent confidence limit)/0.8 percent MCV (95 percent confidence limit)	≤1.0 percent (MCV)
Accuracy of automated differential compared with manual differential (per CLSI H-20A)	neut percent r=0.983, slope=0.97, y=-1.98; lymph r=0.921, slope=0.95, y=0.94; mono r=0.711, slope=1.10, y=1.93; eos r=0.952, slope=1.04, y=0.01; baso r=0.146, slope=0.18, y=1.22	—	neut #&%: ≥0.95, lymph #&%: ≥0.94, mono #&%: ≥0.86, eos #&%: ≥0.84, baso #&%: ≥0.73
Interfering substances: • WBC	fragile WBC, neutrophil aggregates, lytic-resistant RBC, NRBC, PLT clumps, cryofibrinogen, cryoglobulin	cryoglobulin, cryofibrinogen, heparin, monoclonal proteins, nucleated red cells, platelet clumping, unlysed red cells, clotting, smudge cells, uremia plus immunosuppressants	NRBCs (WIC only), lytic-resistant RBCs, PLT clumps, cryoglobulin and cryofibrinogen, fragile WBCs
• RBC	elevated WBC, increased numbers of giant PLT, autoagglutination, in vitro hemolysis	cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/µL), autoagglutination, clotting, hemolysis (in vitro), microcytic red cells	increased number giant PLTs, autoagglutination, in vitro hemolysis
• MCV or Hct	MCV: elevated WBC, hyperglycemia, in vitro hemolysis, increased number of giant PLTs	cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/µL) hyperglycemia (>600 mg/dL), autoagglutination, clotting, hemolysis (in vitro), microcytic red cells, reduced red cell deformability, swollen red cells	MCV: elevated WBC count, increased number giant PLTs, hyperglycemia, in vitro hemolysis
• Platelet	WBC fragments, in vitro hemolysis, microcytic RBC, cryofibrinogen, cryoglobulins, PLT clumping, increased number of giant PLT	cryoglobulin, cryofibrinogen, hemolysis (in vivo and in vitro), microcytic red cells, red cell inclusions, white cell fragments, clotting, giant platelets, heparin, platelet clumping, platelet satellitosis	WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulin, PLT clumps, increased number giant PLTs
• Hemoglobin	elevated WBC, increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lytic-resistant RBC	carboxyhemoglobin (>10 percent), cryoglobulin, cryofibrinogen, hemolysis (in vivo) heparin, high white cell count (>50,000 K/µL), hyperbilirubinemia, lipemia, monoclonal proteins	increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs
Interfering substances: differential	fragile WBC, neutrophil aggregates, lytic-resistant RBC, NRBC, PLT clumps, cryofibrinogen, cryoglobulin, paraproteins	platelet aggregates, NRBCs, giant platelets, cryoglobulins, incomplete lysis of RBC, small lymphocytes, fibrin clots, shift in WBC cell distribution due to EDTA anticoagulant equilibration	see WBC
Maximum CBCs per hour/Maximum CBCs and differentials per hour	84/84	60/60	90/90
Minimum specimen volume open/Closed/Sample dead volume closed	150 µL/230 µL/1.2 mL	9.8 µL/—/—	130 µL/355 µL/1.0 mL
Microsample capability	no	no	yes
Prepares microscope slides automatically or flags problems for slide prep	no	no	yes (flags only)
No. of automatic slidemakers available/List price	—/$125,000	—	—/$125,000
Archives patient data/Previous patient results incl. with recent results	yes/yes	yes/no	yes/yes
Maximum archived data accessible when system online	10,000 results	60,000 on USB and 1,500 results on internal memory	10,000 results
No. specimens for which numeric results saved in memory at once	10,000 results	60,000 on USB and 1,500 results on internal memory	10,000 results
No. specimens for which histo/cytogram results saved in memory at once	10,000 results	60,000 on USB and 1,500 results on internal memory	10,000 results
Performs delta checks	no	no	no
Tags and holds results for followup, confirmatory testing, or rerun	yes	no	yes
Parameters for flags for holding samples defined by user or vendor	user or vendor	no	user or vendor
Scattergram display: cell-specific color	yes	no	yes
Histogram display: color with thresholds	yes	no	yes
User interface can display choice of specimen/result information	yes	yes	yes
LIS interface formats supported	LIS1/LIS2 CLSI	proprietary (instrument or vendor specific)	proprietary
Information transferred on LIS interface	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders	numeric and flag results, instrument to LIS	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast
LOINC codes transmitted with all results	no	no	no
Interface available or planned to automated specimen-handling system	—	—	—
Bar-code symbologies read on specimen tube	Codabar, codes 39 and 128, Interleaved 2 of 5, ISBT	Codabar, codes 39 and 128, Interleaved 2 of 5, Chinese post, code 93, EAN8, EAN13, EAN128, IATA, industrial 2 of 5, Italian pharmaceutical, matrix 2 of 5, MSI/Plessey, UK/Plessey, Telepen, TriOptic, S-Code, UPC A, UPC E	Codabar, codes 39 and 128, interleaved 2 of 5
Accommodates bar-code placement per CLSI standard Auto2A	yes	yes	yes
Time required for maintenance by lab personnel	daily: 30 seconds; weekly: 5 minutes; monthly: 10 minutes	daily: 3 minutes; monthly: 5 minutes; bi-annually: 10 minutes	daily: 30 seconds; bi-weekly: 5 minutes; monthly: 10 minutes
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	no/no	yes/no
Manufacturer can perform diagnostics via modem	yes	no	—
Distinguishing features (supplied by company)	touch-sensitive screen, all optical technology; onboard maintenance videos; lyse-resistant RBC mode; rules-based result annotations	small: sample size, reagent volumes used, and physical size; reliable: system averages one service call per year; easy to use: system has touchscreen software with intuitive icons and minimal layers	MAPSS cell-by-cell analysis; reticulocyte with reportable IRF (immature reticulocyte fraction); up to 60 different animal types can be configured for analysis
Note: a dash in lieu of an answer means company did not answer question or question is not applicable	*please see the CELL-DYN Ruby operator's manual for product labeling, including warnings, limitations, and precautions	*please see the CELL-DYN Emerald operator's manual for product labeling, including warnings, limitations, and precautions	*please see the CELL-DYN 3700 operator's manual for product labeling, including warnings, limitations, and precautions **veterinary applications for medical devices are not currently subject to premarket regulation by FDA

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Hematology analyzers

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	Beckman Coulter Hamid Erfanian herfanian@beckman.com 250 South Kraemer Blvd Brea, CA 92821 305-380-3060 www.beckmancoulter.com	Beckman Coulter Hamid Erfanian herfanian@beckman.com 250 South Kraemer Blvd Brea, CA 92821 305-380-3060 www.beckmancoulter.com	Beckman Coulter Hamid Erfanian herfanian@beckman.com 250 South Kraemer Blvd Brea, CA 92821 305-380-3060 www.beckmancoulter.com
Name of instrument	UniCel DxH 800	LH 1500 Hematology Automation Series	LH 780/LH 785
First year installed in U.S./Outside U.S./No. of units sold in 2010	2008/2008/493 (Sept. 2011 YTD)	2002/2003/15 (Sept. 2011 YTD)	2006/2007/170 (Sept. 2011 YTD)
No. units installed in U.S./Outside U.S./List price	540/371/$229,000	>65/25/varies	629/595/LH 780: $214,500
Test menu: • Chartable *(standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso)*:	standard menu (left) plus: RDW-CV, RDW-SD, MPV, retic#, retic%, IRF, MRV, NRBC# and %, body fluids-total nucleated count, and RBC count for synovial, serous, and CSF fluids	standard menu (left) plus: RDW, MPV, retic %&#, IRF, graded RBC morph., NRBC %&#, TNC & RBC on CSF, synovial, and serous fluids	standard menu (left) plus: RDW, RDW-SD, MPV, retic %&#, IRF, MRV, graded RBC morph., NRBC %&#, TNC and RBC on CSF, synovial, and serous fluids
• Laboratory	—	—	—
• Flags	definitive, suspect and system messages, user-definable extended decision rules, ISLH consensus rules, user-definable differential sensitivity	user-definable age-, gender-, and/or location-based reference intervals; action and critical limits; user-definable RBC morphology; user-selectable sensitivity for differential, abnormal population suspect messages	user-definable age-, gender-, and/or location-based reference intervals; action and critical limits, user-definable RBC morphology; user-definable sensitivity for differential abnormal populations, suspect and definitive messages
FDA-cleared tests not clinically released	—	—	—
Tests not available but submitted for 510(k) clearance	—	—	—
Tests in development	—	—	—
Tests for research use only	high light scatter reticulocytes (HLR% and HLR#), low hemoglobin density (LHD), microcytic anemia factor (MAF), mean sphered cell volume (MSCV), plateletcrit (PCT), platelet distribution width (PDW), reticulocyte distribution width (RDWR-CV and RDWR-SD), red cell size factor (RSF), cell population data	MSCV, HLR %&#, PDW, PCT, WBC research population data (RPD) LH 780: MAF, RSF, RDWR-SD, RDWR-CV	RSF, MAF, MSCV, HLR %&#, RDWR-CV, RDWR-SD, PDW, PCT, WBC research population data (RPD)
Tests unique to analyzer	research parameters	IVD: NRBC, body fluids; RUO: MSCV, WBC RPD	IVD: NRBC, body fluids, RDW-SD; RUO: MSCV, RSF, MAF, WBC RPD
Differential method(s) used	flow cytometric digital analysis using volume, conductivity, and five angles of light scatter, digital signal processing, advanced algorithm applications, high-definition cellular resoluton, DataFusion	Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate, and AccuFlex technologies	Coulter's 3-D VCS biophysical flow cytometry with Intellikinetics, AccuGate, and AccuFlex technologies
Linearity: • WBC count/RBC count	0–400/0–8.5	0–400/0–8.0	0–400/0–8.0
• Hemoglobin/platelet	0–25.5/0–3,000	0–25/0–3,000	0–25/0–3,000
• MCV (fL) or Hct (%)	50–150 (MCV)	50–200 (MCV)	—
Precision: • WBC count/RBC count	≤3.0 percent/≤1.5 percent	<1.7 percent/<0.8 percent	≤1.7 percent/≤0.8 percent
• Hemoglobin/platelet	≤1.5 percent/ ≤3.5 percent	<0.8 percent/<3.3 percent	≤0.8 percent/≤3.3 percent
• MCV or Hct	≤1.0 percent	<0.8 percent (MCV)	≤0.8 percent (MCV)
Accuracy of automated differential compared with manual differential (per CLSI H-20A)	NE = ±2.0; LY, MO = ±3.0; EO,BA = ±1.0 (or 10% percent, whichever is greater)	lymph% = ±3.0%, —; neut% = ±3.0%, —; mono% = ±2.0%, eos% = ±1.0%, baso% = ±1.0%	lymph% = ±3.0%, neut% = ±2.0%, mono% = ±3.0%, eos% = ±1.0%, baso% = ±1.0%
Interfering substances: • WBC	precipitated elevated proteins, cryoglobulin, fragmented white cells, agglutinated white cells, lyse-resistant red cells, giant platelets, platelet clumps, unlysed particles >35 fL in size	unusual RBC abnormalities that resist lysing, NRBC, fragmented WBC, unlysed particle >35 fL, giant PLT, PLT clumps	unusual RBC abnormalities that resist lysing, NRBC, fragmented WBC, unlysed particle >35 fL, giant PLT, PLT clumps
• RBC	very high WBC count, high concentration of very large platelets, autoagglutination	very high WBC, high concentration large PLT, autoagglutinins	very high WBC, high concentration large PLT, autoagglutinins
• MCV or Hct	very high WBC count, high concentration of very large platelets, autoagglutination	very high WBC, high concentration large PLT, autoagglutinins	very high WBC, high concentration large PLT, autoagglutinins (MCV)
• Platelet	platelet clumps, white cell fragments, very small red cells, red cell fragments, giant platelets, electric noise	very small RBCs and WBC fragments may interfere	very small RBCs and WBC fragments
• Hemoglobin	severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs
Interfering substances: differential	elevated triglycerides, precipitated elevated proteins	high triglycerides may affect lysing	high triglycerides may affect lysing
Maximum CBCs per hour/Maximum CBCs and differentials per hour	>100 per hour/>100 per hour	110 per analyzer on automation system/110 per analyzer on automation system	110/110; 105/100 with SMS
Minimum specimen volume open/Closed/Sample dead volume closed	165 µL/165 µL/300–400 µL	200 µL/300 µL, 550 µL with slidemaker/1.0 mL	200 µL/300 µL (550 µL with slidemaker)/1.0 mL
Microsample capability	yes	yes	yes
Prepares microscope slides automatically or flags problems for slide prep	yes	yes	yes
No. of automatic slidemakers available/List price	—/DxH SMS $165,000	>850 (U.S.)/$110,000	>500/$110,000
Archives patient data/Previous patient results incl. with recent results	yes/yes	yes/yes	yes/yes
Maximum archived data accessible when system online	40,000 standalone	20,000 samples per instrument	20,000 samples
No. specimens for which numeric results saved in memory at once	40,000 standalone	20,000 samples per instrument	20,000 samples
No. specimens for which histo/cytogram results saved in memory at once	40,000	20,000 samples per instrument	20,000 samples
Performs delta checks	yes	yes	yes
Tags and holds results for followup, confirmatory testing, or rerun	yes	yes	yes
Parameters for flags for holding samples defined by user or vendor	yes	user or vendor	user or vendor
Scattergram display: cell-specific color	yes	yes	yes
Histogram display: color with thresholds	yes	yes	yes
User interface can display choice of specimen/result information	yes	yes	yes
LIS interface formats supported	CLSI LIS1-A	—	proprietary
Information transferred on LIS interface	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders (available with release of workcell)	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast
LOINC codes transmitted with all results	yes	no	no
Interface available or planned to automated specimen-handling system	Beckman Coulter	Beckman Coulter	Beckman Coulter
Bar-code symbologies read on specimen tube	Codabar, codes 39 and 128, interleaved 2 of 5, NW7	Codabar, codes 39 and 128, Interleaved 2 of 5, NW7	Codabar, codes 39 and 128, Interleaved 2 of 5, NW7
Accommodates bar-code placement per CLSI standard Auto2A	yes	yes	yes
Time required for maintenance by lab personnel	no routine maintenance, all maintenance procedures are on as-needed basis	daily, weekly, monthly, and as needed maintenance procedures, however time varies by automation line	no routine maintenance; only as needed
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	yes/no
Manufacturer can perform diagnostics via modem	yes	yes	yes
Distinguishing features (supplied by company)	integrated automation w/auto repeat/reflex testing based on extended onboard user-defined decision rules; single aspiration pathway negates mode-to-mode comparisons; flow cytometric digital morphology w/five angles of light scatter; separate channel for WBC, NRBC, and reticulocyte analysis; digital signal processing, DataFusion; future scalability	system automatically loads and unloads cassettes, performs reflex and repeat testing, sorts tubes for off-line tests, stores tubes with availability for retrieval for any test type; multiple configurations available; RUO: WBC research population data	extensive onboard user-defined decision support; extended linearity for WBC and PLT using AccuCount technology; enumeration of NRBCs with every differential; random access/automation ready; integrated slidemaker/slidestainer options; proservice; electronic IQAP; expanded QC module; RUO: WBC research population data

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Hematology analyzers

Part 4 of 10	Beckman Coulter **Hamid Erfanian** herfanian@beckman.com 250 South Kraemer Boulevard Brea, CA 92821 305-380-3060 www.beckmancoulter.com	Beckman Coulter **Hamid Erfanian** herfanian@beckman.com 250 South Kraemer Boulevard Brea, CA 92821 305-380-3060 www.beckmancoulter.com	Beckman Coulter **Hamid Erfanian** herfanian@beckman.com 250 South Kraemer Boulevard Brea, CA 92821 305-380-3060 www.beckmancoulter.com
Name of instrument	Coulter LH 750	Coulter LH 500	Coulter HmX
First year installed in U.S./Outside U.S./No. of units sold in 2010	2001/2001/261 (Sept. 2011 YTD)	2003/2003/198 (Sept. 2011 YTD)	1999 HmX AL/—/209 (Sept. 2011 YTD)
No. units installed in U.S./Outside U.S./List price	2,065/1,473/$195,000	1,360/956/$145,000	>1,232/>1,213/$135,000
Test menu: • Chartable *(standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso)*:	standard menu (left) plus: RDW, MPV, retic #&%, IRF, MRV, graded RBC morph., NRBC %&#, TNC & RBC on CSF, synovial, and serous fluids	standard menu (left) plus: retic #, retic %, MRV, IRF, RDW, MPV	standard menu (left) plus: RDW, MPV, retic #&%, graded RBC morph., IRF, MRV
• Laboratory	—	—	—
• Flags	user-definable age-, gender-, and/or location-based reference intervals; action and critical limits; user-definable RBC morphology; gradient messages (=+, ++, +++); user-selectable sensitivity for differential abnormal population suspect messages	user-definable age-, gender- and/or location-based reference intervals, action and critical limits; user-definable RBC morphology; gradient messages	comprehensive high/low, definitive and suspect messages
FDA-cleared tests not clinically released	—	—	—
Tests not available but submitted for 510(k) clearance	—	—	—
Tests in development	—	—	—
Tests for research use only	MSCV, HLR %&#, PDW, PCT, WBC research population data (RPD)	PCT, PDW, WBC RPD	PCT, PDW
Tests unique to analyzer	IVD: NRBC, body fluids; RUO: MSCV, WBC RPD	—	—
Differential method(s) used	Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate, and AccuFlex technologies	Coulter's 3-D biophysical flow cytometry with AccuGate 500, Reaction Manager technologies	Coulter's 3-D VCS technology
Linearity: • WBC count/RBC count	0–400/0–8.0	0–200/0–7.0	0–99.9/0–7.0
• Hemoglobin/platelet	0–25/0–3,000	0–25/0–2,000	0–25/0–999
• MCV (fL) or Hct (%)	—	50–150 (MCV)	50–150 (MCV)
Precision: • WBC count/RBC count	≤1.7 percent/≤0.8 percent	≤2.5 percent/≤2.0 percent	<2.5 percent/<2.0 percent
• Hemoglobin/platelet	≤0.8 percent/≤3.3 percent	≤1.5 percent/≤5.0 percent	<1.5 percent/<5.0 percent
• MCV or Hct	≤0.8 percent (MCV)	≤2 percent (MCV)	<2.0 percent (MCV)
Accuracy of automated differential compared with manual differential (per CLSI H-20A)	lymph% = ±3.0%, neut% = ±2.0%, mono% = ±3.0%, eos% = ±1.0%, baso% = ±1.0%	lymph= ±1.5 % mean diff., mono= ±1.5 % mean diff., neut= ±2.0% mean diff., eos= ±0.5 % mean diff., baso= ±0.5 % mean differential	lymph%= ±3.0%, —; mono%= ±2.0%, —; neut%= ±3.0%, —; eos%= ±1.0%, —; baso%= ±1.0%, —
Interfering substances: • WBC	unusual RBC abnormalities that resist lysing, NRBC, fragmented WBC, unlysed particle >35 fL, giant PLT, PLT clumps	lyse-resistant, nucleated RBCs, frag. WBCs, agglutination WBCs, unlysed particles >35 fL, very large or agg. PLTs, fibrin, cell frag., or other debris	unusual RBC abnormalities that resist lysing, NRBC, fragmented WBC, unlysed particle >35 fL, large PLT
• RBC	very high WBC, high concentration large PLT, autoagglutinins	very high WBC count, many very large PLTs, agglutinin RBCs, RBCs <36 fL, fibrin, cell fragments, or other debris	very high WBC, high concentration of very large PLT, autoagglutinins
• MCV or Hct	MCV and Hct: very high WBC, high concentration large PLT, autoagglutinins	MCV: very high WBC count, high concentration of very large PLTs, agglutinin RBCs, RBC fragments <36 fL, rigid RBCs	MCV and Hct: very high WBC, high concentration of large PLT, autoagglutinins
• Platelet	very small RBCs and WBC fragments may interfere	very small red cells near the upper threshold, cell fragments, clumped PLTs, PLT fragments or cellular debris near the lower PLT threshold, giant PLTs, PLT clumps, red and white cell fragments, electronic noise, very small red cells	very small RBCs and WBC fragments may cause no fit
• Hemoglobin	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs	very high WBC count, severe lipemia, heparin, lyse-resistant RBCs, turbidity such as elevated triglycerides	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs
Interfering substances: differential	high triglycerides may affect lysing	factors that affect WBC count above or high triglycerides that affect lysing, hypogran. anulocytes, agranul. granulocytes, lyse-resist. red cells, very small or multi-population lymphocytes, elevat. trigly., precipitated elev. proteins	high triglycerides may affect lysing
Maximum CBCs per hour/Maximum CBCs and differentials per hour	110/110	75/70	75/75
Minimum specimen volume open/Closed/Sample dead volume closed	200 µL/300 µL, 550 µL with slidemaker/1.0 mL	125 µL/185 µL/tube dependent	125 µL/185 µL/50 µL predilute/0.5 mL
Microsample capability	yes	yes	yes
Prepares microscope slides automatically or flags problems for slide prep	yes, both	no	no
No. of automatic slidemakers available/List price	>1,000 (U.S.)/$110,000	—	—
Archives patient data/Previous patient results incl. with recent results	yes/yes	yes/yes	yes
Maximum archived data accessible when system online	20,000 samples	20,000 samples	5,000 samples
No. specimens for which numeric results saved in memory at once	20,000 samples	20,000 samples	5,000 samples
No. specimens for which histo/cytogram results saved in memory at once	20,000 samples	20,000 samples	5,000 samples
Performs delta checks	yes	yes	no
Tags and holds results for followup, confirmatory testing, or rerun	yes	yes	yes
Parameters for flags for holding samples defined by user or vendor	user or vendor	user	user or vendor
Scattergram display: cell-specific color	yes	yes	four colors/cell types
Histogram display: color with thresholds	yes	yes	colors without thresholds
User interface can display choice of specimen/result information	yes	yes	no
LIS interface formats supported	RS-232, proprietary	RS-232, proprietary	RS-232, proprietary
Information transferred on LIS interface	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast
LOINC codes transmitted with all results	no	no	no
Interface available or planned to automated specimen-handling system	Beckman Coulter	—	—
Bar-code symbologies read on specimen tube	Codabar, codes 39 and 128, Interleaved 2 of 5, NW7	Codabar, codes 39 and 128, Interleaved 2 of 5, NW7	Codabar, codes 39 and 128, Interleaved 2 of 5, NW7
Accommodates bar-code placement per CLSI standard Auto2A	yes	yes	no
Time required for maintenance by lab personnel	no routine maintenance; only as needed	no routine maintenance; only as needed	none
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	yes/no
Manufacturer can perform diagnostics via modem	yes	yes	no
Distinguishing features (supplied by company)	extensive decision support; enumeration of NRBCs with every differential; random access; automation ready; extended linearity for WBC and PLTs; RUO: WBC RPD	extensive decision support, extended linearity for WBC and PLT, low review rate, small footprint, superior reliability, ProService, electronic IQAP	VCS technology; low review rate; no routine daily maintenance; triplicate counting; aperture burn circuit; sweepflow; SmartStart system; autoloader and single-sample models

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Hematology analyzers

Part 5 of 10	**Beckman Coulter** **Hamid Erfanian** herfanian@beckman.com **250 South Kraemer Boulevard** **Brea, CA 92821** **305-380-3060** www.beckmancoulter.com	**CellaVision** **Ron Hagner** ron.hagner@cellavision.com **4107 Burns Road** **Beach Gardens, FL 33410** **919-619-3909** www.cellavision.com	**HORIBA Medical** **Jim Knowles** jimknowles@horiba.com **34 Bunsen** **Irvine, CA 92618** **888-903-5001 ext. 4553** www.horiba.com/us/en/medical
Name of instrument	**Coulter Ac•T 5diff Family; Ac•T 5diff AL**	**CellaVision DM96 and CellaVision DM1200**	**Pentra 60C+ Hematology Analyzer**
First year installed in U.S./Outside U.S./No. of units sold in 2010	**2001/2000; 2003/2003; 317 (combined Sept. 2011 YTD)**	**2004/2003/—**	**2000/2000/85**
No. units installed in U.S./Outside U.S./List price	**1,029/1,454 combined in and out US** **$38,500 (CP)/54,500 (AL)**	**~400/~700/~$135,000–$175,000**	**>350/>600/$47,313**
Test menu: • Chartable *(standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso)*:	**standard menu (left) plus: RDW, MPV**	**%&# neut, mono, lymph, eos, baso, segmented, bands, blast, promyelocytes, myelocytes, metamyelocytes, variant lymphocytes, plasma cells, giant platelets, platelet clumps, erythroblasts; RBC morphology pre-characterizations include anisocytosis, poikilocytosis, polychromasia, microcytosis, macrocytosis, hypochromia**	**standard menu (left) plus: RDW, MPV**
• Laboratory	**atypical lymphocytes # (ATL#), atypical lymphocytes % (ATL%), immature cells # (IMM#), immature cells % (IMM%), PCT, PDW**	**—**	**atypical lymphocytes, atypical lymphocytes %, LIC, LIC %**
• Flags	**complete operator-selectable flagging**	**—**	**operator-selectable flagging**
FDA-cleared tests not clinically released	**—**	**—**	**—**
Tests not available but submitted for 510(k) clearance	**—**	**—**	**—**
Tests in development	**—**	**—**	**—**
Tests for research use only	**PCT, PDW, IMM, ATL**	**—**	**PCT, PDW, ATL, LIC**
Tests unique to analyzer	**—**	**analysis of cytocentrifuged samples, body fluids (reported parameters: neutrophils, eosinophils, lymphocytes, macrophages (including monocytes), other (basophils, lymphoma cells, atypical lymphocytes, blast cells, and tumor cells)**	**—**
Differential method(s) used	**AcV technology combining cytochemistry, focused flow impedance, and light absorbance prinicples of measurement**	**light microscopy, image analysis, and artificial neural networks**	**DHSS technology combining cytochemistry, focused flow impedance, and light absorbance principles of measurement**
Linearity: • WBC count/RBC count	**0.4–90.0/.23–7.7; AL: 0.4–120.0/0.3–8.0**	**—**	**0–120/0–8**
• Hemoglobin/platelet	**0–22.9/4–1000; AL: 1.3–24.0/10.0–1,000**	**—**	**0–24/0–1,900**
• MCV (fL) or Hct (%)	**1.8–63.8 (Hct)**	**—**	**0–67 (Hct)**
Precision: • WBC count/RBC count	**<2 percent/<2 percent**	**—**	**<2 percent/<2 percent**
• Hemoglobin/platelet	**<1 percent/<5 percent**	**—**	**<1 percent/<5 percent**
• MCV or Hct	**<2.0 percent (Hct); AL: <2.0% (Hct)**	**—**	**<2 percent (Hct)**
Accuracy of automated differential compared with manual differential (per CLSI H-20A)	**not available in CLSI H-20A format**	**seg neut% y=0.97x + 1.3 r= 0.987, lymph% y=0.97x + 1.2 r= 0.979, eos% y=1.01+0.1, r=0.960, mono% y=0.97+0.2, r=0.941, band neut% y=0.87x+0.1, r=0.917**	**neut% r=0.99, —; lymph% r=0.98, —; mono% r=0.96, —; eos% r=0.89, —; baso% r=0.54, —**
Interfering substances: • WBC	**NRBCs, PLT clumps, large PLTs, lyse-resistant RBCs**	**—**	**NRBCs, PLT clumps, lyse-resistant RBCs**
• RBC	**cold agglutinins, PLT clumps, WBC overlinearity**	**—**	**cold agglutinins**
• MCV or Hct	**Hct: lipemic samples, high WBC, cold agglutinins**	**—**	**Hct: extreme leukocytosis**
• Platelet	**RBC and WBC fragments**	**—**	**microcytes, PLT clumps**
• Hemoglobin	**elevated WBC, lipemia**	**—**	**extreme lipemia/leukocytosis**
Interfering substances: differential	**lyse-resistant RBCs, NRBCs, lipemia**	**—**	**NRBC, lyse-resistant RBCs, extreme hyperbilirubinemia**
Maximum CBCs per hour/Maximum CBCs and differentials per hour	**60/60; 80/80**	**—/35 differentials per hour**	**60/60**
Minimum specimen volume open/Closed/Sample dead volume closed	**30 µL for CBC/30 µL/varies by tube size; 53 µL for CBC differential/53 µL for CBC differential/varies by tube size**	**—**	**30 µL for CBC and 53 µL for CBC and differential/30 µL for CBC and 53 µL for CBC and differential/—**
Microsample capability	**yes**	**—**	**yes**
Prepares microscope slides automatically or flags problems for slide prep	**no**	**—**	**yes**
No. of automatic slidemakers available/List price	**—**	**—**	**—**
Archives patient data/Previous patient results incl. with recent results	**yes**	**yes/no**	**yes/yes, with MultiLink Data Manager**
Maximum archived data accessible when system online	**10,000 samples**	**unlimited**	**100,000**
No. specimens for which numeric results saved in memory at once	**10,000 samples**	**~4,000**	**unlimited with backup**
No. specimens for which histo/cytogram results saved in memory at once	**10,000 samples**	**—**	**unlimited with backup**
Performs delta checks	**no**	**no**	**yes**
Tags and holds results for followup, confirmatory testing, or rerun	**yes**	**—**	**yes**
Parameters for flags for holding samples defined by user or vendor	**user or vendor**	**—**	**user**
Scattergram display: cell-specific color	**no**	**—**	**yes**
Histogram display: color with thresholds	**yes**	**—**	**yes**
User interface can display choice of specimen/result information	**yes**	**—**	**yes**
LIS interface formats supported	**proprietary; proprietary ASTM**	**ASTM 1394**	**ASTM 1394 and 1238, HL7, IEEE MIB**
Information transferred on LIS interface	**numeric and flag results, histograms and differential plots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast**	**numeric and flag results, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders (when bar code is read, host is queried for orders**	**numeric and flag results, histograms and scatter-plots, instrument to LIS; patient demographics, LIS to instrument—broadcast**
LOINC codes transmitted with all results	**no (yes on AL model)**	**no**	**yes**
Interface available or planned to automated specimen-handling system	**no**	**—**	**no**
Bar-code symbologies read on specimen tube	**Codabar, codes 39 and 128, Interleaved 2 of 5, EAN 8 and 13**	**Codabar, codes 39 and 128, Interleaved 2 of 5, QR, DataMatrix**	**Codabar, codes 39 and 128, ASTM, Interleaved 2 of 5**
Accommodates bar-code placement per CLSI standard Auto2A	**yes**		**yes**
Time required for maintenance by lab personnel	**none**	**less than 5 minutes per week**	**weekly: 15 minutes**
Onboard diagnostics for troubleshooting/Limited to software problems	**yes/no**	**yes/no**	**yes/yes**
Manufacturer can perform diagnostics via modem	**no**	**no**	**yes, with Data Manager**
Distinguishing features (supplied by company)	**quantitative five-part WBC differential; aspirates only 30 µL of sample; requires small space footprint and runs quietly; AL has auto repeat based on decision rules**	**fully automated slide handling and oiling available in two models for medium and large laboratories; performs peripheral blood and body fluid differentials; WBC and other nucleated cells preclassified into 18 different categories; RBC morphology pre-characterized for 6 categories; network use allows remote review of blood smears and capability to link multiple analyzers in multiple locations, regardless of model**	**reliable five-part WBC differential technology—MTBF more than 200 days; small footprint; small sample size of 53 µL**

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

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Hematology analyzers

Part 6 of 10	HORIBA Medical Jim Knowles jimknowles@horiba.com 34 Bunsen Irvine, CA 92618 888-903-5001 ext. 4553 www.horiba.com/us/en/medical	HORIBA Medical Jim Knowles jimknowles@horiba.com 34 Bunsen Irvine, CA 92618 888-903-5001 ext. 4553 www.horiba.com/us/en/medical	Siemens Healthcare Diagnostics Rita White rita.f.white@siemens.com 500 GBC Drive Newark, DE 19702 888-899-2896 www.usa.siemens.com/diagnostics
Name of instrument	Pentra XL 80	Pentra DX120	Advia 120 Hematology System
First year installed in U.S./Outside U.S./No. of units sold in 2010	2004/2003/31	2005/2004/6	1998/1998/—
No. units installed in U.S./Outside U.S./List price	>250/>900/$76,808	>20/>400/$207,560	>750/3,500/$169,000–$189,000
Test menu: • Chartable *(standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso)*:	standard menu (left) plus: automatic dilution of overrange results (WBC × 3, RBC/hgb/PLT × 2), RDW, MPV	standard menu (left) plus: NRBCs, reticulocytes, IRF, MRV	standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, CHr, CHCMr, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono; cellular Hgb
• Laboratory	atypical lymphocytes, atypical lymphocytes %, LIC, LIC%	LIC%&#, atypical lymphocytes %&#, IMG %&#, IML %&#, IMM %&#, RETL%, RETM%, RETH%, IMR%, MRU, MFI%, CRC%	%: hypo, hyper, macro, micro; calc. Hb, MPXI; %: blasts, PMN, MN; large PLT count; RBC fragment count; RBC ghost count; CSF: WBC, RBC, three-part differential; body fluids: TNC, RBC
• Flags	operator-selectable flagging	—	left shift, atyp. lymph, blasts, immature grans, myeloperoxidase deficiency, aniso, micro, macro, Hb variation, hypo, hyper, NRBC, RBC fragments, RBC ghost, large PLT, PLT clumps
FDA-cleared tests not clinically released	—	—	—
Tests not available but submitted for 510(k) clearance	—	—	—
Tests in development	—	—	IRF, MPC, MPM
Tests for research use only	PCT, PDW, ATL, LIC	PCT, PDW, ATL, LIC, IMG, IML, IMM	CSF, eos
Tests unique to analyzer	automatic dilution protocol	—	CHCM, HDW, CHr, CHCMr, MPC, MPM; CSF: WBC RBC, MN, PMN, neut, lymph, mono
Differential method(s) used	DHSS technology combining cytochemistry, focused flow impedance, and light absorbance	cytochemistry (chlorazol black E) and absorbance	perox–peroxidase cytochemistry staining with light scatter and absorption; baso–cytochemistry stripping with two-angle laser light scatter
Linearity: • WBC count/RBC count	0–120/0–8	0–150/0.5–8.1	0.02–400/0–7.0; CSF WBC 0–5,000/µL; CSF RBC 0–1,500/µL
• Hemoglobin/platelet	0–24/0–1,900 (>2 g/dL Hb)	2–25/0–2,000	0–22.5 /5–3,500
• MCV (fL) or Hct (%)	0–67 (Hct)/0–2,800 (<2 g/dL Hb)	0–80 (Hct)	30–180 (MCV)
Precision: • WBC count/RBC count	<2 percent/<2 percent	<2 percent/<2 percent	2.7 percent/1.2 percent
• Hemoglobin/platelet	<1 percent/<5 percent	<1 percent/<5 percent	0.93 percent/2.93 percent
• MCV or Hct	<2 percent (Hct)	<2 percent (Hct)	0.78 percent (MCV)
Accuracy of automated differential compared with manual differential (per CLSI H-20A)	neut% r=0.99, —; lymph% r=0.98, —; mono% r=0.96, —; eos% r=0.89, —; baso% r=0.54, —	neut% r=0.99, —; lymph% r=0.98, —; mono% r=0.92, —; eos% r=0.97, —; baso% r=0.71, —	neut% r=0.997, y=1.02x–0.6; lymph% r=0.997, y=1.00x+0.8; mono% r=0.943, y=0.85x–0.3; eos% r=0.979, y=0.87x+0.2; baso% r=0.772, y=0.67x+0.0; luc% r=0.994, y=0.92x+0.6
Interfering substances: • WBC	NRBCs, PLT clumps, lyse-resistant RBCs	NRBCs, PLT clumps, lyse-resistant RBCs	incomplete RBC lysis (perox only)
• RBC	cold agglutinins	cold agglutinins	cold agglutinins, extreme sickle cell
• MCV or Hct	Hct: extreme leukocytosis	Hct: extreme leukocytosis	none
• Platelet	microcytes, PLT clumps	microcytes, PLT clumps	none
• Hemoglobin	extreme lipemia, leukocytosis	extreme lipemia, leukocytosis	high WBC, lip., extremely high bilirubin, interfere with cyanmethemoglobin only, none with direct cellular Hb (CHCM)
Interfering substances: differential	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia	incomplete lysis of RBCs, complete myeloperoxidase deficiency
Maximum CBCs per hour/Maximum CBCs and differentials per hour	80/80	120/120	120/120
Minimum specimen volume open/Closed/Sample dead volume closed	30 µL for CBC/53 µL for CBC and differential/0.5 mL	130 µL/200 µL/1 mL	157 µL/157 µL/<300 µL (tube size dependent)
Microsample capability	yes	yes, open mode	yes
Prepares microscope slides automatically or flags problems for slide prep	yes	yes	yes
No. of automatic slidemakers available/List price	—/—	—/—	—
Archives patient data/Previous patient results incl. with recent results	yes/yes, with MultiLink Data Manager	yes/yes, with MultiLink Data Manager	yes/no
Maximum archived data accessible when system online	100,000	100,000	10,000 samples
No. specimens for which numeric results saved in memory at once	unlimited with backup	unlimited with backup	10,000 samples
No. specimens for which histo/cytogram results saved in memory at once	unlimited with backup	unlimited with backup	10,000 samples
Performs delta checks	yes	yes	yes
Tags and holds results for followup, confirmatory testing, or rerun	yes	yes	yes
Parameters for flags for holding samples defined by user or vendor	user	user	user or vendor
Scattergram display: cell-specific color	yes	yes	yes
Histogram display: color with thresholds	yes	yes	yes
User interface can display choice of specimen/result information	—	yes	yes
LIS interface formats supported	proprietary, ASTM 1394 and 1238, HL7, IEEE MIB	proprietary, ASTM 1394 and 1238, HL7, IEEE MIB	proprietary (Spec 79)
Information transferred on LIS interface	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast; host query for demographics and orders
LOINC codes transmitted with all results	—	—	no
Interface available or planned to automated specimen-handling system	yes	yes	LabCell (Siemens)
Bar-code symbologies read on specimen tube	Codabar, codes 39 and 128, ASTM, Interleaved 2 of 5	Codabar, codes 39 and 128, ASTM, Interleaved 2 of 5	Codabar, codes 39 and 128, ASTM, Interleaved 2 of 5
Accommodates bar-code placement per CLSI standard Auto2A	yes	yes	yes
Time required for maintenance by lab personnel	weekly: 15 minutes	weekly: 15 minutes	daily: 10 minutes; weekly: 15 minutes; monthly: 15 minutes
Onboard diagnostics for troubleshooting/Limited to software problems	no/yes	no/yes	yes/no
Manufacturer can perform diagnostics via modem	yes	yes	yes
Distinguishing features (supplied by company)	compact five-part differential instrument with autoloader and autodilution capability, auto rerun feature, autovalidation	high-throughput cell counter with integrated reticulocyte methodology and slidemaker/stainer; fluorescent NRBC counting, auto rerun and reflex testing, autovalidation	laser technology provides cellular Hb for RBCs and retics; 2-D PLT analysis that eliminates interference from RBC fragments and inclusion of large PLTs; dual WBC counts with a linearity of up to 400,000; CSF assay

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Hematology analyzers

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	Siemens Healthcare Diagnostics Rita White rita.f.white@siemens.com 500 GBC Drive Newark, DE 19702 888-899-2896 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Rita White rita.f.white@siemens.com 500 GBC Drive Newark, DE 19702 888-899-2896 www.usa.siemens.com/diagnostics	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Parkway Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
Name of instrument	Advia 2120 Hematology System	Advia 2120i	Sysmex pocH-100i
First year installed in U.S./Outside U.S./No. of units sold in 2010	2004/2004/—	2008/2008/130	2004/2003/100
No. units installed in U.S./Outside U.S./List price	>200/>900/$225,000	>150/>400/$225,000	>950/>4,000/$18,000
Test menu: • Chartable *(standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso)*:	standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, CHr, CHCMr, cellular Hgb, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono	standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic. %&#, CHr, CHCMr, cellular Hgb, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, lymph, MXD, RDW-SD, RDW-CV, MPV
• Laboratory	% hypo, hyper, macro, micro; MPXI, %: blast, PMN, MN, large PLT count, RBC fragment count; RBC ghost count; NRBC; CSF: WBC, RBC, three-part differential; body fluids: TNC, RBC	%hypo, hyper, macro, micro, MPXI, %blast, PMN, MN, large PLT count, RBC fragment count, RBC ghost count, NRBC; CSF: WBC, RBC, three-part differential; body fluids: TNC, RBC	—
• Flags	left shift, atyp. lymph, blasts, immature grans, myeloperoxidase deficiency, aniso, micro, macro, Hb variation, hypo, hyper, NRBC, RBC fragments, RBC ghost, large PLT, PLT clumps	left shift, atyp. lymph, blasts, immature grans, myeloperoxidase deficiency, aniso, micro, macro, Hgb variation, hypo, hyper, NRBC, RBC fragments, RBC ghost, large PLT, PLT clumps	histogram error flags; WBC, RBC, PLT
FDA-cleared tests not clinically released	—	—	—
Tests not available but submitted for 510(k) clearance	—	—	—
Tests in development	MPC, MPM	MPC, MPM	—
Tests for research use only	IRF, CSF, eos	IRF, CSF eos	—
Tests unique to analyzer	CHCM, HDW, CHr, CHCMr, cellular Hgb, MPC, MPM, CSF: WBC, RBC, PMN, MN, neut, lymph, mono	CHCM, HDW, CHr, CHCMr, cellular Hgb, MPC, MPM, CSF: WBC, RBC, PMN, MN, neut, lymph, mono	—
Differential method(s) used	peroxidase WBC—peroxidase cytochem. staining with light scatter and absorption; baso—cytochem. stripping with two-angle laser light scatter	peroxidase WBC: peroxidase cytochem. staining with light scatter and absorption; baso: cytochem. stripping with two-angle laser light scatter	direct current (DC)
Linearity: • WBC count/RBC count	0.02–400; CSF WBC 0–5,000/0–7.0; CSF RBC 0–1,500	0.02–400 CSF: 0–5,000/0–7.0 CSF: 0–1,500	1.0–99.9/0.3–7.0
• Hemoglobin/platelet	0–22.5/5–3,500	0–22.5/5–3,500	0.1–25.0/10–999
• MCV (fL) or Hct (%)	30–180 (MCV)	30–180 (MCV)	10–60 Hct
Precision: • WBC count/RBC count	2.7 percent/1.2 percent	2.7 percent/1.2 percent	<=3.5 percent/<=2.0 percent
• Hemoglobin/platelet	0.93 percent/2.93 percent	0.93 percent/2.93 percent	<=1.5 percent/<=6.0 percent
• MCV or Hct	0.78 percent (MCV)	0.78 percent (MCV)	<=2.0 percent Hct
Accuracy of automated differential compared with manual differential (per CLSI H-20A)	neut% r=0.997, y=1.02x–0.6; lymph% r=0.997, y=1.00x+0.8; mono% r=0.943, y=0.85x–0.3; eos% r=0.979, y=0.87x+0.2; baso% r=0.772, y=0.67x+0.0; luc% r=0.994, y=0.92x+0.6	neut% r=0.997, y=1.02x-0.6; lymph% r=0.997, y=1.00x+0.8; mono% r=0.943, y=0.85x–0.3; eos% r=0.979, y=0.87x+0.2; baso% r=0.772, y=0.67x+0.0; luc% r=0.994, y=0.92+0.6	neut% R=0.98, LYM% R=0.99, MXD % R=0.75, neut# R=1.00, LYM# R=1.00, MXD# R=0.90
Interfering substances: • WBC	incomplete RBC lysis (peroxidase only)	incomplete RBC lysis (peroxidase only)	lyse-resistant RBC, cold agglutinins/ cryoglobulins, PLT aggregation, NRBC
• RBC	cold agglutinins, extreme sickle cell	cold agglutinins, extreme sickle cell	cold agglutinins, microcytosis (severe), fragmented RBCs
• MCV or Hct	—	none	cold agglutinins, fragmented RBCs, leukocytosis (>100,000/uL)
• Platelet	—	none	PLT aggregation, giant PLTs, microcytic RBCs, fragmented RBCs
• Hemoglobin	extreme lipemia, high WBC, extreme high bilirubin interference with colorimetric Hb only, none with cellular Hb	extreme lipemia, high WBC, extreme high bilirubin—interference with colorimetric Hgb only, none with cellular Hgb	lipemia (severe), abnormal protein, leukocytosis (>100,000/uL)
Interfering substances: differential	incomplete RBC lysis, complete myeloperoxidase deficiency	incomplete RBC lysis, complete myeloperoxidase deficiency	—
Maximum CBCs per hour/Maximum CBCs and differentials per hour	120/120	120/120	30/30
Minimum specimen volume open/Closed/Sample dead volume closed	175 µL/175 µL/<300 (tube size dependent)	175 µL/175 µL/<300 (tube size dependent)	15 µL/15 µL/15 µL
Microsample capability	yes	yes	yes
Prepares microscope slides automatically or flags problems for slide prep	if integrated to Advia Autoslide	yes	no
No. of automatic slidemakers available/List price	Advia Autoslide, —/$98,000	Advia Autoslide, —/$98,000	—
Archives patient data/Previous patient results incl. with recent results	yes/no	yes/no	yes/yes
Maximum archived data accessible when system online	10,000	10,000 samples	100 samples
No. specimens for which numeric results saved in memory at once	10,000	10,000 samples	100 samples
No. specimens for which histo/cytogram results saved in memory at once	10,000	10,000 samples	100 samples
Performs delta checks	yes	yes	yes
Tags and holds results for followup, confirmatory testing, or rerun	yes	yes	no
Parameters for flags for holding samples defined by user or vendor	user or vendor	yes	yes
Scattergram display: cell-specific color	yes	yes	no
Histogram display: color with thresholds	yes	yes	yes
User interface can display choice of specimen/result information	yes	yes	yes
LIS interface formats supported	proprietary	proprietary (instrument or vendor specific)	RS-232C
Information transferred on LIS interface	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders (when bar code is read, host is queried for orders)	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders	numeric and flag results, histograms and scatterplots, patient demographics, patient orders, host query for patient demographics and orders
LOINC codes transmitted with all results	no	no	yes
Interface available or planned to automated specimen-handling system	LabCell (Siemens)	LabCell (Siemens)	—
Bar-code symbologies read on specimen tube	Codabar, codes 39 and 128, Interleaved 2 of 5	Codabar, codes 39 and 128, ASTM, Interleaved 2 of 5	codes 39 and 128, ASTM, ITF, NW7, JAN-8 and 13
Accommodates bar-code placement per CLSI standard Auto2A	—	yes	yes
Time required for maintenance by lab personnel	weekly: 15 minutes; monthly: 15 minutes	daily: 10 minutes; weekly: 15 minutes; monthly: 15 minutes	daily: <two minutes; weekly: <two minutes; monthly: <two minutes
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	no/no
Manufacturer can perform diagnostics via modem	yes	yes	yes
Distinguishing features (supplied by company)	laser technology provides direct cellular Hb for RBCs and reticulocytes; 2-D PLT analysis that eliminates interference from RBC fragments and inclusion of large PLTs; dual WBC counts with a linearity of up to 400,000; CSF assay	laser technology provides direct cellular Hgb for RBCs and reticulocytes; 2-D PLT analysis eliminates interference from RBC fragments and inclusion of large PLTs; dual WBC counts with a linearity of up to 400,000; CSF assay	hydrodynamic focusing, automatic floating discriminators, ISBT-compliant, data masking software for blood donor centers

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

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Hematology analyzers

Part 8 of 10	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Parkway Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Parkway Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Parkway Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
Name of instrument	Sysmex KX-21N	XS-1000i and XS-1000i AutoLoader (20 sample autoloader option)	Sysmex XT-1800i
First year installed in U.S./Outside U.S./No. of units sold in 2010	2001/1999/130	2006/2005/>320	2002/2001/>40
No. units installed in U.S./Outside U.S./List price	>1,100/>4,400/$26,780	>1,400/>6,000/$85,000 (XS-1000i) $95,000 (AutoLoader)	>400/4,600/$128,750
Test menu: • Chartable *(standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso)*:	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, lymph, MXD, RDW-SD, RDW-CV, MPV	standard menu (left) plus: MPV, RDW-SD, RDW-CV	standard menu (left) plus: MPV, RDW-SD, RDW-CV, immature granulocytes %&#
• Laboratory	—	—	—
• Flags	histogram error flags; WBC, RBC, PLT	PLT clumps, PLT abnormal distribution, WBC abnormal scattergram, blast immature granulocytes, left shift, atypical lymphocytes, abnormal lymphocytes/blasts, RBC abnormal distribution, RBC lyse resistance, RBC agglutinins, turbidity, NRBC	PLT clumps, PLT abnormal distribution, WBC abnormal scattergram, blast immature granulocytes, left shift, atypical lymphocytes, abnormal lymphocytes/blasts, RBC abnormal distribution, RBC lyse resistance, RBC agglutinins, turbidity, NRBC, body fluids
FDA-cleared tests not clinically released	—	—	—
Tests not available but submitted for 510(k) clearance	—	—	—
Tests in development	—	IG%	—
Tests for research use only	—	research screen	—
Tests unique to analyzer	—	—	immature granulocytes (IG%&#)
Differential method(s) used	direct current (DC)	fluorescent flow cytometry	fluorescent flow cytometry
Linearity: • WBC count/RBC count	1.0–99.9/0.3–7.0	0–400/0–8	0–310/0–8
• Hemoglobin/platelet	0.1–25.0/10–999	0-25/0–5,000	0–25/0–5,000
• MCV (fL) or Hct (%)	10–60 Hct	0–60 (Hct)	0–60 (Hct)
Precision: • WBC count/RBC count	<=3.5 percent/<=2.0 percent	—/—	≤3.0 percent/≤1.5 percent
• Hemoglobin/platelet	<=1.5 percent/<=6.0 percent	—/—	≤1.5 percent/≤4.0 percent
• MCV or Hct	<=2.0 percent Hct	—	≤1.5 percent (Hct)
Accuracy of automated differential compared with manual differential (per CLSI H-20A)	neut% R=0.98, LYM% R=0.99, MXD % R=0.75, neut# R=1.00, LYM# R=1.00, MXD# R=0.90	neut% r=0.96, y=0.9074x+3.8948; lymph% r=0.97, y=0.9017x+2.4817; mono% r=0.78, y=0.8626x+3.5938; eos% r=0.94, y=0.9076x+0.3651; baso% r=0.29, y-0.1538x+0.298	neut% r=0.95, y=0.95x+3.38; lymph% r=0.96, y=0.85x+1.67; mono% r=0.90, y=11.37x+1.89; eos% r=0.94, y=0.87x+0.04; baso% r=0.76, y=0.48x+0.24
Interfering substances: • WBC	cold agglutinins, PLT aggregation, erythroblastosis, NRBC, cyroglobulins	cold agglutinins, PLT aggregation, cryoglobulins, lyse-resistant RBCs, NRBCs	cold agglutinins, PLT aggregation, cryoglobulins, lyse-resistant RBCs, NRBCs
• RBC	cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis (>100,000/µL)	cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis	cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis
• MCV or Hct	Hct: cold agglutinin, leukocytosis (>100,000/µL), abnormal red cell fragility, spherocytosis	Hct: cold agglutinins, abnormal red cell fragility, spherocytosis, leukocytosis (>100,000/µL)	Hct: cold agglutinins, abnormal red cell fragility, spherocytosis, leukocytosis (>100,000/µL)
• Platelet	pseudothrombocytopenia, PLT aggregation, increased microcytosis, megalocytic PLTs	pseudothrombocytopenia, PLT aggregation, increased microcytosis, megaloblasts	pseudothrombocytopenia, PLT aggregations, increased microcytosis, megaloblasts
• Hemoglobin	leukocytosis (>100,000/µL), lipemia, abnormal protein	lipemia, abnormal proteins, leukocytosis (>100,000/µL)	lipemia, abnormal proteins, leukocytosis (>100,000/µL)
Interfering substances: differential	—	lyse-resistant RBCs	lyse-resistant RBCs
Maximum CBCs per hour/Maximum CBCs and differentials per hour	60/60	60/60	80/80
Minimum specimen volume open/Closed/Sample dead volume closed	50 µL/—/—	20 µL/20 µL/1.0 mL	85 µL/150 µL/1 mL
Microsample capability	yes	yes	yes
Prepares microscope slides automatically or flags problems for slide prep	no	no	no
No. of automatic slidemakers available/List price	—	—	—
Archives patient data/Previous patient results incl. with recent results	yes/yes	yes/yes	yes/yes
Maximum archived data accessible when system online	300 samples	10,000 samples	10,000 samples
No. specimens for which numeric results saved in memory at once	300 samples	10,000 samples	10,000 samples
No. specimens for which histo/cytogram results saved in memory at once	300 samples	10,000 samples	10,000 samples
Performs delta checks	yes	yes	yes
Tags and holds results for followup, confirmatory testing, or rerun	yes	yes	yes
Parameters for flags for holding samples defined by user or vendor	yes	user or vendor	user or vendor
Scattergram display: cell-specific color	no	yes	yes
Histogram display: color with thresholds	yes	yes	yes
User interface can display choice of specimen/result information	yes	yes	yes
LIS interface formats supported	RS-232C	proprietary, ASTM 1394, TCP-IP	RS-232C/TCP-IP, ASTM
Information transferred on LIS interface	numeric and flag results, histograms and scatterplots, host query for patient demographics and orders	numeric and flag results, histograms and scatterplots, patient demographics, orders	numeric and flag results, histograms and scatterplots, patient demographics, orders
LOINC codes transmitted with all results	yes	yes	yes
Interface available or planned to automated specimen-handling system	—	—	—
Bar-code symbologies read on specimen tube	codes 39 and 128, ITF, NW-7, JAN, UPC-A, UPC-E, EAN13, EAN8	Codabar, codes 39 and 128, ASTM, Interleaved 2 of 5, NW7, EAN 8 and 13, ITF	Codabar, codes 39 and 128, Interleaved 2 of 5, ITF, NW7, EAN 8 and 13
Accommodates bar-code placement per CLSI standard Auto2A	yes	yes	yes
Time required for maintenance by lab personnel	daily: <two minutes; weekly: <two minutes; monthly: <two minutes	daily: three minutes; weekly: none; monthly: nine minutes	daily: <three minutes
Onboard diagnostics for troubleshooting/Limited to software problems	no/no	yes/no	yes/no
Manufacturer can perform diagnostics via modem	yes	yes, also via Internet	yes, also via Internet
Distinguishing features (supplied by company)	automatic floating discriminators	standardized technology, reagents, controls, and operations with other X series analyzers; small sample volume requirements for CBC and five-part differential; remote diagnostics, online QC, discrete analysis, reagent monitoring, chartable report; remote calibration verification	remote diagnostics; online QC; random access; discrete testing; reagent monitoring; chartable report formats; unique specimen-gating, software is FDA Part II compliant; body fluids now FDA cleared; standardized technology, reagents, controls, and operations with other X series analyzers; XT-V for use in toxicology, research, and veterinary reference labs

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Hematology analyzers

Part 9 of 10	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Parkway Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Parkway Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Parkway Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
Name of instrument	Sysmex XT-2000i	Sysmex XT-4000i	Sysmex XE-2100D
First year installed in U.S./Outside U.S./No. of units sold in 2010	2002/2001/>70	2010/2009/80	2004/2004/>15
No. units installed in U.S./Outside U.S./List price	>900/>5,200/$149,500	100/>250/$195,700	190/>205/$200,000
Test menu: • Chartable *(standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso)*:	standard menu (left) plus: retic %&#, IRF, PLT-O, MPV, RDW-SD, RDW-CV, reticulocyte hemoglobin, immature granulocytes %&#	standard menu (left) plus: IG% and #, retic % and #, IRF, RET-He, PLT-O, BF: RBC/WBC/TC/two-part differential	standard menu (left) plus: RDW-SD, RDW-CV
• Laboratory	—	—	—
• Flags	PLT clumps, PLT abnormal distribution, WBC abnormal scattergram, blast immature granulocytes, left shift, atypical lymphocytes, abnormal lymph./blasts, RBC abnormal distribution, RBC lyse resistance, RBC agglutinins, turbidity, NRBC, body fluids	PLT clumps, PLT abnormal distribution, blast immature granulocytes, left shift, atypical lymphocytes, abnormal lymph/blasts, NRBC, RBC lyse resistance, RBC abnormal distribution, RBC agglutination, turbidity	PLT clumps, PLT abnormal distribution, WBC abnormal scattergram, blast, left shift, atypical lymphocytes, abnormal lymph/blasts, RBC abnormal distribution, RBC lyse resistance, RBC agglutinins, turbidity
FDA-cleared tests not clinically released	—	—	—
Tests not available but submitted for 510(k) clearance	—	—	—
Tests in development	—	—	—
Tests for research use only	—	—	P-LCR, PCT, PDW
Tests unique to analyzer	PLT-O, immature granulocytes (IG) %&#, reticulocyte hemoglobin (RET-He)	reticulocyte hemoglobin, immature reticulocyte fraction, reportable immature granulocyte # and %, PLT-O, BF: RBC/WBC/TC/two-part differential	optional: IG% & IG#
Differential method(s) used	fluorescent flow cytometry	fluorescent flow cytometry	fluorescent flow cytometry
Linearity: • WBC count/RBC count	0–310/0–8	0–440/0–8	0–440/0–8
• Hemoglobin/platelet	0–25/0–5,000	0-25/0-5,000	0–25/0–5,000
• MCV (fL) or Hct (%)	0–60 (Hct)	0-60 (Hct)	0–75 (Hct)
Precision: • WBC count/RBC count	≤3.0 percent/≤1.5 percent	<=3.0 percent/<=1.5 percent	≤3 percent/≤1.5 percent
• Hemoglobin/platelet	≤1.5 percent/≤4.0 percent	<=1.5 percent/<=4.0 percent	≤1.0 percent/≤4.0 percent
• MCV or Hct	≤1.5 percent (Hct)	<=1.5 percent (Hct)	≤1.5 percent (Hct)
Accuracy of automated differential compared with manual differential (per CLSI H-20A)	neut% r=0.95, y=0.95x+3.38; lymph% r=0.96, y=0.85x+1.67; mono% r=0.90, y=11.37x+1.89; eos% r=0.94, y=0.87x+0.04; baso% r=0.76, y=0.48x+0.24	neut % r=0.95, lymph% r=0.96, mono% r=0.90, eos% r=0.94, baso% r=0.76; neut % y=0.95x+3.38, lymph % y=0.85x+1.67, mono % y=11.37x+1.89, eos% y=0.87x+0.04, baso% y=0.48x+0.24	neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922
Interfering substances: • WBC	cold agglutinins, PLT aggregation, cryoglobulins, lyse-resistant RBCs, NRBCs	cold agglutinins, PLT aggregation, cryoglobulin, lyse-resistant erythrocytes, NRBC	cold agglutinins, PLT aggregation, cryoglobulin, lyse-resistant RBCs, NRBCs
• RBC	cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis	cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis	cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis
• MCV or Hct	Hct: cold agglutinins, abnormal red cell fragility, spherocytosis, leukocytosis (>100,000/µL)	Hct: cold agglutinins, fragmented RBCs, spherocytosis, leukocytosis (lymphocytes>100,000/µL)	Hct: cold agglutinins, abnormal red cell fragility, spherocytosis, leukocytosis
• Platelet	pseudothrombocytopenia, PLT aggregation, increased microcytosis, megaloblasts	PLT aggregation, pseudothrombocytopenia, giant platelets, microcytosis, cryoglobulin	pseudothrombocytopenia, PLT aggregation, increased microcytosis, megaloblasts
• Hemoglobin	lipemia, abnormal proteins, leukocytosis (>100,000/µL)	leukocytosis (lymphocytes>100,000/µL), lipemia, abnormal protein	lipemia, abnormal proteins, leukocytosis (>100,000/µL)
Interfering substances: differential	lyse-resistant RBCs	lyse-resistant RBCs	lyse-resistant RBCs
Maximum CBCs per hour/Maximum CBCs and differentials per hour	80/80	100/100	150/150
Minimum specimen volume open/Closed/Sample dead volume closed	85 µL/150 µL/1 mL	85 µL/150 µL/1 mL	130 µL/200 µL/1 mL
Microsample capability	yes	yes	yes
Prepares microscope slides automatically or flags problems for slide prep	no	no	yes, with Alpha or HST upgrade
No. of automatic slidemakers available/List price	—		>1,000/price depends on configuration
Archives patient data/Previous patient results incl. with recent results	yes/yes	yes/yes	yes/yes
Maximum archived data accessible when system online	10,000 samples	10,000 samples	10,000 samples
No. specimens for which numeric results saved in memory at once	10,000 samples	10,000 samples	10,000 samples
No. specimens for which histo/cytogram results saved in memory at once	10,000 samples	10,000 samples	10,000 samples
Performs delta checks	yes	yes	yes
Tags and holds results for followup, confirmatory testing, or rerun	yes	yes	yes
Parameters for flags for holding samples defined by user or vendor	user or vendor	yes	user or vendor
Scattergram display: cell-specific color	yes	yes	yes
Histogram display: color with thresholds	yes	yes	yes
User interface can display choice of specimen/result information	yes	yes	yes
LIS interface formats supported	RS-232/TCP-IP, ASTM	ASTM	RS-232C/TCP IP
Information transferred on LIS interface	numeric and flag results, histograms and scatterplots, patient demographics, orders	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders	numeric and flag results, histograms and scatterplots, patient demographics, orders
LOINC codes transmitted with all results	yes	yes	yes
Interface available or planned to automated specimen-handling system	—	—	on automation platform
Bar-code symbologies read on specimen tube	Codabar, codes 39 and 128, Interleaved 2 of 5, ITF, NW7, EAN 8 and 13	Codabar, codes 39 and 128, ASTM, Interleaved 2 of 5, ITF, NW7	Codabar, codes 39 and 128, ASTM, Interleaved 2 of 5, ITF, NW7, EAN 8 and 13, ISBT
Accommodates bar-code placement per CLSI standard Auto2A	yes	yes	yes
Time required for maintenance by lab personnel	daily: <three minutes	daily: <three minutes	daily: <three minutes
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	yes/no
Manufacturer can perform diagnostics via modem	yes, also via Internet	yes	yes, also via Internet
Distinguishing features (supplied by company)	high throughput, remote diagnostics; online QC; random access; fluorescent optical platelets; discrete testing; reagent monitoring; customized chartable report formats; body fluids, standardized technology, reagents, controls, and operations with other X series analyzers; IG # & %, RET-He; XT-V unit for use in toxicology, research, and veterinary reference labs	testing parameters: fluorescent optical platelets, IG #&%, RET-He, body fluids (CSF, serous, synovial), WBC/RBC/TC and two-part differential; standardized technology, reagents, controls, and operations with other X series analyzers; simplified operations with extended linearities, high-throughput, remote-monitoring capabilities	150 CBCs per hour; platelet linearity—5 million, hematocrit extended to 75 percent; standardized technology, reagents, controls and operations; ISBT-compliant; FDA-cleared application for blood component products in specified anticoagulants

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Hematology analyzers

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Name of instrument	Sysmex XE-2100	Sysmex XE-5000	Sysmex XE-Alpha N/HST-N
First year installed in U.S./Outside U.S./No. of units sold in 2010	1999/—/~75	2008/2008/>125	2000/—/>120
No. units installed in U.S./Outside U.S./List price	1,325/>5,000/$240,000	>640/>2,000/$265,122	>950/1,400/$360,000–$1,000,000
Test menu: • Chartable *(standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso)*:	standard menu (left) plus: NRBC %&#, retic %&#, RDW-SD, RDW-CV, IRF, PLT-O, HPC#, MPV, IG%, IG#, RET-He, IPF	standard menu (left) plus: NRBC %&#, retic %&#, RDW-SD, RDW-CV, IRF, PLT-O, HPC#, MPV, IG%, IG#, RET-He, IPF	standard menu (left) plus: NRBC%&#, retic%&#, RDW-SD, RDW-CV, IRF, PLT-O, HPC#, MPV, IG%, IG#, RET-He, IPF
• Laboratory	—	—	—
• Flags	PLT clumps, RBC agglut, turbidity, WBC abnormal scattergram, RBC abnormal distribution, PLT abnormal distribution, RBC lyse resistance, blasts, left shift, atypical lymphocytes, abnormal lymph./blast, reticulocyte abnormal scattergram	PLT clumps, PLT abnormal distribution, WBC abnormal scattergram, blast, left shift, atypical lymphocytes, abnormal lymph./blast, RBC abnormal distribution, RBC lyse resistance, RBC agglut., turbidity	user-defined, all-inclusive
FDA-cleared tests not clinically released	—	—	—
Tests not available but submitted for 510(k) clearance	—	—	—
Tests in development	—	—	—
Tests for research use only	P-LCR, PCT, PDW	—	P-LCR, PCT, PDW
Tests unique to analyzer	HPC#, IG%, IG#, RET He, IPF	reticulocyte hemoglobin, immature platelet fraction, hematopoietic progenitor cell, immature reticulocyte fraction, reportable immature granulocyte #&%, RBC/WBC/TC/two-part differential	NRBC, HPC#, IG%, IG#, RET-He, immature platelet function (IPF)
Differential method(s) used	fluorescent flow cytometry, RF/DC detecting method	fluorescent flow cytometry, RF/DC detection method	fluorescent flow cytometry, RF/DC detecting method
Linearity: • WBC count/RBC count	0–440/0–8	0–440/0–8	0–440/0–8
• Hemoglobin/platelet	0–25/0–5,000	0–25/0–5,000	0–25/0–5,000
• MCV (fL) or Hct (%)	0–75 (Hct)	0–75 (Hct)	0–75 (Hct)
Precision: • WBC count/RBC count	<3 percent/<1.5 percent	<3 percent/<1.5 percent	<3 percent/<1.5 percent
• Hemoglobin/platelet	<1.0 percent/<4.0 percent	<1.0 percent/<4.0 percent	<1.0 percent/<4.0 percent
• MCV or Hct	<1.5 percent (Hct)	<1.5 percent (Hct)	<1.0 percent (Hct)
Accuracy of automated differential compared with manual differential (per CLSI H-20A)	neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922	neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922	neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922
Interfering substances: • WBC	cold agglutinins, PLT aggregation, nucleated RBCs, cryoglobulin, lyse-resistant RBCs	cold agglutinins, PLT aggregation, nucleated RBCs, cryoglobulin, lyse-resistant RBCs	cold agglutinins, PLT aggregation, nucleated RBCs, cryoglobulins, lyse-resistant RBCs
• RBC	cold agglutinins, severe microcytosis, fragmented RBCs, large No. giant PLTs, in vitro hemolysis	cold agglutinins, severe microcytosis, fragmented RBCs, large number giant PLTs, in vitro hemolysis	cold agglutinins, severe microcytosis, fragmented RBCs, large No. giant PLTs, in vitro hemolysis
• MCV or Hct	Hct: cold agglutinins, leukocytosis, abnormal red cell fragility, spherocytosis	Hct: cold agglutinins, leukocytosis, abnormal red cell fragility, spherocytosis	Hct: cold agglutinins, leukocytosis, abnormal red cell fragility, spherocytosis
• Platelet	pseudothrombocytopenia, PLT aggregation, increased microcytosis, megalocytic PLTs	pseudothrombocytopenia, PLT aggregation, increased microcytosis, megalocytic PLTs	pseudothrombocytopenia, PLT aggregation, increased microcytosis, megalocytic PLTs
• Hemoglobin	lipemia, abnormal proteins, leukocytosis (>100,000/µL)	lipemia, abnormal proteins, leukocytosis (>100,000/µL)	lipemia, abnormal proteins, leukocytosis (>100,000/µL)
Interfering substances: differential	lyse-resistant RBCs	lyse-resistant RBCs	lyse-resistant RBCs
Maximum CBCs per hour/Maximum CBCs and differentials per hour	150/150	150/150	150/150 per analyzer on automation system
Minimum specimen volume open/Closed/Sample dead volume closed	130 µL/200 µL/1 mL	130 µL/200 µL/1 mL	130 µL/200 µL/1 mL
Microsample capability	yes	yes	yes
Prepares microscope slides automatically or flags problems for slide prep	yes (with Alpha or HST upgrade)	yes (with Alpha or HST upgrade)	yes
No. of automatic slidemakers available/List price	>1,000/price depends on configuration	>1,200/price depends on configuration	>1,700/$250,000
Archives patient data/Previous patient results incl. with recent results	yes/yes	yes/yes	yes/yes
Maximum archived data accessible when system online	10,000 samples	10,000 samples	10,000 samples
No. specimens for which numeric results saved in memory at once	10,000 samples	10,000 samples	10,000 samples; 20,000 orders
No. specimens for which histo/cytogram results saved in memory at once	10,000 samples	10,000 samples	10,000 samples; two years plus, with optional decision logic software
Performs delta checks	yes	yes	yes
Tags and holds results for followup, confirmatory testing, or rerun	yes	yes	yes
Parameters for flags for holding samples defined by user or vendor	user or vendor	yes	user and vendor
Scattergram display: cell-specific color	yes	yes	yes
Histogram display: color with thresholds	yes	yes	yes
User interface can display choice of specimen/result information	yes	yes	yes
LIS interface formats supported	RS-232C/TCP IP	ASTM 1394, TCP-IP, ASTM E1381	RS-232C/TCP IP
Information transferred on LIS interface	numeric and flag results, histograms and scatterplots, patient demographics, orders	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders	numeric and flag results, histograms and scatterplots, patient demographics, orders
LOINC codes transmitted with all results	yes	yes	yes
Interface available or planned to automated specimen-handling system	on automation platform	Roche Diagnostics, and Labotix, A & T, Thermo, IDS	Roche, Labotix, IDS, A & T, Thermo engen
Bar-code symbologies read on specimen tube	Codabar, codes 39 and 128, Interleaved 2 of 5, ITF, NW7, EAN 8 and 13	Codabar, codes 39 and 128, ASTM, Interleaved 2 of 5, ITF, NW7, EAN 8 and 13	Codabar, codes 39 and 128, Interleaved 2 of 5, ITF, NW7, EAN 8 and 13
Accommodates bar-code placement per CLSI standard Auto2A	yes	—	yes
Time required for maintenance by lab personnel	daily: <three minutes	daily: <three minutes	daily: <three minutes (operator time)
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	yes/no
Manufacturer can perform diagnostics via modem	yes, also via Internet	yes, also via Internet	yes, also via Internet
Distinguishing features (supplied by company)	throughput of 150 CBCs per hour; random access; discrete testing; online QC; remote diagnostics, body fluid analysis; platelet linearity to 5 million, hematocrit linear to 75 percent; hematopoietic progenitor cell testing; immature granulocyte enumeration; immature platelet fraction; reticulocyte hemoglobin equivalent; standardized reagents, controls, and operations with other X series analyzers	low-end linearity for all body fluids; two-part differential (mono nuclear % + # and polymorphonuclear % + # or body fluid; reticulocyte hemoglobin content; immature platelet fractions; throughput of 150 CBCs per hour; random access; discrete testing; online QC; remote diagnostics, body fluid analysis; platelet linearity to 5 million, hematocrit linear to 75 percent; hematopoietic progenitor cell testing; immature granulocyte enumeration; immature platelet fraction; reticulocyte hemoglobin equivalent; standardized reagents, controls, and operations with other X series analyzers	high-throughput, flexible, scalable configurations available (>125 standard configurations available); platelet linearity—5 million; new parameters for platelet monitoring—IPF and reticulocyte Hb measurement and RET-He, hematopoietic progenitor cell analysis, lavender top management, standardized technology, reagents, controls, and operations; broader clinical reportable ranges; enhanced clinical parameters to support preventive care and disease management

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

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